

SaluSTIM[®]

User Guide



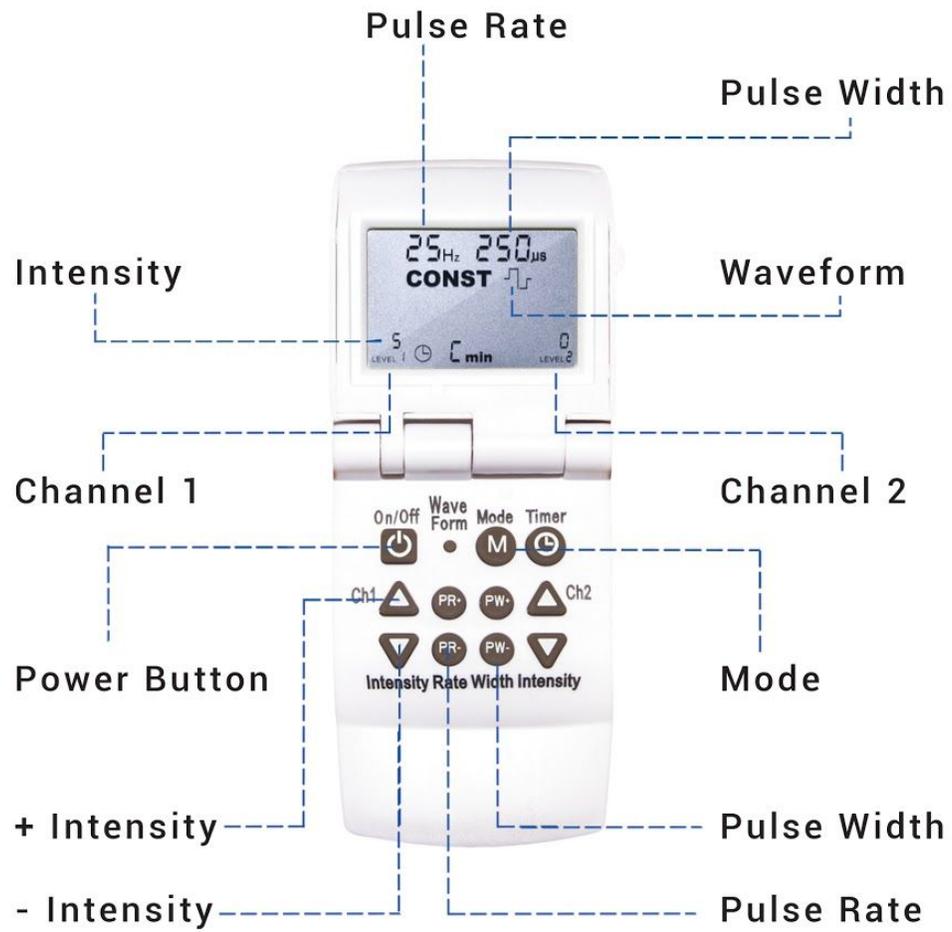
*tVNS device for
Non-invasive stimulation of the Vagus Nerve*

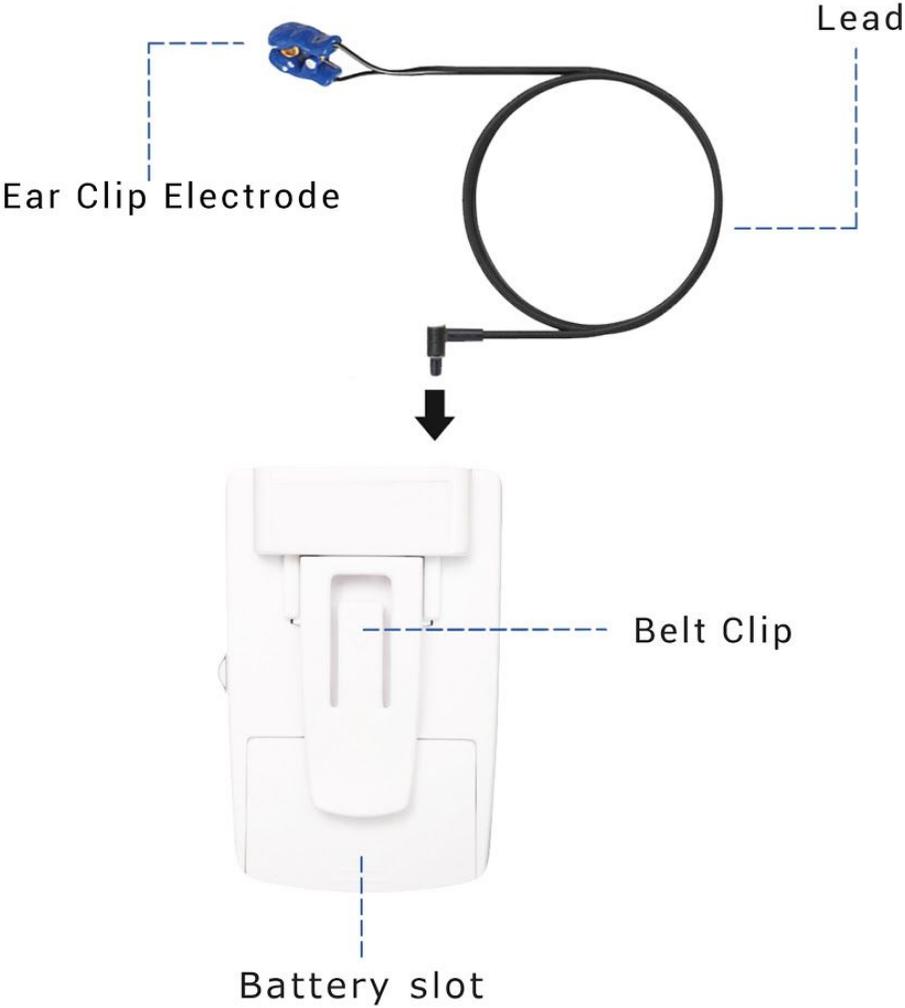
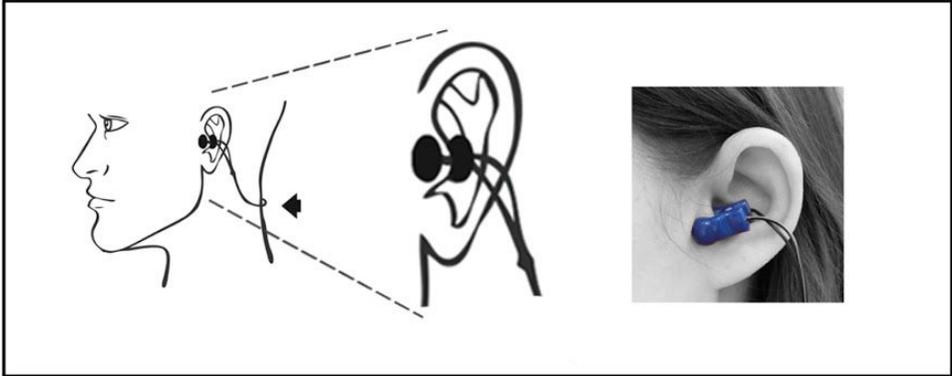
hello

Welcome to your new 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 the setup and safety details in this guide.





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

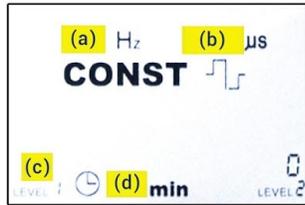
3. Clip the electrode on your left tragus

(See diagram on Page 4) - 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 6)

Settings



- (a) Pulse Rate = **25 Hz**
- (b) Pulse Width = **250 μs**
- (c) Intensity = **See section below**
- (d) Time = **60+ Minutes/day**

Mode: **Const**

Waveform = 

1. Adjust the settings with the corresponding +/- buttons to match the display shown above. (Reference diagram on page 3)

2. Treatment time is recommended at least 60 minutes per day. This can be achieved by setting the timer or choosing C for Custom time. 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 1mA -15mA. 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.

During treatment you should **not** be able to feel any sensation from stimulation.^[1] 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.4).
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 25mA^[2]. (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. You should **not** be able to perceive stimulation sensation during treatment.^[1]

[1] While you should not feel stimulation on the tragus locally during treatment, it is common to experience awareness of tVNS taking effect, such as increased relaxation.

[2] If no stimulation is felt at 25mA, repeat steps 1 to 3 again making sure to start from 0mA. Altering the Hz (pulse rate), between 1 and 20 Hz can help with this. Further, 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 SaluSTIM and ear-clip electrode are CE approved and pose no patient risk if used correctly.

- For safety, intensity **should not be set above 25mA** for treatment. 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.

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 4), 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:

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Version 2.2

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