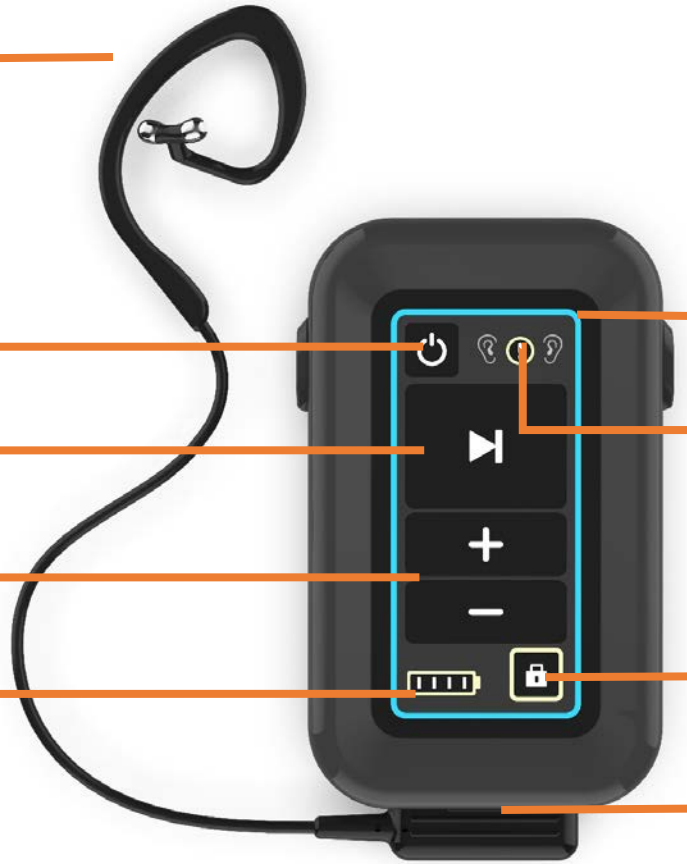
tVNS

tVNS®

Using tVNS® *L*

tVNS® *L* Overview



Ear Electrode

ON/OFF Button
Turn stimulator on and off

Start/Stop Button
Start and stop the stimulation

Control Buttons
Control the stimulation strength

Battery Indicator
Indicates Battery Capacity
Red : Battery Empty
Yellow : Currenct Capacity

Progress Indicator
Remaining stimulation duration

Connectivity Indicators

Key Lock
Lock and unlock buttons

Micro-USB Plug
Connection for charger

Connectivity Indicator(s)

Ear Electrode
Left / Right / Both

Green : Active stimulation
Red : Contact problem

Exclamation Mark

Permanently Yellow: active treatment in the stimulation phase (ON Phase)

Blinking Yellow: active treatment in the pause phase (OFF Phase)

Permanently Red: defective device – Stop using the device and contact Customer Service

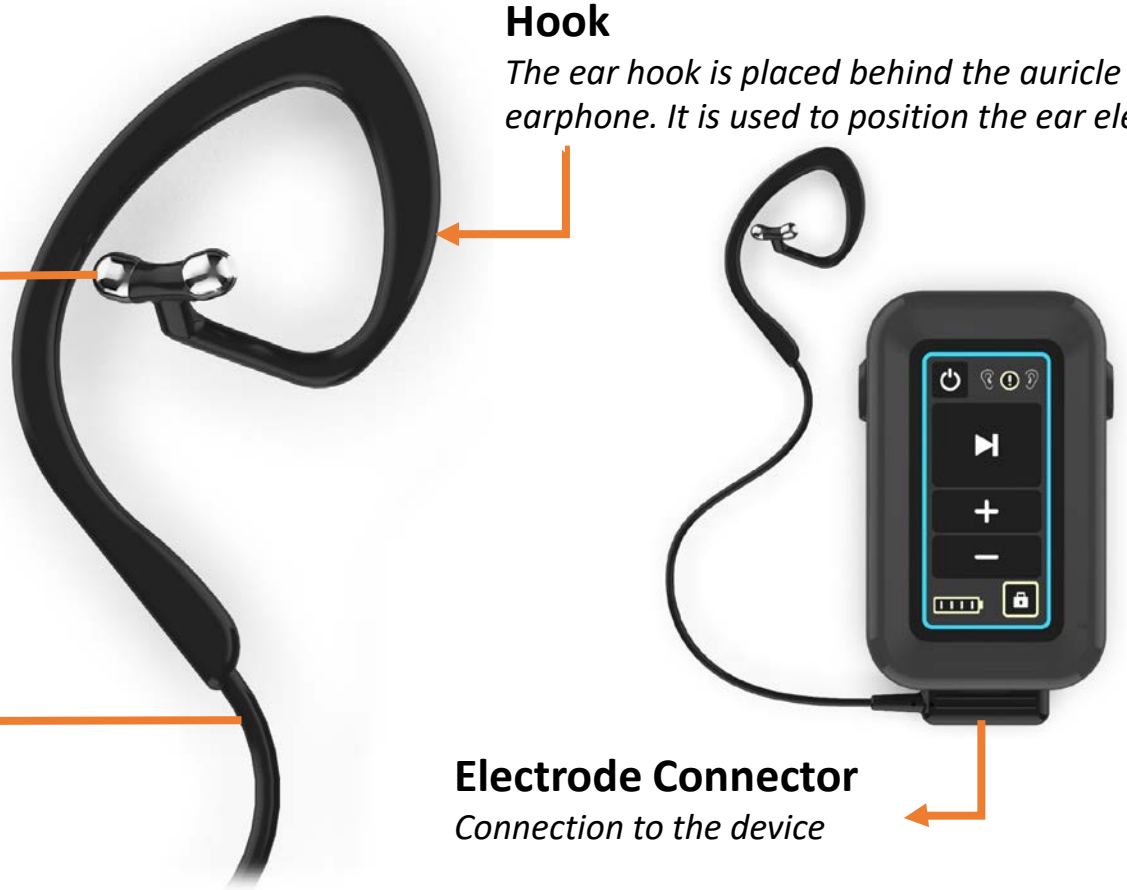
Ear Electrode - Hook

Hook

The ear hook is placed behind the auricle like an earphone. It is used to position the ear electrode.

Electrode

The electrodes transmit the electrical impulse from the stimulator to the surface of the skin.



Cable

The cable conducts the electrical impulse from the stimulator to the electrodes of the ear electrode.

Electrode Connector

Connection to the device

Ear Electrode - Legacy

1. Electrodes: The electrodes transfer the electrical impulse of the stimulator to the surface of the skin

2. Cable: The cable transfers the electrical impulse from the stimulator to the electrodes

3. Earpiece: The earpiece is inserted into the ear like headphones. Its used to allow correct positioning of the electrodes.

4. Silicone ring: The silicone ring aids in the fixation of the electrode and are placed over the earpiece. Silicone rings in three different sizes are included during shipment to allow for different ear sizes.

Steps before Use - I

Before Using it for the first time;

- Charge the device fully. You can check the charge status using the battery indicator.
- Download the tVNS Patient app in the Apple AppStore or in the Google PlayStore and start the app on your mobile phone. Bluetooth must be activated on your mobile phone.
- Pair your device with the app by switching on your device and pressing the — button and START / STOP button at the same time.
- Under Configuration (app), select the indication for which you are using the device.

Steps before Use - II

- Clean Ear and Ear Electrode

  Clean the ear at the orange-marked spot (location of the electrode)

  Use commercially available alcohol swabs with 70% isopropyl alcohol

  Clean the ear electrode with a commercially available alcohol swab.

- Connect the ear electrode to the stimulator. The cable must point to the left

- Put on the ear electrod

Using the Cream

Electrode Cream Bottle

Cream Jar

USING THE ELECTRODE CREAM

Electrode cream is used to help conduction of the electrode. Electrode cream is a special cream that transmits stimulation.

- Fill some electrode gel into the provided gel jar
- Push the electrode heads into the gel one at a time.
- Insert the electrode immediately.

Do not let the cream dry first!

Never apply the cream to the electrode directly from the bottle!

Cream application

legacy electrode applying the cream properly

IMPORTANT

The area between the two electrode heads must remain dry.

If you do not feel any tingling or pulsing during stimulation, this is an indication that there is gel between the electrode heads. In this case, dry the ear electrode

Using the Ear Electrode

USING THE EAR ELECTRODE

Hook Electrode

Legacy Electrode

Cream the electrode contacts separately. Then place the electrode in your left ear.

It is very important that the ear and the ear electrode are clean before using the device.

Place the ear loop behind the corresponding ear and insert the electrodes into the "cymba conchae".

Use of electrode covers

Electrode covers are used to solve contact problems and to optimize comfort during wear.

Step 1: Slide electrode covers onto the electrodes.

Step 2: Important: The electrode covers are not allowed to touch.

Step 3: Fill cream into the provided travel cream jar and push the heads electrodes into the cream one at a time.

Tip 1 Fill some electrode cream into the provided travel jar.

Tip 2 The electrode pads must be completely covered with the cream.

Step 4: Insert ear-electrode immediately into ear. Do not let it dry.

Important: The electrode covers must be changed daily.

Impulse parameters: (tVNS ® *L*)

- The current pulses for transcutaneous stimulation of the vagus nerve on the auricle are characterized by the following properties:
- Waveform : Bi-phasic
- Impulse duration : 28 sec on, 32 sec off
- Impulse frequency : 25 Hz

Using tVNS® *L*

- Hold the **ON/OFF** button down for approximately two seconds. The stimulator will turn on.
- Press the **START/STOP** button once. The stimulation will start if;
  - *You have properly cleaned the contact points.*
  - *The ear electrode is connected to the device.*
  - *You have put on the ear electrode correctly.*
- Use the +/- buttons to adjust the stimulation strength until you feel tingling and pulsating.
- Stimulation with tVNS® *L* is carried out with a preset stimulation program that the user cannot change. The program consists of an "**ON phase**" (28 sec.) and an "**OFF phase**" (32 sec). tVNS® *L* automatically switches the stimulation on and off.

Important *It is not possible to change the stimulation during the "OFF phase"*

- You can adjust the intensity of the pulses during stimulation. The minimum stimulation intensity is 0.1 mA (Miliampere), the maximum stimulation intensity is 5.0 mA.
- The keylock is automatically activated if the device is not used for 20 seconds.
- Press the **START/STOP** button. The stimulation will stop.

Setting the Optimum Stimulation Intensity

- The stimulation strength of the stimulation pulse can be set within the predefined limits with the + and - buttons in steps of 0.1 mA each.

By holding down the + or - buttons for a longer period, the intensity can be changed quickly.

When the device starts, the current is always set to the minimum current value.

If you have only paused the treatment, the current value set last is saved and automatically set again when you start it.

- Slowly increase the strength of the stimulation by 0.1. mA at a time (one keystroke at a time) until a tingling sensation or pulsation can be felt at the stimulation location. The stimulation should be clearly noticeable but not painful or uncomfortable.

Important *Since your perception can vary from day to day or even during use, you should adjust the stimulation strength again and again if necessary. This could also be necessary several times during the treatment unit.*

Troubleshooting

- If the ear electrode loses contact with the skin or if the skin resistance is too high, a signal tone will ring.
- If you do not feel any tingling or pulsing during stimulation, this is an indication that there is cream between the electrode heads.
- When the ear electrode is disconnected from the stimulator, the stimulation will stop automatically.

How to find the right stimulation intensity?

- Depending on ear anatomy, skin thickness, humidity and many other parameters the threshold current is a very individual parameter.
- If it is too low it is not effective, if it is too high it causes negative side effects and hurts.
- According to Erlanger and Gasser the peripheral nerves are classified according to table 1. The larger the nerve the better it can be stimulated. The reason is that a larger nerve allows more current to flow through and thus the depolarization is achieved earlier. Safi it al [1] studied the anatomy of the auricular branch of the vagus nerve (ABVN) and found an average number of 385 myelinated axons. Appr. 20% (64 to 78 axons) were larger than 7 µm and of Ab type. The other axons were also myelinated but smaller.

How to find the right stimulation intensity?

Axon type	Myelinated	Diameter (µm)	Speed (m/s)	Sensory receptors
Aa	Yes (thick)	10-20	60-120	Proprioceptors of skeletal muscle
Ab	Yes	7-12	30-75	Mechanoreceptors of skin
Ac	Yes	4-8	20-40	
Ad	Yes (thin)	2-5	10-30	Pain, temperature
B	Yes (thin)	1-3	3-20	
C	No	0,5-1,5	0,5-2	

Table 1: Nerve classification according to Erlanger and Gasser.

- Interestingly Safi found some bodies (mostly diabetic) with no thick myelinated axons. This may explain why some people do not respond to tVNS.

How to find the right stimulation intensity?

Since pain signaling fibers are smaller Ad or C fibres there is an easy way to find the right current level :

- The patient simply has to start from low levels and increase the output amplitude until he feels a little tickling or pain.
- Reduce the output until the patient doesn’t feel pain anymore.
- The thick axons will be successfully excited and the pain driving axons will not be excited.

Thank you…