Physician's Manual

Paired VNS Therapy® Serenity System® Model 2000 Wireless Transmitter & Model 4000 Tinnitus Application Programming Software (TAPS)

For Healthcare Professionals

November 2012

CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use.

NOTE: This identifies the parts included in this Physician's Manual. The information contained in any one part is not intended to serve as a substitute for a complete and thorough understanding of the material presented in all of the physician's manual sections for the Paired VNS Therapy Serenity 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 Paired VNS Therapy Serenity System manuals must be included for full disclosure; copies are available from MicroTransponder Inc. This manual contains information that **shall not be made available to patients.**

Released Version A

Table of Contents

List of Figures & Tables

1. BRIEF DEVICE DESCRIPTION

The Paired VNS Therapy Serenity System non-implantable components include the Tinnitus Application & Programming software (TAPS) and Wireless Transmitter (WT, a communication and trigger system). The TAPS and the Wireless Transmitter enable the audiologist or physician to set Paired VNS Therapy parameters, initiate a therapy setting, and test and modify the implanted device and its settings.

The Paired VNS Therapy Serenity System, when used as intended, provides a drug-free way to treat chronic tinnitus by pairing tone therapy with Vagus Nerve Stimulation (VNS). The Tinnitus Application & Programming Software (TAPS), via the Wireless Transmitter, allows the physician to program the output settings of the Implantable Pulse Generator (IPG), including amplitude, frequency, and pulse width, to stimulate the vagus nerve while simultaneously providing tones through a laptop and headphones to the patient's ears. Once the physician and site personnel have set the system settings and verified operation, the patient will be trained in proper use of the device system to initiate daily stimulation at their own home. The complete device system, called the Serenity System, is shown in Figure 1.0-1.

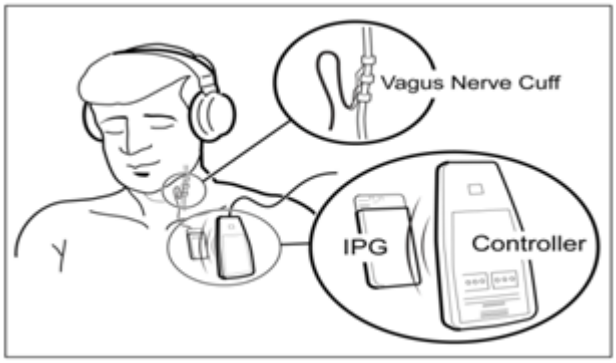
The communication system of the Paired VNS Therapy Serenity System Programming Software Model 4000 is designed to minimize the possibility of mis-programming or "phantom" programming with the IPG. Phantom programming is the inadvertent programming via environmental sources of electromagnetic interference. All IPG parameters are programmed and verified during each programming event.

Software capabilities include:

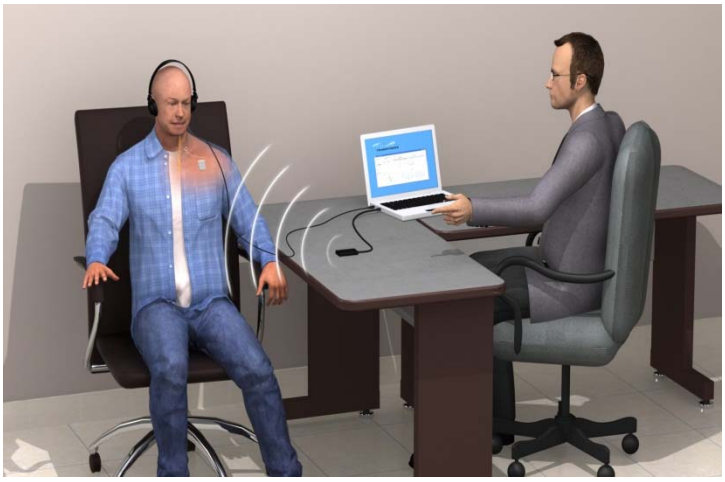
- Use of TAPS *with the Wireless Transmitter* by an audiologist or physician to interrogate and program an IPG's parameters and assess IPG function.
- Use of TAPS *without the Wireless Transmitter* to display the operating histories of all the IPGs interrogated with your computer.
- Use of screen displays that provide prompts and messages to aid in interrogating and programming.
- Use of TAPS *with the Wireless Transmitter* by a patient to initiate a therapy session. Patients are not able to modify device settings.

Figure 1.0-1 (A) Device Placement, (B) In-Office Set-up, and (C) Home Set-up

A.



B.



C.

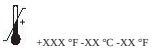
1.1. Symbols and Definitions

This physician's manual and accompanying device labeling use these symbols and definitions:

 Notice for reader to pay special attention to details that follow

 Serial Number

 Date of Manufacture

 Storage Temperature

 Representative

 Do Not Use if Package is Damaged

 Manufacturer

 MRI Unsafe

 Consult Instructions for Use Sidebar Note (cross-references and other useful information)

RX Only Prescription Statement Symbol – US Federal law restricts this device to sale or use by or on the order of a physician.

1.2 Intended Use / Indication

The MicroTransponder Paired VNS Therapy Serenity System is intended to be used to simultaneously stimulate the vagus nerve and provide tones to the ears in order to reduce or eliminate a patient's perception of tinnitus (ringing in the ears).

TAPS is intended for use only with the MicroTransponder Implantable Pulse Generator (IPG) and Wireless Transmitter (WT) and is subject to the same indications for use.

The patient must satisfy the following conditions:

- Have a good overall health condition
- Be conscious and able to perform, by their own, all the instructions provided by the physician to receive the therapy at their home
- Not use any other medical device (implanted or external) that is not part of the Serenity System while receiving therapy.

1.3 System Requirements

The computer must have the following minimum specifications:

Operating System Genuine Windows® 7 Home Premium, 64-Bit, English

Processor 2nd generation Intel® Core™ i5-2430M processor 2.40 GHz with Turbo Boost 2.0 up to 3.00 GHz

Memory 6GB Shared Dual Channel DDR3 Memory

Sound HD Audio 2.0 Support SRS™ Premium Sound Serial communication capability.

Note: The TAPS system, as described herein, should only be used with equipment described in this manual. TAPS should not be used with medical device equipment other than the MicroTransponder Paired VNS Therapy Serenity System.

 Warning: Do not modify this equipment without authorization of MicroTransponder.

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

1.4 Conventions

The TAPS Model 4000 Version 1.0 operates in a Windows environment with drop-down menus. Standard mouse and keypad functions are used to navigate through a Windows environment on the computer.

- 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 list of symbols is found in the front of this manual. A glossary is found in the back of this manual.

For more information, see “Troubleshooting” in Section 10.

1.5 Communication Signals

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

1.6 Wireless Transmitter

The WT has a cable with a USB connector that plugs into the laptop and converts the information from TAPS into a radio-frequency (RF) signal that is transmitted to the IPG. The WT converts the digital signals from the computer and software into RF signals that can be transmitted through the air and skin to the IPG and also receives RF signals back from the IPG. The IPG then translates the signal and acts on the commands given to it from TAPS. The WT has a cable of at least 6 feet long and will communicate with the IPG at a distance up to 1 meter from the WT. It is powered via the USB connection and does not require any additional power source, such as battery, or additional power connection. The WT is shown in Figure 1.6-1.

Figure 1.6-1 – Wireless Transmitter

Table – 1.6-1: Characteristics of the Wireless Transmitter

Outer Material	ABS Plastic
Size	~ 10cm X 7.5cm X 2.5cm; no sharp corners
Cable length	~ 2 meters
Weight	~ 131 grams
Connector Type	USB
Communication Distance	1 meter
Communication Band	Medical Implantable Band (MICS, 403 Hz.)

1.7 Tinnitus Application & Programming Software (TAPS)

The TAPS allows the physician to control the tone frequencies, amplitude and relative timing of the tones to the stimulation, in addition to setting the IPG stimulation parameters. The TAPS also stores the therapy history. The TAPS (loaded and tested on a provided laptop), headphones, and WT will be taken home by the patient so that therapy can be continued at home. When taken home, most features of the software are locked out so that the patient cannot change the stimulation parameters or tone therapy, but only initiate a therapy session. The TAPS system also allows the status of the IPG to be checked for battery level and lead impedance.

2.0 HOW TO GET STARTED

The TAPS Model 4000 Version 1.0 has been pre-installed on the computer laptop provided. Before proceeding to the next section, be sure you have arrived at the Startup Menu as shown in Figure 2.0-1 below.

Figure 2.0-1. Startup Menu Screen

1. Turn on the computer by pressing the on-off button. The computer will open at the Startup Menu Screen with the reminder to ensure all applications are closed.

2. If the computer doesn't display the Startup Menu, see **Precautions** in Section 9.0 and **Troubleshooting** in Section 10.3 before proceeding.

3. For proper operation and communication, the WT must be plugged into the computer. The USB plug from the WT must be plugged into the USB port of the computer. The "Interface" indicator on the user interface screen shall be GREEN in color when inserted properly, RED when disconnected, and alternating WHITE/GREEN when communicating (see Figures 2.0-2 through 2.0-4).

Figure 2.0-2. Wireless Transmitter Interface Connected Indicator (Green)

Figure 2.0-3. Wireless Transmitter Interface Disconnected Indicator (Red)

Figure 2.0-4. Wireless Transmitter In-Progress Indicator (alternating between white and green)

3. HOW TO USE TAPS

It is MicroTransponder's intent to make the software as intuitive and "user friendly" as possible. Messages and prompts will guide you through this software.

There are two modes in this software, ***At Home*** and ***Physician*** modes. The only mode available, unless the ***Physician Login*** has been accessed and the appropriate password entered, is the ***At Home*** mode. In this mode, only the ***Deliver Tinnitus Therapy*** option is enabled (see Figure 2.0-1); the ***At Home*** mode allows patients to initiate a therapy session – this is the only function allowed by this mode. The ***At Home*** mode use is explained in detail in Section 6.0 below. In order to access the rest of the program, the ***Physician Login*** button must be selected. This allows the Physician to type in a password which allows access to the rest of

the software (see Fig. 3.0-1).

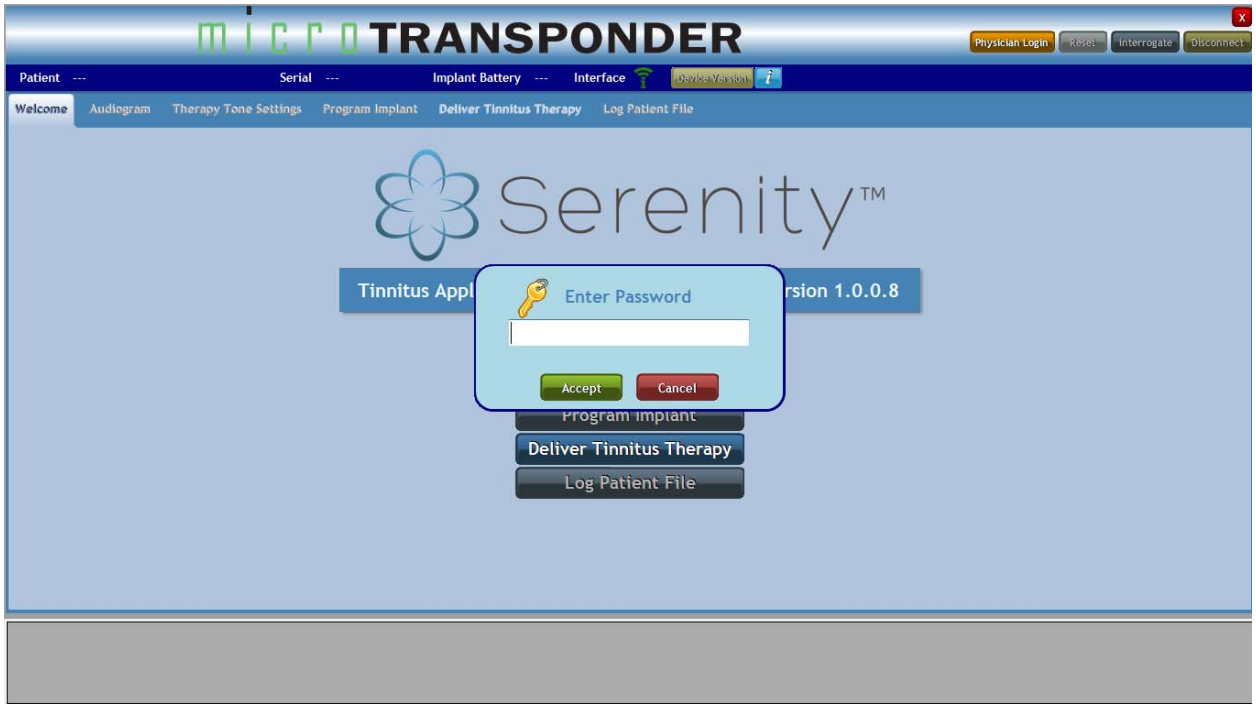


Figure 3.0-1. Physician Login

To login and access all other TAPS screens, the audiologist or physician selects the ***Physician Login*** button (upper right menu bar, 4th button from the right – innermost button) and enters the password as shown in Figure 3.0-1 above. This opens full access to the software and allows all settings to be established and modified. The Password is “mti”. At this point the program is “unlocked” and all menus in the program are available (see Figure 3.0-2).

Figure 3.0-2. "Physician Mode" of TAPS – Startup Menu

Notice the orange ***Physician Login*** button has toggled to ***At Home*** (see red circle in Figure 3.0-2) so that, if desired, the user may select the ***At Home*** button and switch back to ***At Home*** Mode from ***Physician Mode*** (limits TAPS functionality to only start therapy).

3.1 Overview of Physician/Audiologist Screens (Therapy/Tone Setup)

3.1.1 Audiogram overview

The first option, ***Audiogram***, is used by the physician/audiologist to enter the audiogram data. See Section 4.0 for more detail.

3.1.2 Therapy Tones Settings overview

The second option, ***Therapy Tones Settings***, is used by the physician/audiologist to set the tones. See Section 4.0 for more detail.

3.1.3 Program Implant overview

The third option, ***Program Implant***, is used to set the stimulation settings and allows impedance checks during implant. See Section 5.0 for more detail.

3.1.4 Deliver Tinnitus Therapy overview

The fourth option, ***Deliver Tinnitus Therapy***, is used to initiate a therapy session either in the physician's office or at home by the patient.

4. THERAPY TONES SET-UP

In order for therapy to be delivered, the tones and stimulation parameters must be set by the audiologist, physician, or healthcare worker. The tones must be set first. To set the tones, the ***Audiogram*** and the ***Therapy Tone Settings*** tabs must be completed. The ***Audiogram*** is accessed as shown in Figure 4.0-1.

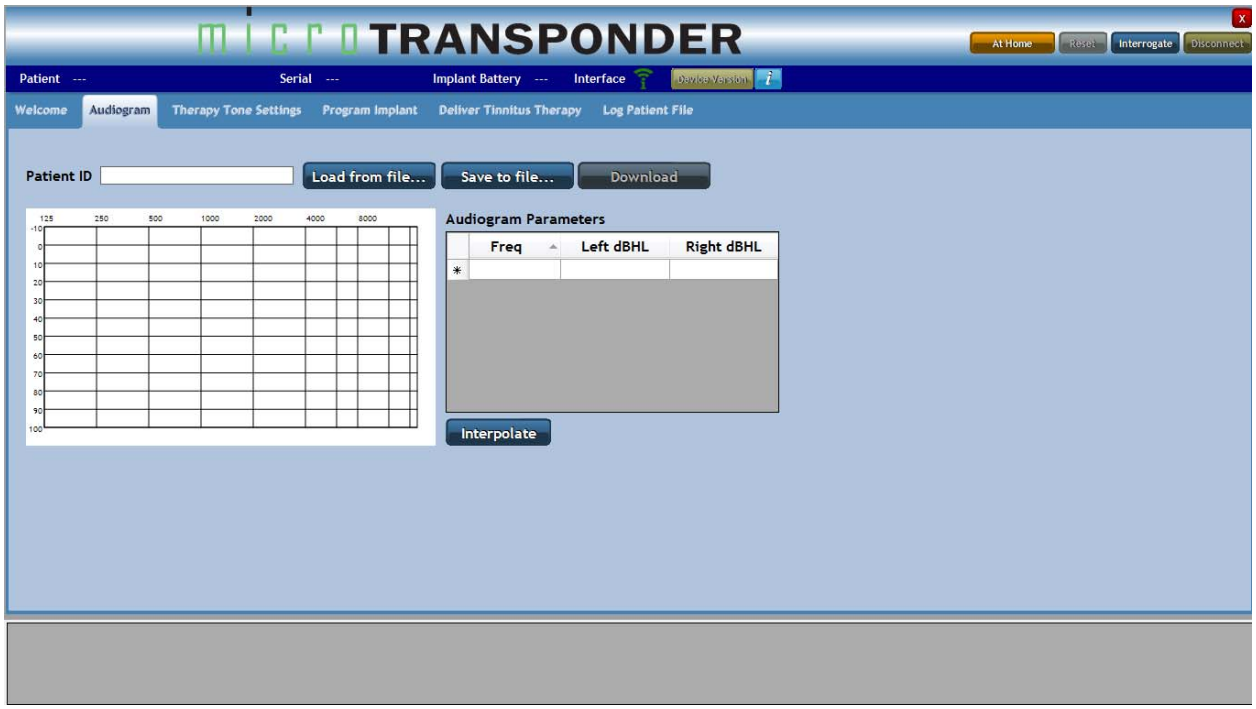


Figure 4.0-1. Audiogram Tab

This is the screen where Audiogram information is added and interpolated. The information may be loaded from a file that was previously generated in TAPS or entered manually. Once the audiogram is entered it can be saved to a file. In order to manually enter the data, the audiologist or physician clicks in the appropriate cells of the ***Audiogram Parameters*** table and types the values in as needed for frequency and hearing loss of both the Left and Right ears, see Figure 4.0-2. The user must interpolate the audiogram in order to be able to access ***Therapy Tone Settings*** and continue with therapy set up. In order to interpolate the data into

the Therapy Tone Settings, following the successful entry of all audiogram parameters, the ***Interpolate*** button must be selected (see Figure 4.0-3). The interpolated data populates the ***Therapy Tone Parameters*** table on the ***Therapy Tone Settings*** tab automatically. This data will not be saved until either the ***Save to file…*** button or the ***Download*** button is selected. The ***Save to file…*** function prompts the user to save the file in a preferred location (an external USB drive is recommended), and the ***Download*** function saves the data into the IPG. In order to deliver proper therapy, the ***Download*** function must be performed so that the therapy information is loaded into the IPG's memory.

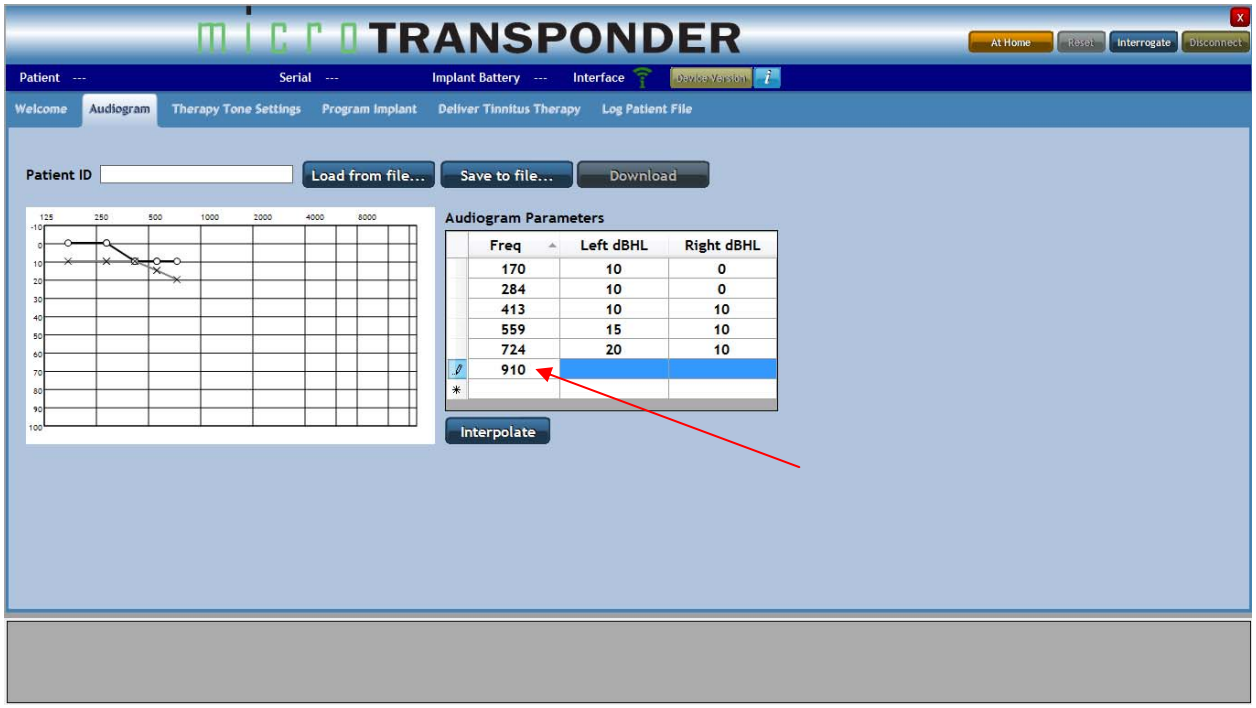


Figure 4.0-2. Audiogram Entries

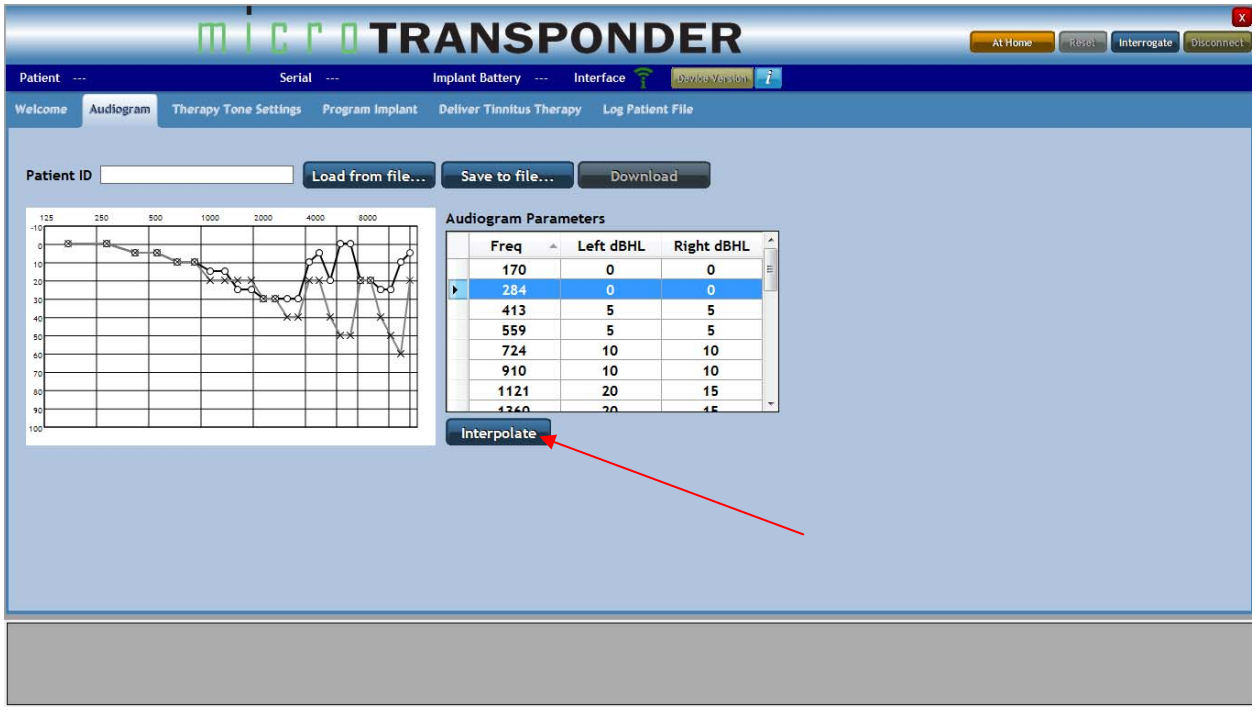


Figure 4.0-3. Interpolate Audiogram

After the Audiogram parameters are populated with Audiogram-based data (either manually or from a file) and subsequently interpolated, the “Therapy Tone Settings” tab can be selected. The interpolated data is shown in both the graph and in the ***Therapy Tones Parameters*** table (Figure 4.0-4). The ***Tinnitus Frequencies*** can now be added. This is also where the manual testing of the tones occurs and can be adjusted. Frequencies can be deselected in order to notch out frequencies around the Tinnitus frequency(ies).

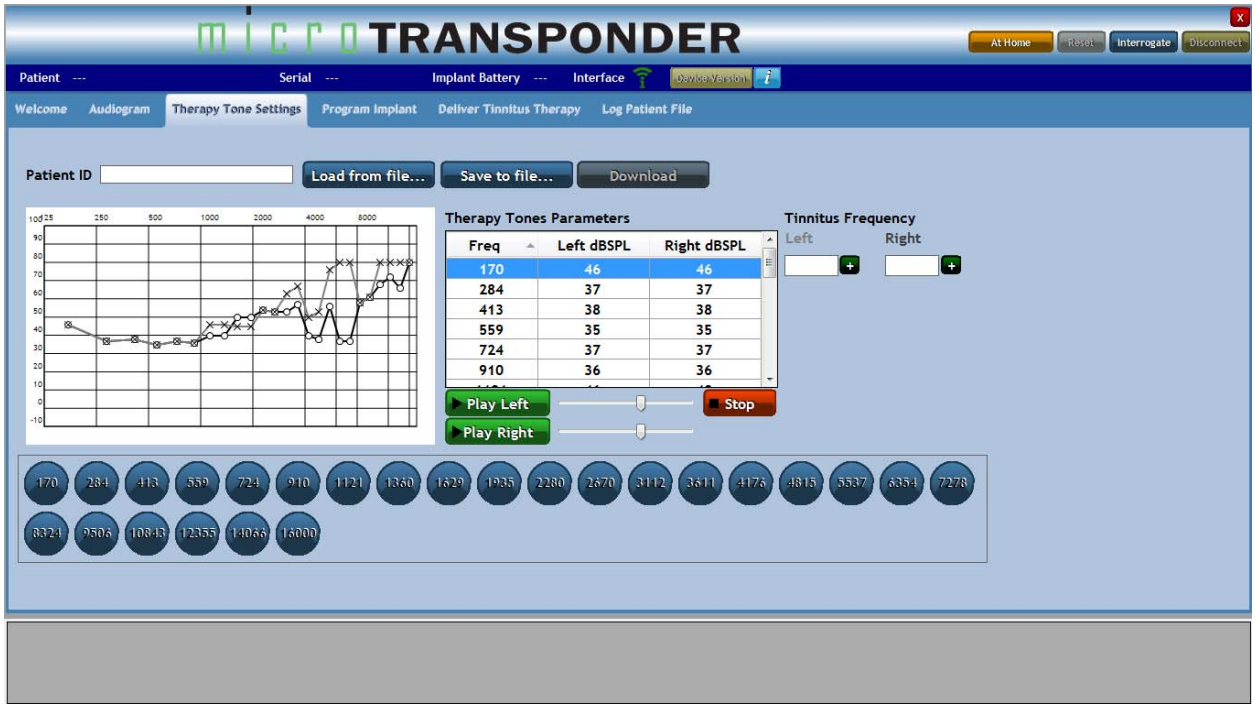


Figure 4.0-4. Therapy Tone Settings (interpolated)

For example, if a patient has tinnitus in the left ear, around a frequency of 1100 Hz., the audiologist is recommended to notch out tones being played in a ½ Octave around 1100 Hz. To do this, the frequency of 1100 is input into the drop down menu under ***Left*** and ***Tinnitus Frequency*** as shown below (right middle of screen, Figure 4.0-5). The software will then automatically select the frequencies of 910, 1121, and 1360. If necessary, the audiologist or physician can manually modify this by clicking on a frequency and selecting or deselecting the frequency.

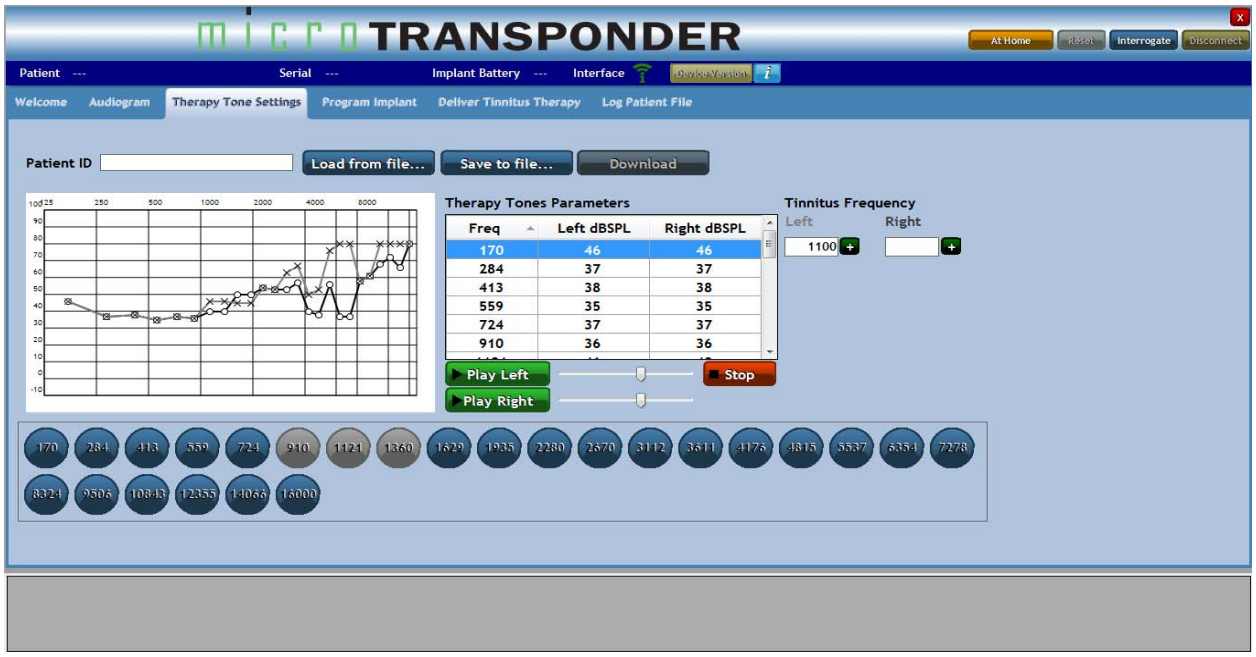


Figure 4.0-5. Left Tinnitus Frequency Entry

If the patient also has a tinnitus frequency of 3500 in the right ear, the audiologist would add "3500" in the ***Right - Tinnitus Frequency*** box, and the software will again automatically "notch out" frequencies ½ Octave around 3500, as shown below. Note that the "**+**" box next to the tinnitus frequency can be selected, and additional tinnitus frequencies can be added (Figure 4.0-6).

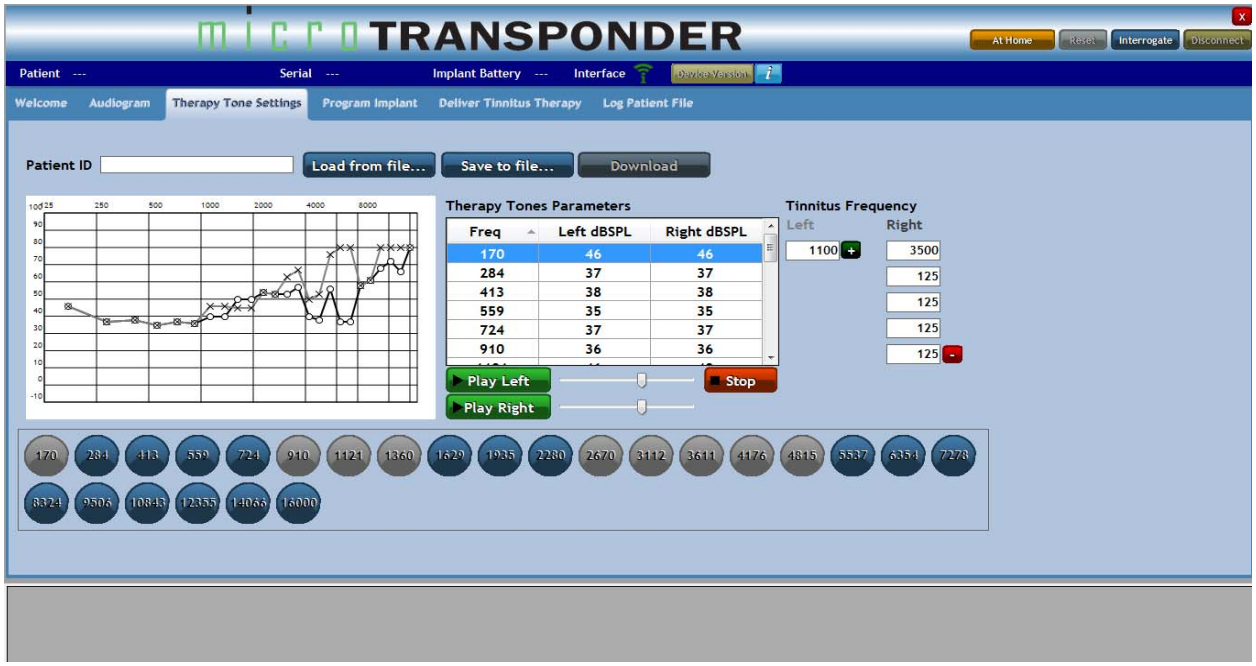


Figure 4.0-6. Right Tinnitus Frequency & Multiple Entries

The screen below (Figure 4.0-7) shows two (2) tinnitus frequencies, with ½ Octaves around those frequencies notched out (inactive frequency buttons are grey).

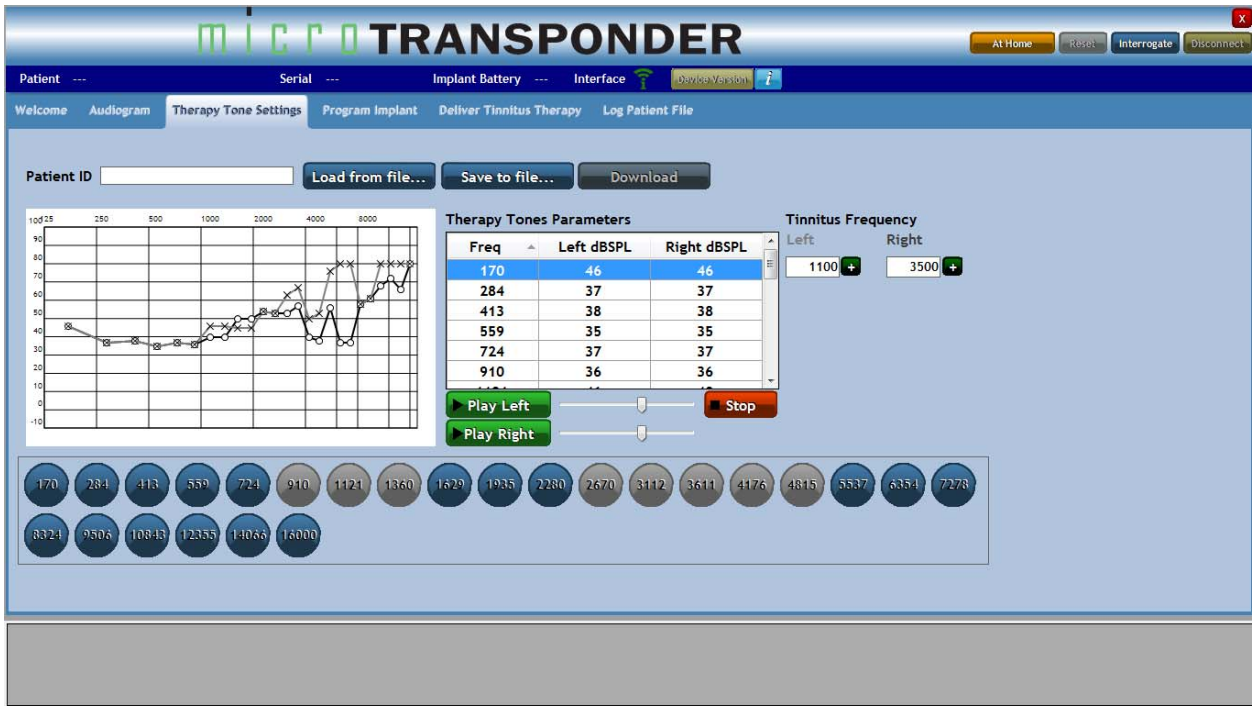


Figure 4.0-7. Two (2) Tinnitus Frequencies

The tone volume for the sound level that the tone is played at for each frequency is also available for input under ***Therapy Tone Parameters*** in the middle of the screen (white box as shown in Figure 4.0-8). The volume played in the left and right ear is adjustable – in the example below, the 170 Hz frequency is being adjusted to 80 dB for both the left and right ears. The green ***Play Left*** or ***Play Right*** button can be selected to test the tones and volume levels.

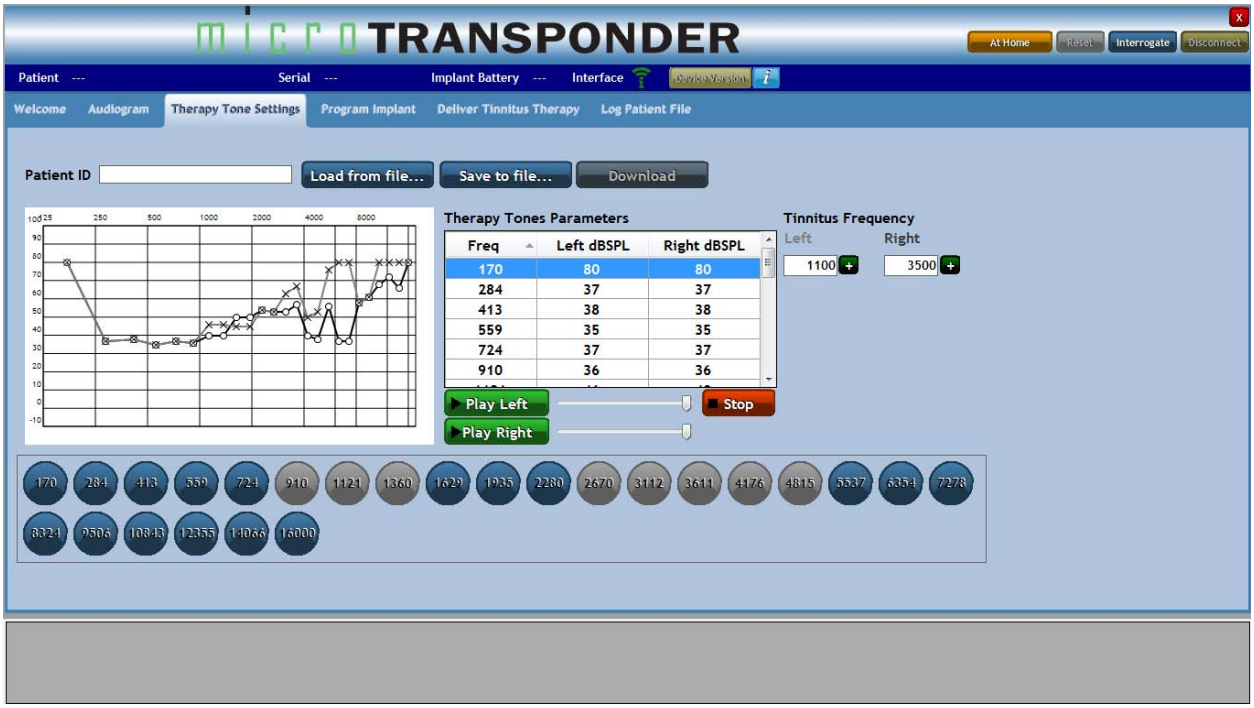


Figure 4.0-8. Tone Volume Adjust

The user may also want to notch out additional frequencies. This can be done by deselecting a frequency (where its color changes from blue to grey). The example below (Figure 4.0-9) shows an additional three (3) frequencies being notched-out (7278, 8324, 9506), as indicated by the grey deselected buttons.

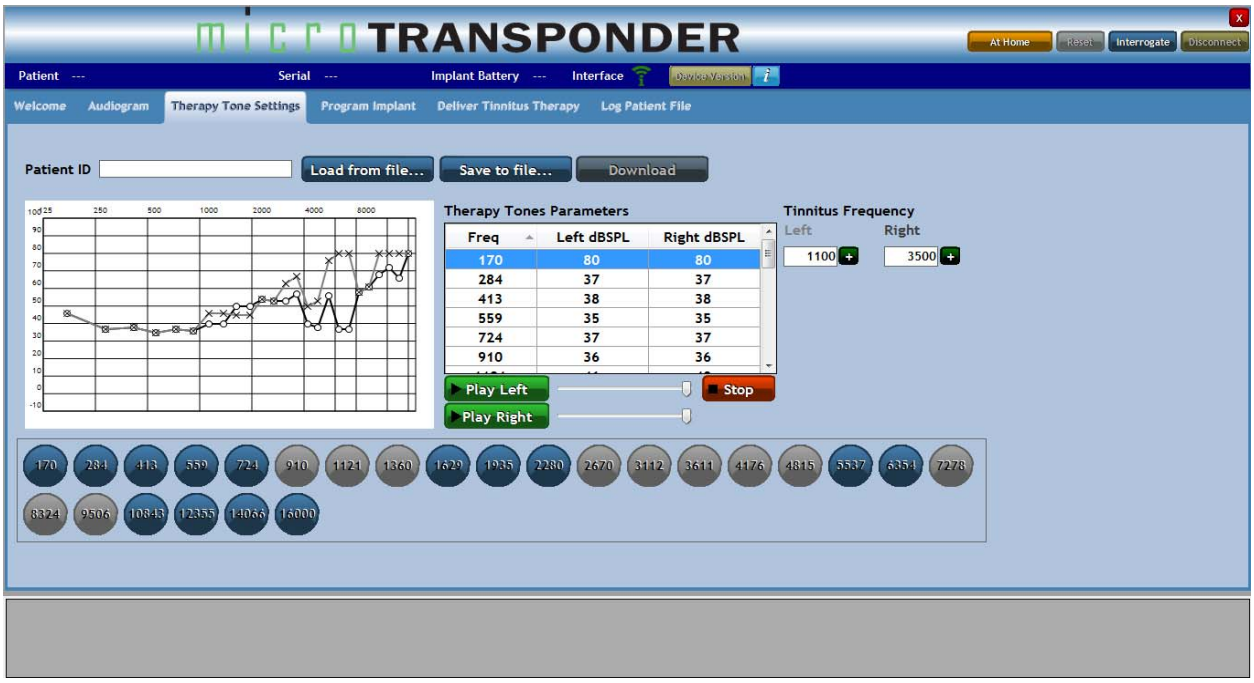


Figure 4.0-9. Additional Notched-out Frequencies

5. PROGRAM IMPLANT

The ***Program Implant*** menu (Figure 5.0-1) allows the user to set the VNS ***Parameters***, check the lead impedance, and then ***Test*** and ultimately ***Program*** the parameters into the IPG.

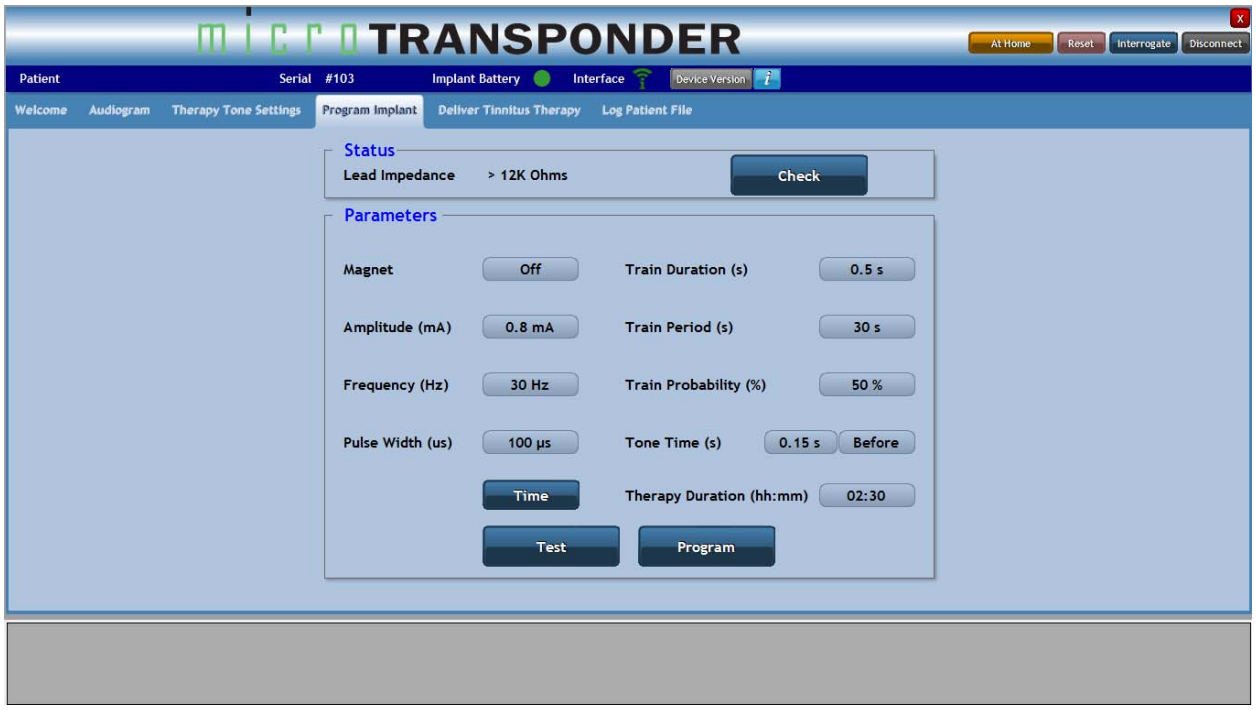


Figure 5.0-1. Program Implant

For each of the settings (Magnet, Train Duration, Amplitude, Train Period, Frequency, Train Probability, Pulse Width, Tone Time and Therapy Duration), the box next to the setting can be selected, and all available parameters are shown in a drop down box. The appropriate value should be selected for each parameter. After all of the parameters are set, the user may ***Test*** or ***Program*** the displayed parameters.

It is recommended the user verify that the VNS settings chosen are tolerable for the patient. This is done by selecting the ***Test*** button which delivers a single train of stimulation per the parameters displayed in the ***Parameters*** menu. This does not permanently program the IPG but only performs a one-time stimulation.

Once the user is satisfied that the chosen parameters are appropriate and tolerable, the ***Program*** button must be selected in order to program the IPG with the therapy parameters displayed in the ***Parameters*** menu. The values programmed via the ***Program*** function are input into the IPG and 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.

The user may also want to verify the lead impedance. In the ***Status*** portion of the ***Program Implant*** menu the lead impedance can be checked by selecting the ***Check*** button (Figure 5.0-2). Doing so delivers a small current pulse through the lead to calculate the lead impedance.

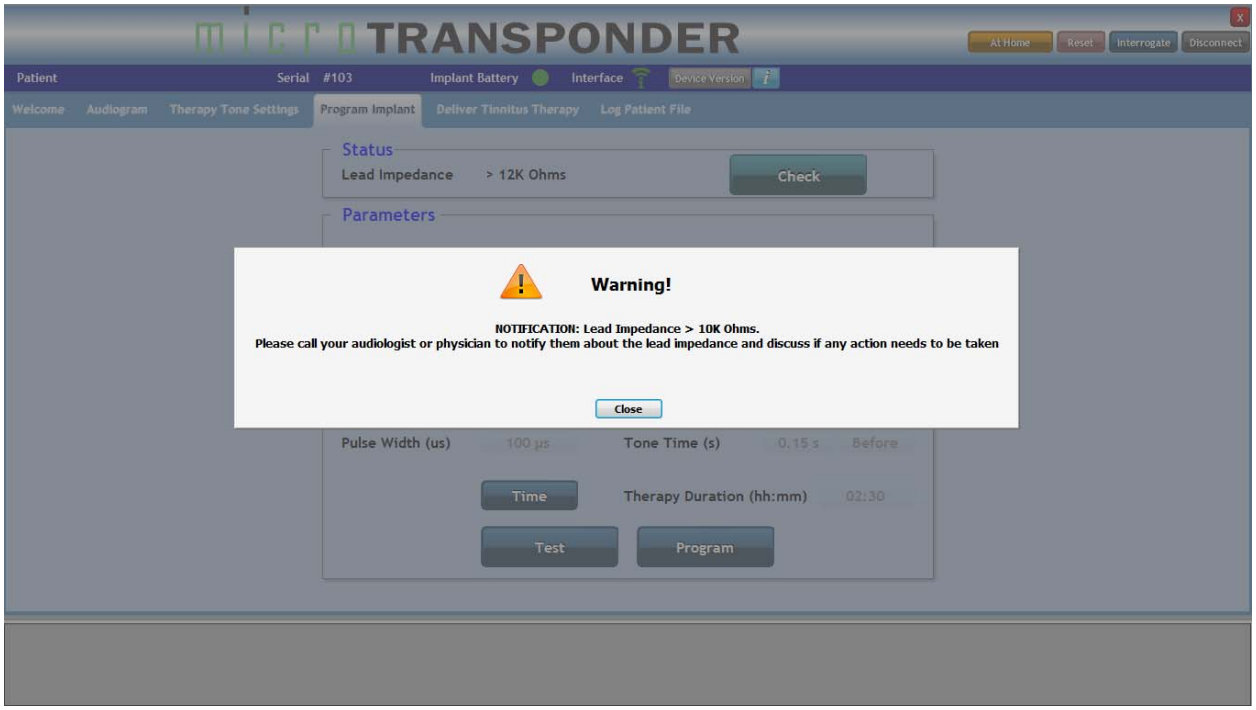
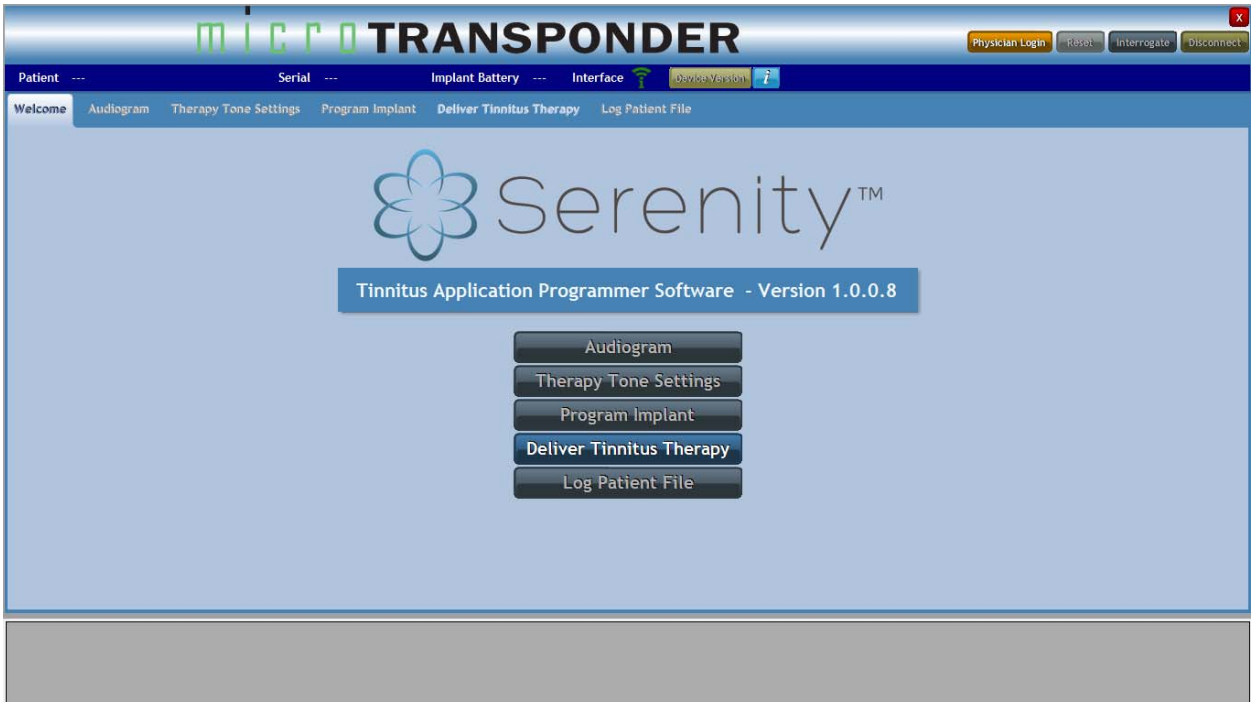


Figure 5.0-2. Lead Impedance Check

After the ***Check*** button is selected, the Lead impedance value is shown. For any value above 10,000 ohms, the "Warning!" screen above reminds the patient to contact their audiologist or physician to see if any action needs to be taken.

6.0 DELIVER TINNITUS THERAPY (AT HOME USE)

Deliver Tinnitus Therapy allows the user (typically a patient) to initiate therapy using settings that are already set. The ***At Home*** mode, which is the proper mode for patient use, does not allow the patient to modify any setting – it only allows the initiation of therapy (only ***Deliver Tinnitus Therapy*** is selectable).



Repeat Figure 2.0-1. Startup Menu Screen

However, if in ***Physician's Mode***, all other menu selections are available (see repeat of Figure 3.0-2). Nevertheless, whether selected in ***At Home*** mode or ***Physician's mode***, when ***Deliver Tinnitus Therapy*** is selected, the software operates the same way.

Repeat Figure 3.0-2. "Physician Mode" of TAPS – Startup Menu

When ***Deliver Tinnitus Therapy*** is selected, the following screen appears (Figure 6.0-1).

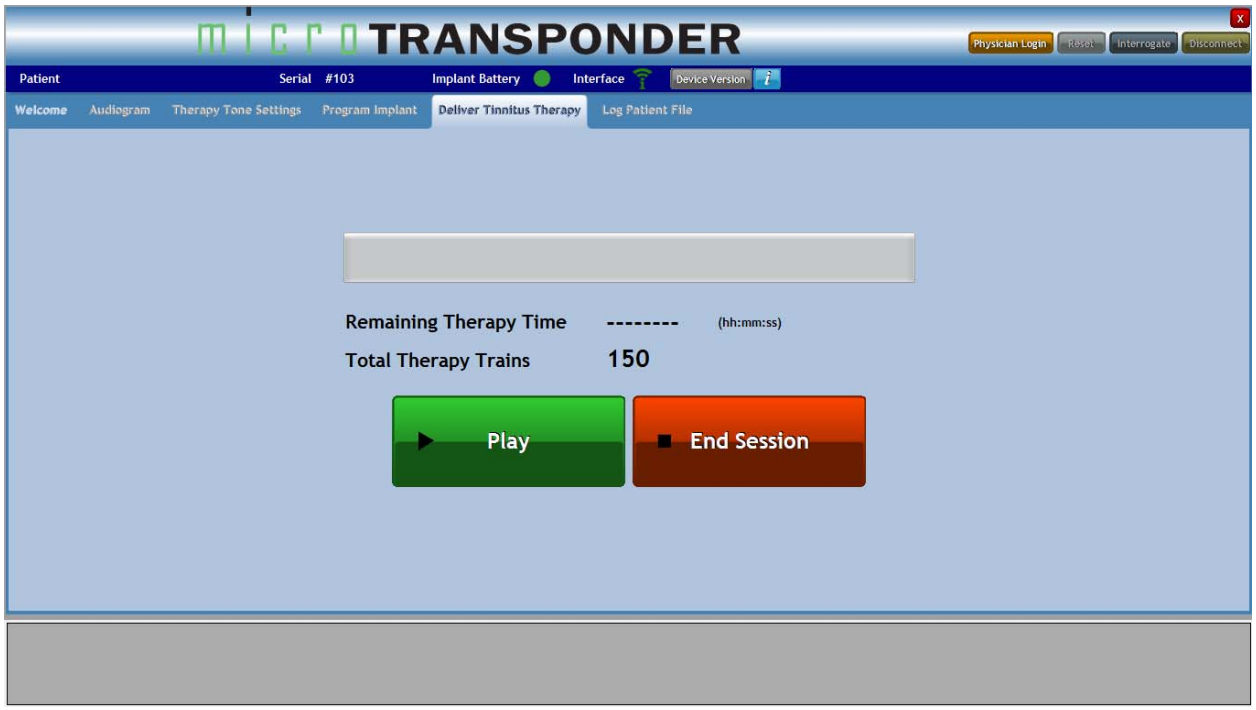


Figure 6.0-1. Deliver Tinnitus Therapy

This allows the user (patient or physician) to start therapy by selecting the ***Play*** button. The screen indicates the time remaining and total therapy to be delivered (Total Therapy Trains) in the session. In addition, the grey box is populated with a percentage completion amount, indicating time completed (shown in green) and remaining (grey) for the initiated therapy session (see Figure 6.0-2).

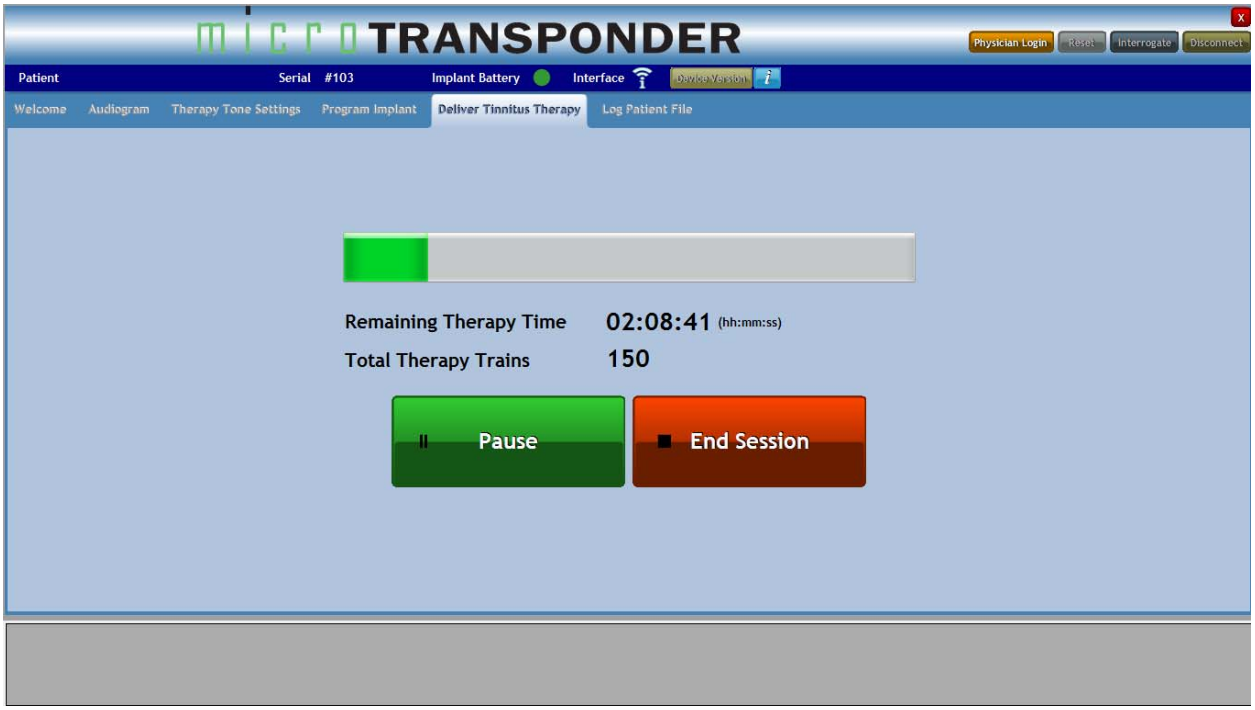


Figure 6.0-2 Therapy In Progress

The therapy can be paused at any time if the patient needs a break (Example: going to use the restroom) by selecting the ***PAUSE*** button. The ***PAUSE*** button toggles to a ***RESUME*** button and the ***INTERFACE*** indicator stops flashing and remains green (see Figure 6.0-3). NOTE: Pausing the therapy is not recommended; if a ***PAUSE*** is absolutely necessary, the patient should return to therapy as soon as possible and minimize the amount of paused time during a therapy session.

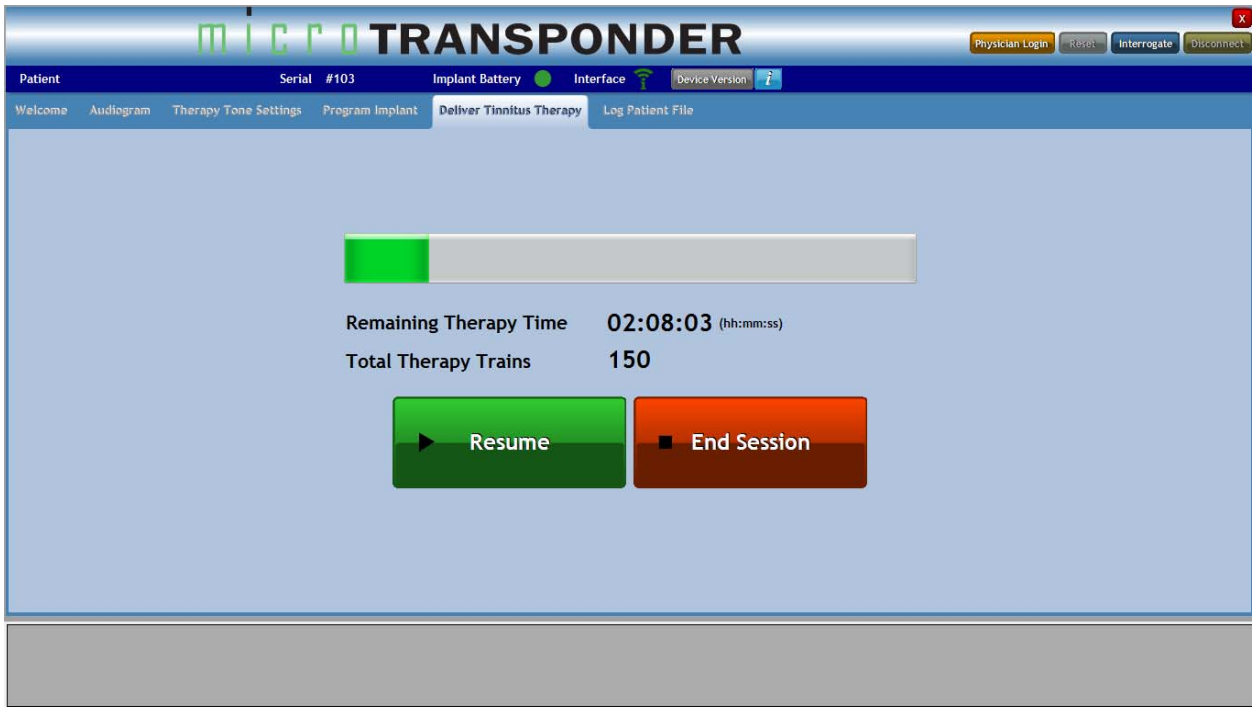


Figure 6.0-3 Paused Therapy Session

Additionally, if the patient moves outside the range of the Wireless Transmitter (1 meter), communication will be lost and the therapy session is automatically paused as a result. In both of these scenarios the user must resume their session within 45 minutes or the session will be automatically terminated by the software and a new session must be started to restart therapy. The user will receive a message as shown (Figure 6.0-4) that states "*Last therapy was interrupted for more than 45 min. A new therapy will be started.*"

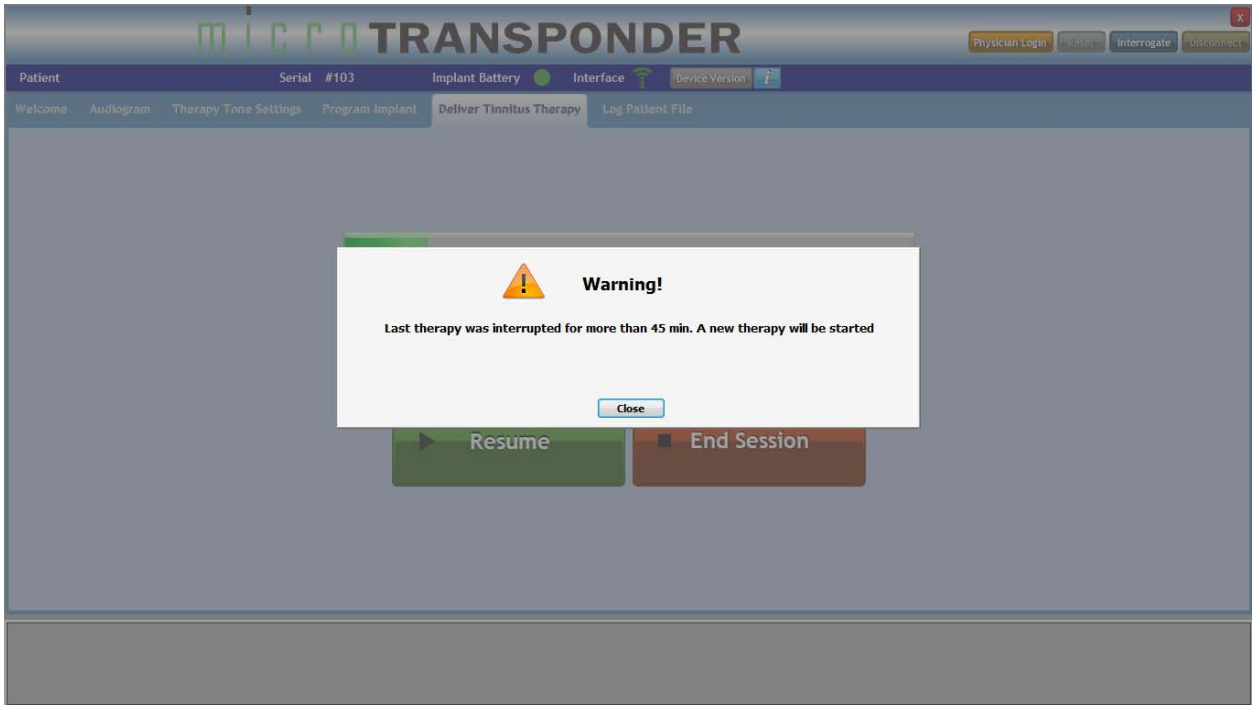


Figure 6.0-4 Therapy Session Idle Time Out

The ***END SESSION*** button can be selected at any time to stop therapy. If the ***END SESSION*** button is selected, the current session is ended and a new session must be started as previously described. Otherwise, the session will end automatically after the preset time limit (typically 2.5 hours) is reached.

7.0 BATTERY

There is no battery in the Wireless Transmitter, and the laptop should be plugged into AC power to maintain charge.

8.0 MAINTENANCE, HANDLING, AND STORAGE

The Wireless Transmitter shall not be permanently affected by exposure to or storage in temperatures in the range of -20°C to +70°C. Humidity up to and including 100% shall have no effect on the Wireless Transmitter. Additionally:

- The Wireless Transmitter shall be cleanable by wipe down with water, soap and alcohol.
- The Wireless Transmitter is standard lab type equipment and shall be re-useable.

- Please return the Wireless Transmitter to MicroTransponder after completion of the study or in the case of malfunction for evaluation and disposal.

9.0 PRECAUTIONS 

If problems occur with TAPS, review the information in this section:

- When in use, MicroTransponder recommends the computer be operated with sufficient battery power or be plugged into AC power to maintain charge.

- MicroTransponder recommends that no other software be loaded onto the Paired VNS Therapy Serenity System computer because it may interfere with proper functioning of the software already installed on the computer.

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

- Programming in the presence of an EMI signal can be difficult or impossible, but problems can usually be resolved by repositioning the patient, the Wireless Transmitter, or the EMI source.

- Programming while the IPG and/or patient are on a metal table can be difficult or impossible, but problems can usually be resolved by placing the Wireless Transmitter closer to the IPG.

- The TAPS system, as described herein, should only be used with equipment described in this manual. TAPS should not be used with medical device equipment other than the MicroTransponder Paired VNS Therapy Serenity System.

- Do not modify this equipment without authorization of MicroTransponder.

- It is important that the PC 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.

10. TROUBLESHOOTING

This section provides troubleshooting instructions in four parts: (1) general recommendations, (2) hardware issues, (3) problems in the Operating Room (OR) and (4) problems at patient follow-up visits.

10.1 General Recommendations

Non-responsive Computer

The TAPS laptop will power up in the ***At Home*** mode of the TAPS application. If for any reason this does not occur, power off the laptop and power it back on. If the problem persists, contact MicroTransponder Technical Support at the number provided in Section 11.

10.2. Hardware Issues

10.2.1. Restore and reinstall software

The TAPS should be installed on the laptop hard drive when you receive it. However, if for some reason reinstallation is necessary, a software disk is provided to the physician with the computer. This disk can be used to reinstall the software at the treatment facility by designated personnel, not by the patient. Contact MicroTransponder Technical Support at the number provided in Section 11 for assistance in reinstalling the software.

10.2.2. Other hardware issues

For all other hardware issues for the computer, contact MicroTransponder Technical Support at the number provided in Section 11.

10.3. Troubleshooting in the OR

10.3.1. Communication problems in the OR

An example of an error message following a communication problem is shown in “Telemetry Lost” Figure 10.3-1.

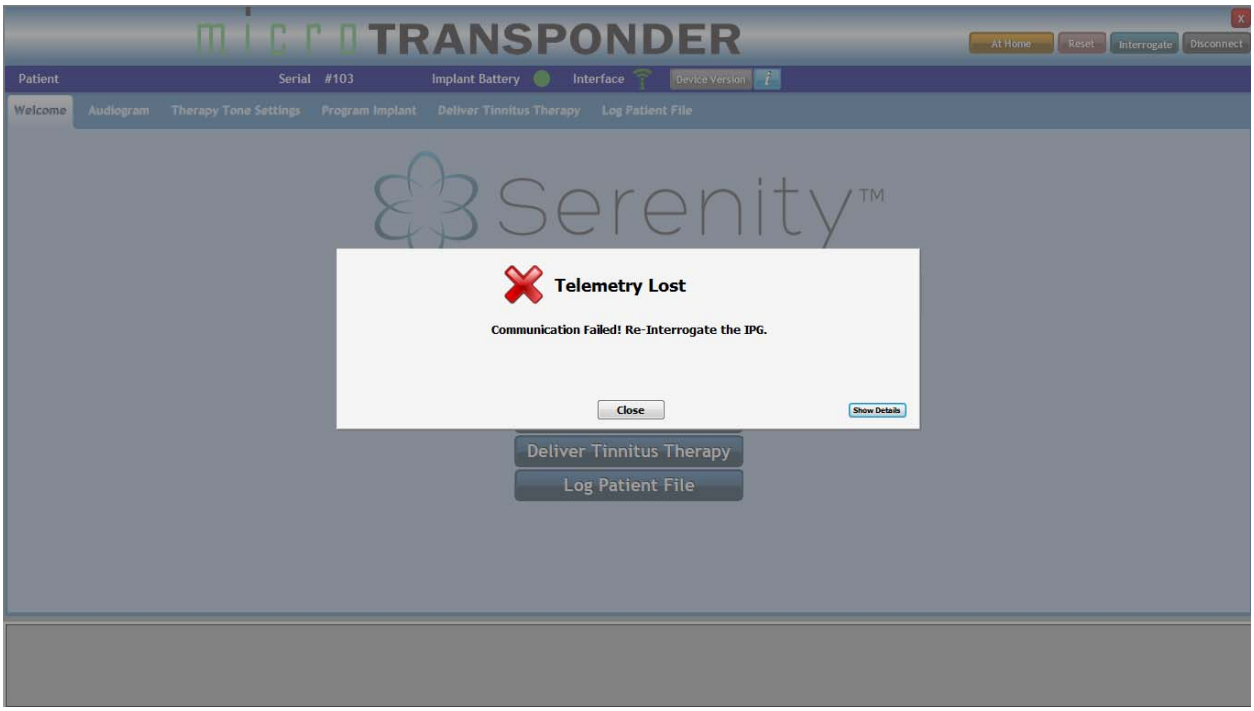


Figure 10.3-1 Telemetry Lost

Failure of the IPG and Wireless Transmitter to clearly communicate with each other to interrogate, program, or run diagnostic tests can be attributed to several factors:

- Movement of the patient away from the Wireless Transmitter during communication
- Wireless Transmitter not properly connected to laptop
- Electromagnetic interference (EMI) i.e., OR lights, other Medical Device Systems
- Proximity of IPG or WT to a metal table
- IPG battery at end of service (EOS)
- Defective Wireless Transmitter
- Defective laptop
- Defective IPG

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

A communication problem causes an error message such as “Telemetry Lost” during interrogation, when programming of audiogram, therapy tone settings, VNS parameters, checking impedance, or any therapy required communications. Performing these steps may restore communication.

1. Verify that the Wireless Transmitter is properly connected to the Computer. The USB plug from the Wireless Transmitter should be placed into one of the Computer’s USB ports. Figure 2.0-2 shows the indicator for proper connection.
2. Verify that the patient and IPG are within 1 meter of the Wireless Transmitter
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 computer 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.

11. INFORMATION AND SUPPORT

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

MicroTransponder, Inc.

2802 Flintrock Trace, Suite 226
Austin, TX 78738

Phone: 512-371-4160
Fax: 888-822-5206 or 214-299-8660.

For Clinical and Technical Support, call:

Telephone: 512-371-4160

Internet
www.microtransponder.com

12.0 GLOSSARY

Electrode – The mechanical and electrical interface of the Paired VNS Therapy Serenity System to the vagus nerve. The electrode is part of the Lead.

EMI - Electromagnetic interference

EOS – End of Service

High Lead impedance - Any impedance above 10,000 ohms. TAPS notifies the user and then appropriate follow-up can occur. Impedance is how easy or difficult it is for current to flow through a specific object. In this case, it is how easy or difficult it is to deliver current from the IPG through the lead to the nerve. As impedance rises, it means the IPG must increase the voltage needed to deliver the same current. Therefore, higher impedances mean higher voltages – which ultimately means that battery use is higher and IPG life is shorter. Possible reasons for an increase in impedance are: 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 service.

IPG – Implantable Pulse Generator – The stimulator portion of the Paired VNS Therapy Serenity 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 Paired VNS Therapy Serenity 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 Therapy® - VNS delivered by MicroTransponder's Paired VNS Therapy Serenity System. The Serenity system pairs VNS with tone therapy.

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 μsec.

Serenity – Trade name of the Paired VNS for tinnitus system

Signal frequency - Repetition rate of pulses in a stimulation; measured in number of 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 (not including ramp-up and ramp-down times); measured in seconds.

TAPS (tinnitus application & programming software) – Software that allows the physician or healthcare worker to set the VNS setting and initiate stimulation paired with tones.

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

VNS - Vagus Nerve Stimulation

VNS Therapy® - VNS delivered by Cyberonics' VNS Therapy System. Paired VNS Therapy is delivered by the MicroTransponder Serenity System.

WT – Wireless Transmitter – A radio frequency device that connects via a USB plug to the computers USB port and provides communication with the IPG, used in conjunction with TAPS.