

Tragus clip Instruction manual 2024-01

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Quick start guide

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Introduction and limitations

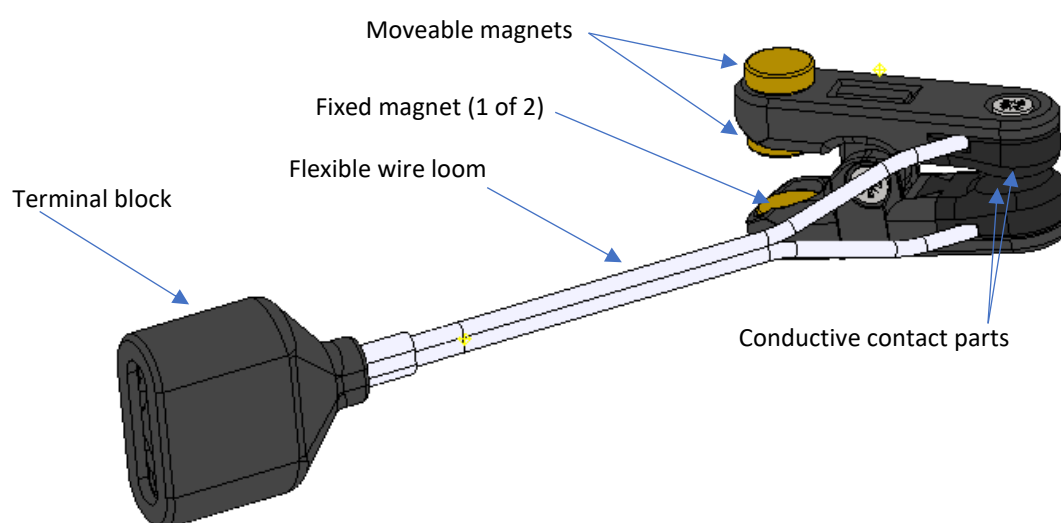
If your doctor has recommended transcutaneous vagus nerve stimulation (tVNS) you will need a good fitting clip electrode that fits your ear.

This instruction manual outlines how to adjust the tragus clip electrode for the best fit and includes tips for the most consistent effectiveness. Safety aspects are addressed as well as best use.

The electrode itself is passive and does not perform any useful function on its own; it is intended for use with a transcutaneous electrical nerve stimulator (TENS). This manual references a few general tips for use with your TENS machine but it is not a comprehensive guide to your TENS machine. For more information about your TENS machine you should consult the instruction manual that is included with that device.

This manual is not a guide to tVNS treatment protocols or strategies for any ailment or symptoms and these topics are not discussed. Please work with your doctor for treatment recommendations including indications, precautions, and contraindications, and use the clip electrode as well as any TENS as directed by your doctor. Check with your doctor if you have any concerns during use.

Tragus clip electrode parts reference



Skin inspection and preparation

The tragus clip electrode attaches to the tragus part of the outer ear.



Before first use, make sure the skin on your tragus is clean and intact, without rashes, cuts, or any other skin injury. Regularly inspect the skin on your tragus for rashes, cuts, or any other skin injury. It is easy to view the outside of the ear in the mirror but difficult to see the inside surface without help of a friend or family member. Ask for help as required.

Wash your ear in the shower or bath with soap and water, or whatever else you use to wash with. Use a cloth to gently rub away dead skin that may have accumulated over time. Make it a part of your shower or bath routine to keep this part of your ear clean, on both the inner and outer surface of the tragus.

The tragus clip electrode is gentle and generally non-allergenic but if irritation occurs, cease use and ask your doctor when to resume. If one ear is irritated but the other is okay, ask your doctor about swapping ears.

Normal skin sensation is the simplest way to protect from excess high currents during application to skin. Do not use the tragus clip if you have numbness in the skin of the tragus. If your skin sensation is okay, you will normally feel the tapping or buzzing sensation of TENS at a safe level; it may feel a little prickly. Limit the maximum intensity of the stimulus to a comfortable level.

Ear piercings in any other part of the ear other than the tragus are of no concern. Hardware can stay in other parts of the ear as desired.

If the tragus itself is recently pierced, you should wait until the skin is well healed before trying the clip electrode. Note that tragus piercings may take a long time to heal. Consult your piercing provider for more advice. Remove whatever hardware you wear through your tragus piercing hole before using the electrode.

Inspect and clean the electrode

The tragus electrode clip is a small plastic device with thin flexible wiring. If treated with care, it should last a long time. Keep out of reach of children as they could easily damage the clip. Check it is in good condition before each use. If there are any signs of broken plastic parts, or if the wires are cut, pulled out, or otherwise damaged, do not use it.

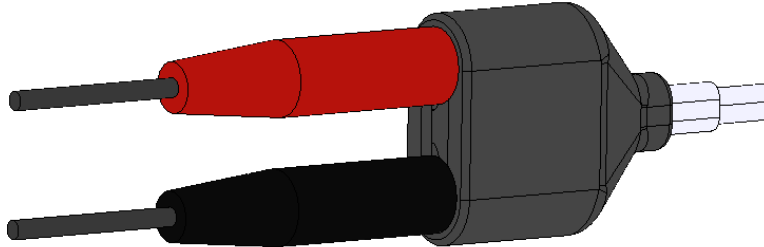
The tragus clip electrode is intended for single patient use and you should not share it with other people. The main source of soiling from single person use is earwax. Clean the conductive contact parts with a damp cloth before use. You can use water on the cleaning cloth, or isopropyl alcohol if you desire.

When not in use, store the clip in a small plastic bag or similar to keep it clean. The clip is supplied clean, not sterile. It is to be used on intact skin only and does not need to be sterilised between use on a single patient.

Attach clip to TENS, power off

Start with your TENS machine turned off.

Plug the pins (usually red and black) from the TENS lead wires into the terminal block.



The orientation of red and black is not important.

If your TENS machine does not have the usual electrode pins, then please contact us to find a suitable wire attachment. Use the contact details on our website: <https://tragusclip.com/contact>

Wet skin and attach clip to ear

Start with the TENS machine turned off.

The tragus clip electrode is intended for use on the tragus part of the outer ear. Fit it as pictured. Allow the wiring loom to hang down. Use a peg to attach the wiring to your shirt to keep things tidy (optional). Leave enough slack for your head to move without tugging the wires



Dry skin will not conduct electricity very well. Before fitting the clip, apply a conducting medium and wet the skin where you will attach the electrode. Wet both the inside surface and outside surfaces of the tragus. The three main conducting options, in order of increasing effectiveness are:

- Tap water, just dip your finger in and wipe on the inside and outside of the tragus part of the ear.
- Clean your finger, then use your own saliva on the inside and outside. This may last a little longer than tap water.
- Electrolyte gel. Only a tiny amount is needed.

Read the tip in the power off section below to determine how well your ear-wetting has lasted.

Power on

Follow these universal tips for a controlled experience with any TENS machine.

- Always check that the TENS device is off before fitting the electrode to your ear.
- Only turn the TENS on, and turn the intensity up, when the tragus clip is in place on your ear.
 - This will avoid having the intensity accidentally too high
- Turn intensity up slowly.
- Limit the maximum intensity of the stimulus to no more than a comfortable level.
- Set timer on your TENS if available, else set timer on your phone to monitor treatment time

Intensity settings

Most common TENS devices are designed and specified for large gel electrodes and the milliamps (mA) displayed on the device are approximate for those larger electrodes (500ohm load). The mA displayed is not usually accurate at all for small ear clip electrodes. Generally, the output intensity rises faster than indicated. Some TENS brands rise faster than others.

This manual does not seek to advise what intensity to use for your treatment but a few notes apply: As above, the mA displayed on your device are unlikely to be remotely accurate or even indicative. A common method for setting the intensity during tVNS, that does not rely on the intensity display, is to carefully increase the intensity until the softest sensation is felt. Then perhaps reduce by one click so that intensity is just around the threshold of sensation. This is an inherently soft approach and can work regardless of what TENS device is used.

Some machines will cause a sensation after just one or two increments of the intensity setting. In these cases, a synthetic load wire can be used to improve output behaviour and cause a more gradual increase in intensity for better control of the stimulation threshold.

Previously, our tragus clips included a synthetic load built into the connector block to moderate the output intensity on common TENS machines. In 2024 this feature is split into a separate synthetic load wire; sold separately.

Parasym users do not need the synthetic load as that device is optimised for use with smaller ear clip electrodes.

Power off, and end of session testing

When your treatment time is over its time to turn the TENS machine off.

- If your TENS has a dial, for intensity as well as off mode, turn the dial slowly and carefully.
 - It is easy enough to accidentally turn the dial the wrong way, and increase the intensity. Don't do this fast!
 - If your TENS device has a timer shutoff, then you can just remove the clip and be done, or read on below to do some tests.

- By the time your treatment session is finished, depending on how you wet it, your ear may have dried out. You can test the conductivity of your setup. It is not necessary to do this all the time, but can be helpful in working out your best method to achieve reliable conduction over the course of your treatment sessions:
 - Is the machine still on? Turn the intensity up carefully.
 - If you feel a ready increase in the stimulation, then the skin is still conducting well. If you feel no stimulation, then your ear may be dry.
 - Turn the intensity down before restarting the machine if necessary.
- If you conclude that your ear has indeed dried out such that the stimulation does not work anymore, then you can take note for future sessions. Either pause your future session part way through and re-wet the ear, or choose a different conducting medium that lasts longer, such as gel.

- If you want to stop the treatment at any time but can't remember the instructions or how to turn the dial, you can just remove the clip from your ear at any time.
 - be sure to turn the intensity down before re-fitting the clip to your ear.
- Even though the tragus clip fits well, it may still come off your ear by accident during treatment. For example you may accidentally snag the wiring loom and tug on it while moving about. Be sure to turn the intensity down before refitting as the new fit may be different.

Adjusting the clip force

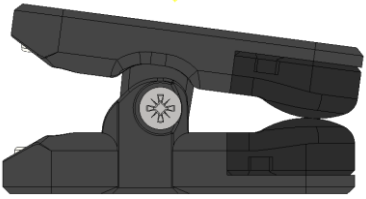
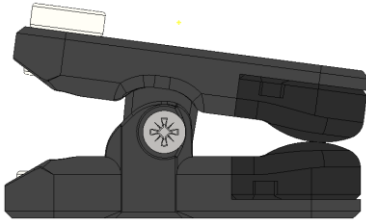
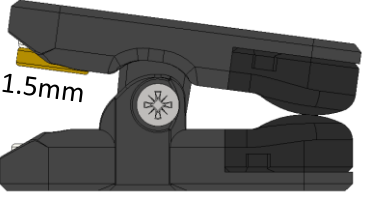
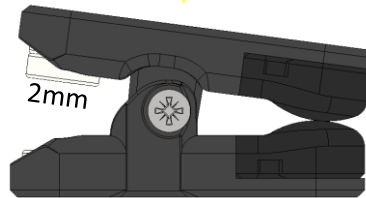
The tragus clip has design features including shape, texture, and wire path that make it fit well, but there is such great variation from person to person in the shape and size of the tragus that further adjustments are often necessary.

The tragus clip features moveable magnets that allow the user to adjust the clip closing force.

Note there are two different magnet sizes in the package, 1.5mm (gold) and 2mm (silver).

The table below shows the most common variations for magnet placement but is not exhaustive; other combinations are possible but result in small differences only. In the table, the clamping force increases from configuration 1 through to 4.

Use the least forceful combination that stays in place whilst feeling comfortable.

	
1) two embedded magnets only → softest	2) Magnet(s) added externally
	
3) Thinner magnet internally	4) Thicker magnet internally → stronger

Some people have a very small tragus that is hard to grip securely, or just an awkward shape. If you cannot get a comfortable fit, read the section below about the tragus clip with wire appendage. The wire versions also allow a very secure fit for all ears and can usually stay comfortably in place during activity.

Clip with support-wire appendage

A clip with support-wire appendage is sold separately.

The user can bend and shape the wire to fit over his/her ear and support the weight of the clip and wires. This results in a very secure fit such that a person can move around, and be active, with confidence that the clip will stay in place.

The support-wire version of the tragus clip is not universal for use on both ears. Left-side and right-side versions are sold separately. Typically, in tVNS, the left ear is targeted most often. The right ear may be used as an alternative, especially if there is a skin problem on the left ear. Discuss this aspect with your doctor if you are considering buying the tragus clip with support wire.



Warranty

The tragus clip electrode and wire may last a long time if treated with care, but it has moving parts, is in contact with the body, and inevitably it will wear out. The most likely cause of breakage or failure is tangling or snagging the flexible wire loom either when in use, or when in transport. Do not stuff the clip into a pocket, or handbag, or similar for transport without separately bagging to avoid tangles.

3D Physio will, at their discretion, repair, or replace, or refund the product, or any necessary component part if it is found to be defective in materials or workmanship within 6 months of purchase.

Any claim for warranty must be made via the tragusclip website. Visit the service page and follow the necessary instructions. Add the warranty item to your cart (\$0) and check out. You will receive an email with your order number, which will act as your return authority number (RA#). This RA# must be written on the outside of the package when returned.