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

Wireless Transmitter: Model 2100

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 0

PAT. www.microtransponder.com/patents

Rx Only

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 2100 Wireless Transmitter communicate with each other using ultra-low power Medical Implant Communications Service (MICS Band) telemetry in the frequency range 402 – 405 MHz.

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

This device may not interfere with stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

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.

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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 µs.

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

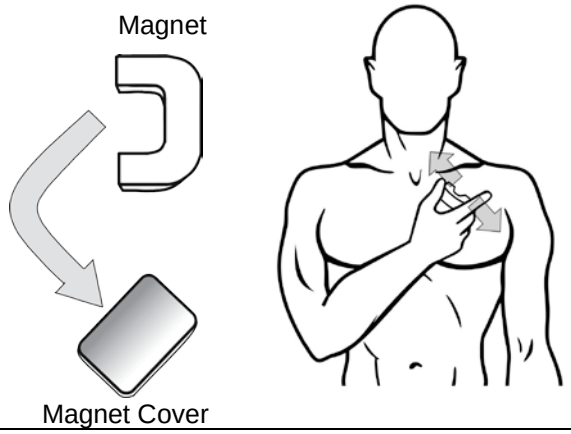
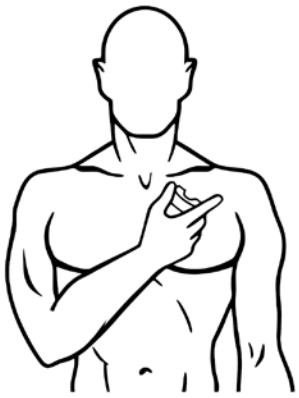
Serial Number

Temperature Limitation (Storage and Transport)

Number of Radio Frequency (RF) Communication Channels

Keep Dry

Vivistim® Paired VNS™ System
Quick Start Guide for Patients

<table>
<tr><td>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.</td><td> 
</td></tr>
<tr><td>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.</td><td rowspan="2">  </td></tr>
<tr><td>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]</td></tr>
<tr><td>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.</td><td>Magnet Force: 4.5+ kg</td></tr>
<tr><td>5. The magnet provided to you may damage TVs, computer disks, credit cards, and other items affected by strong magnetic fields.</td><td>Please keep the magnet away from such items.</td></tr>
</table>

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.