

Parasym[®]

User Guide



*tVNS device for
Non-invasive stimulation of the Vagus Nerve*

hello

Welcome to your new Parasym tVNS device

This guide shows you how to use tVNS (transcutaneous vagus nerve stimulation) therapy, helps you setup your device, and gets you on a treatment schedule you can use every day. Two AA alkaline batteries are included so you can start straight away.

Before using your device, please make sure you have read all the precautions, warnings and safety information, followed by the guidance for proper setup. If in doubt of the suitability of the Parasym device, consult your doctor before use.

Caution

Keep out of reach of children.

Contraindications

The Parasymp device can affect the operation of demand type cardiac pacemakers or other implantable devices. In patients with known myocardial disease, arrhythmias or heart conditions, Parasymp should be used only with consultation and evaluation by a Doctor. Do not use Parasymp on children under the age of 12.

Warnings

Safety of Parasymp device for use during pregnancy or delivery has not been established. Electronic equipment such as EKG monitors and EKG alarms may not operate properly when Parasymp is in use. Do not attempt to use the Parasymp or its accessories in any other way than that described in this User Guide.

Skin Irritation

Reactions such as irritation at the stimulation site are rare. If this does occur, and becomes unpleasant, stop the stimulation. The irritation or discomfort should cease shortly after stopping stimulation. If skin irritation persists, discontinue use and consult your doctor.

Precautions

- Turn the unit off before applying or removing the electrode.
- Do not pull leadwires to remove electrode.
- Do not use if the device or electrode are damaged
- Do not raise the stimulation intensity level to where there is pain or discomfort on the tragus for an extended period
- Do not use the clip electrode on a site other than the tragus
- Only use alkaline batteries in the device
- Stop use if you experience pain or discomfort
- Long-term tVNS stimulation at the electrode site may cause skin irritation. If the therapy becomes unpleasant, discontinue use until re-evaluated by a therapist or physician.
- Do not place the Parasym unit near excessive heat or in water.
- Keep the Parasym unit out of the reach of children.
- Use only the batteries specified in this user guide and remove batteries if the unit is not to be used for a long period of time.
- Keep the Parasym unit away from sources of high magnetic fields for example TVs, microwave ovens and hi-fi speakers, as these may affect the LCD screen.
- The Parasym Device cannot be used by an individual who has a cardiac pacemaker or an implanted or wearable defibrillator.
- The Parasym Device cannot be used by an individual who has an implanted metallic or electronic device in their head.
- The Parasym Device should not be used during pregnancy.
- The Parasym Device should only be applied at the designated anatomical site on the outer ear. It should not be used in the presence of electronic monitoring equipment (e.g cardiac monitors), in the bath or shower, while sleeping, while driving or while operating machinery.
- The Parasym Device should never be used on broken skin.

Care and Maintenance

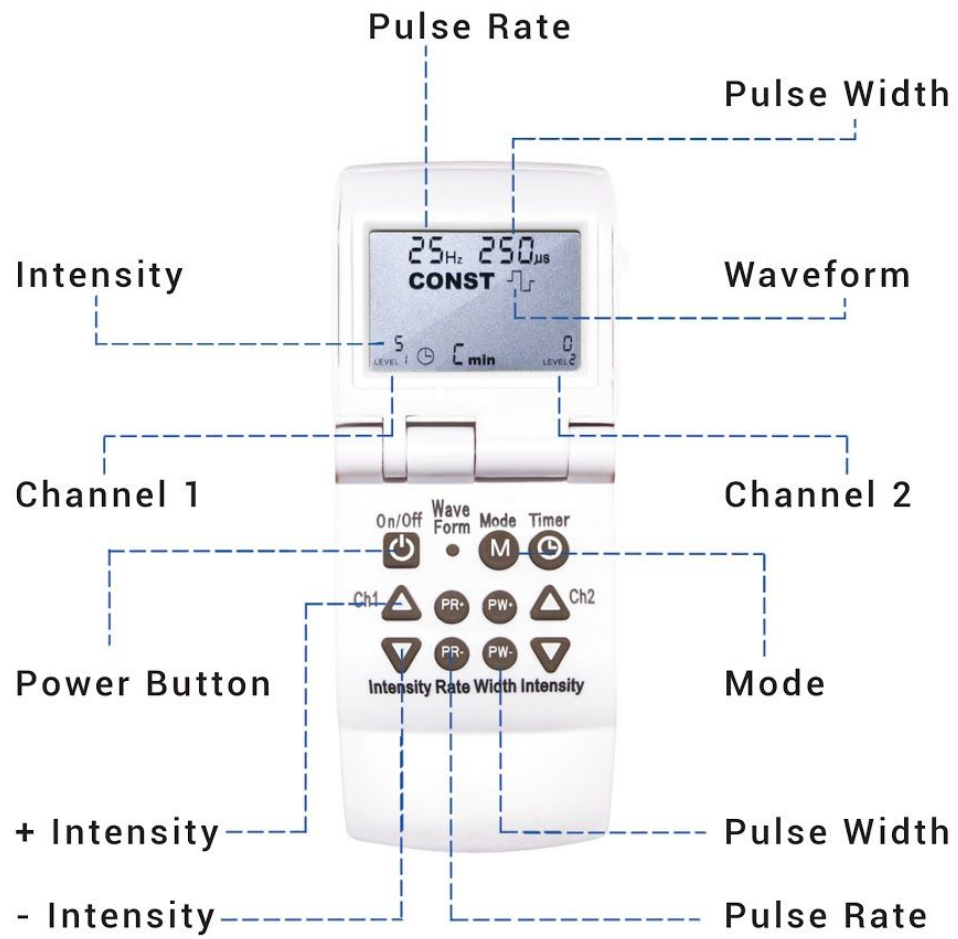
The unit and/or electrode may be cleaned by wiping it with a damp cloth and a solution of mild soap and water. Wipe dry after cleaning. Do not immerse the unit or electrode in water. Replace batteries as soon as flashing symbol appears. Care should be taken to not get moisture in the internal circuitry or inside the battery compartment. No other user maintenance of the main unit is required.

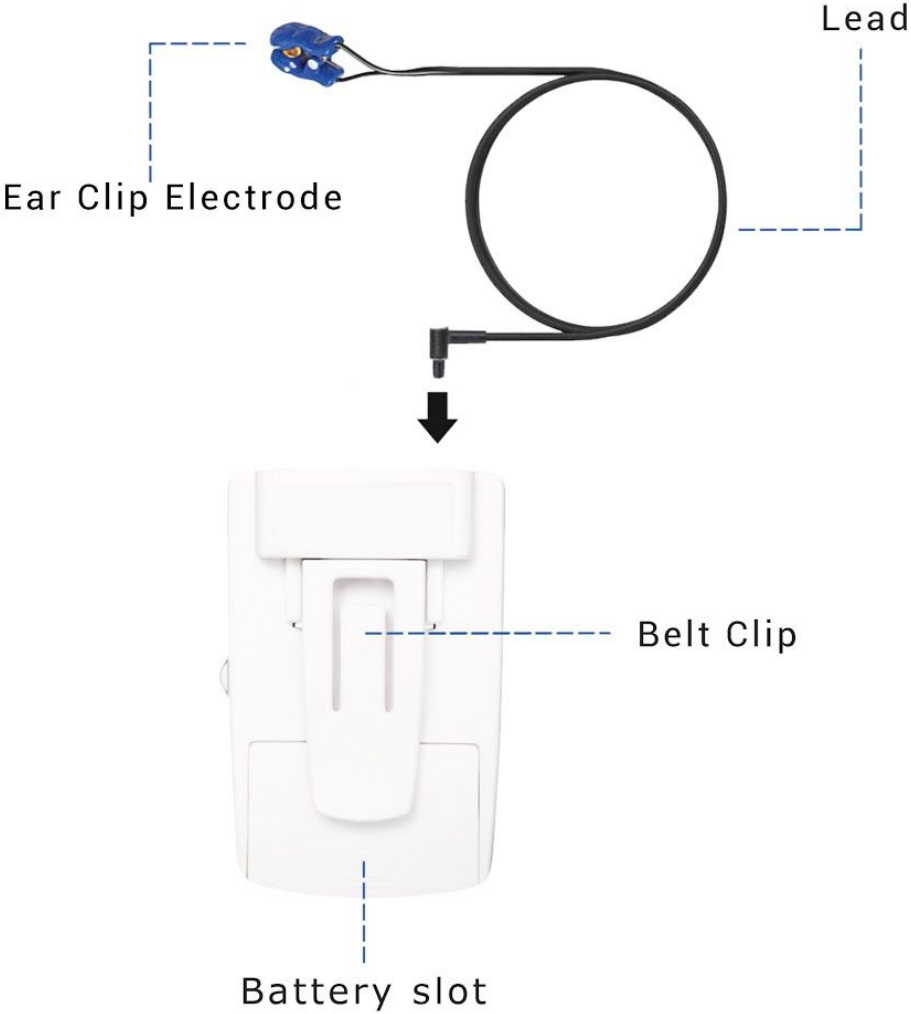
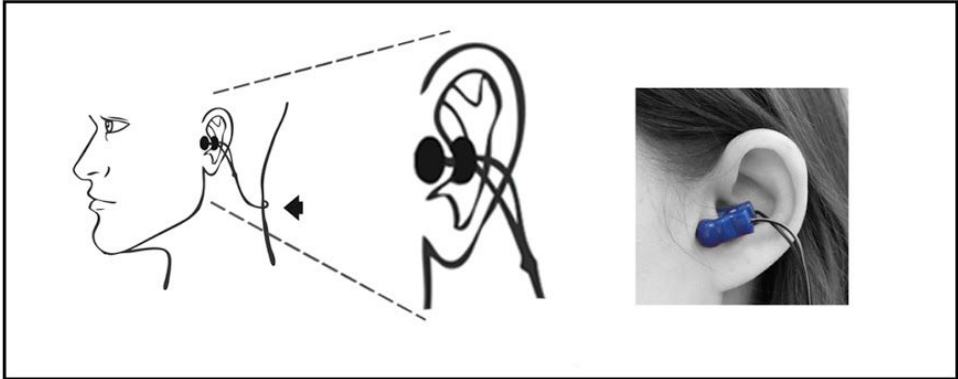
Testing the Device

The device can be tested by making sure the batteries are in the device correctly, pressing the power button where the LCD screen should turn on and remain on.

Testing the Electrode

The electrode can be tested before each treatment session with the standard sensory and therapeutic threshold protocol found in the Quick Start Section. If the electrode is found to no longer work, replacements can be reordered from your supplier.







Quick Start Guide

- 1.** Insert the two AA alkaline batteries

Take care in doing this, be careful not to strip the material covering the batteries as this can lead to a short circuit

- 2.** Plug the lead included into channel 1

- 3.** Electrode Placement

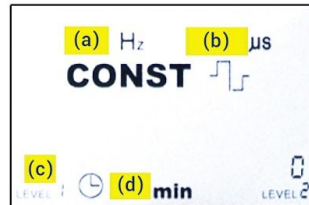
- 3.1.** Clip the electrode to your left tragus

(See diagram on Page 7) - Make sure this is a good connection with both gold plates having a firm contact with the skin

- 4.** Push the Power Button


- 5.** You can now input the settings for your treatment (Page 9)

Settings



- (a) Pulse Rate = **20 Hz**
- (b) Pulse Width = **200 μs**
- (c) Intensity = **See section below**
- (d) Recommended Time = **60m/day**

Mode: **Const**

Waveform = 

1. Adjust the settings with the corresponding +/- buttons to match the display shown above. (Reference diagram on page 6)

2. We recommend 60 minutes of use per day. This can be achieved by pressing the timer button to '60 Min'. The device will automatically shut down after 60 minutes. Please find a convenient time each day, using the treatment at the same time each day, for consistency.

Intensity Information (c)

Treatment stimulation intensity should be just below the level where it can be perceived or felt. For most people this is between Level 1 -Level 15. This stimulation threshold will vary from patient to patient because different people have different levels of sensitivity. Tolerance and sensitivity can also vary depending on time of day, activity levels and stress levels.

The tragus is a sensitive area and it is important not to over-stimulate with too high an intensity or for too long a period of time. Follow the steps below to find your therapeutic level before each treatment session.

Setting Up Intensity (c)

Repeat for each treatment session

1. Firmly connect earclip to left tragus (See image on p.7).
2. Press the ON/OFF key where settings will display on the LCD screen.
3. Slowly increase the intensity by 1 increment at a time to the point where a tingling is felt on the tragus, going to a maximum of Level 36^[1]. (use the up arrow on the left, for channel 1, to do this). Take care in doing this as it can be difficult to perceive the stimulation at first.
4. When you feel sensation take a note of the intensity level and turn the device off by pressing the OFF key. Perception of sensation may be sudden.
5. Turn the device back on again, where the intensity will be reset to 0.
6. Slowly increase the intensity to 1 below the level where you felt sensation. This is now set at the therapeutic level you can use for treatment. If sensitivity increases during the course of treatment, you can reduce intensity.

[1] If no stimulation is felt at Level 36, repeat steps 1 to 3 again making sure to start from Level 0. Altering the Hz (pulse rate), between 1 and 20 Hz can help with this. Furthermore, it is also important to have a clean tragus for an effective connection with the earclip. If stimulation is still not felt, a small amount of moisture applied to the tragus can facilitate conductivity. If all of the above fails, please contact us for further instructions.

Safety

The Parasymp device and ear-clip electrode are CE marked and pose no patient risk if used correctly in accordance with the user guide.

- It is also important that stimulation intensity is not raised to the level where there is pain or discomfort on the tragus for an extended period.
- **Do not use the ear-clip on the right tragus.** External studies have used this method with no contraindications, however our research focuses on stimulation via the left tragus and we do not endorse any other use.
- Only use alkaline batteries in the device.
- Do not strip the batteries when inserting (for risk of short-circuiting), this can be avoided by taking care when inserting.



Troubleshooting

If the unit does not appear to be operating correctly, refer below to determine the cause. Should none of these measures correct the problem, please contact your supplier.

-The unit does not function at all

Check the batteries are inserted correctly.
Replace batteries.

-Unit switches off unexpectedly

This is likely to be the power-save function. If no buttons are pressed and the intensity level is zero, the unit will power-off automatically after a few minutes.

-There is no stimulus from one channel

Check the intensity is set above zero.

Check the lead wire is inserted into the unit correctly, firmly in the socket.

Check the lead wire is in Channel 1 (when controlling channel 1).

Check position of the earclip with the skin, where both metal plates are firmly pressed against the skin.

Other points to note

The device has 2 channels, however you will only be using Channel 1 for treatment. Make sure the ear-clip is plugged firmly into Channel 1 (the left channel). Make sure that intensity is set on Channel 1 (the left side of the display).

Make sure the ear-clip electrode is clipped so that it has a firm connection to your tragus, with both gold plates pressed firmly against the skin.

You can arrange the lead behind your neck (as shown in the image on page 7), this will help take the weight off the connection, increasing mobility.

If you have further questions regarding treatment, the device, settings or other queries, please get in touch:

hello@parasym.co

Parasym HEALTH

Version 2.5

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