TVNS®-L VAGUS NERVE STIMULATION DEVICE

Frequently Asked Questions Guide

tVNSTECHNOLOGIES
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Welcome to tVNS Family

tVNS is the world's only approved medical device used in the treatment of sympatovagal balance. It is used for Epilepsy, Depression, Migraine, Insomnia, Autism, Anxiety, Parkinson's, Cognitive Disorder, Inflammation, Prader-Willy, Tinnitus and Stroke.

tVNS therapy is a long-term treatment with few side effects compared to many alternative treatments.

We hope this guide will help you on any topics you may need throughout therapy.

In this long-term treatment, our recommendations are:

- Be patient, since tVNS is not an acute therapy
- Please follow the therapy instructions
- During therapy, if you are using the device for your child, all sessions must be supervised by an adult, to avoid any risk related with the device and cables.
- Please remember that tVNS becomes a routine in daily life, so give yourself or your child the adequate time for adaptation and orientation, with no rush.

We wish you healthy days,

tVNS International Team

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tVNS Support and Info

Training Video Channel — tVNS International

Therapy Support and Requests

tVNS Turkey Call Center

Requests Online Form — www.t-vns.com/tVNSSupport

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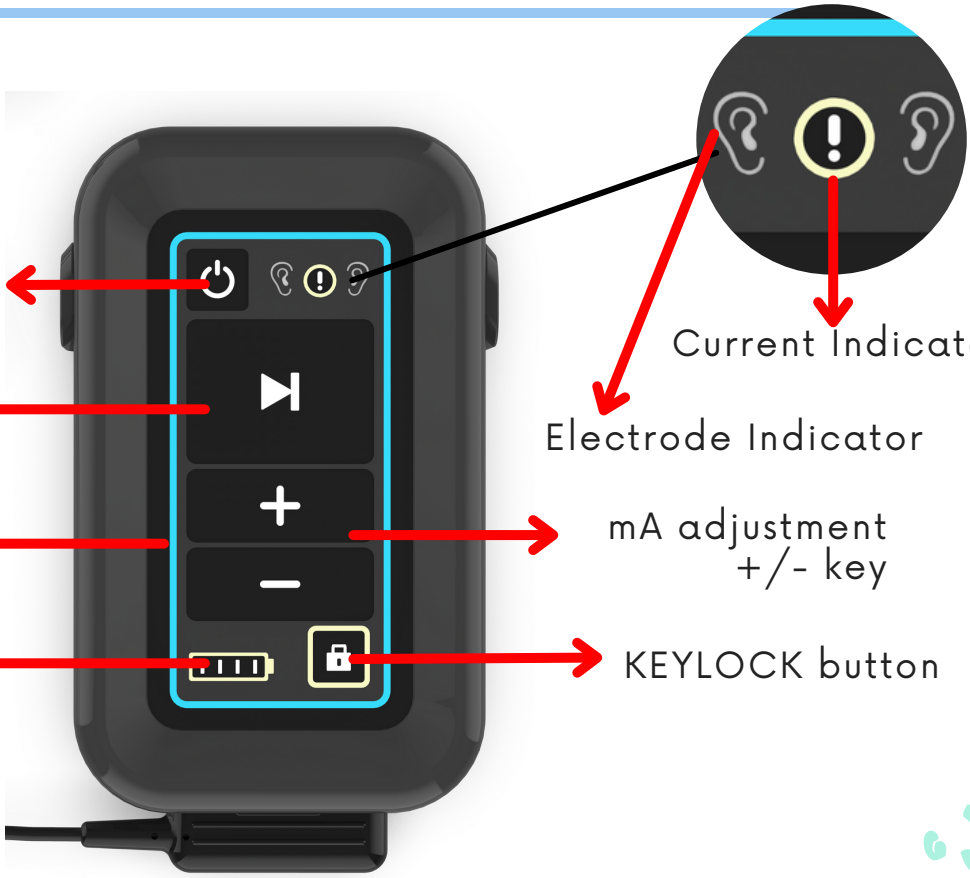
Device Basics



EAR ELECTRODES

There are 2 types of ear electrodes that can be used with tVNS Devices , with their different advantages.

The selection criterias should be based on:

- The size and anatomical structure of the ear.
- The position to be used mostly, in standing or lay-down
- Presence of glasses/hearing aids
- The age

Hook Electrode

Legacy Electrode

Device Usage

QUESTION 1: The device has stopped without my interference, what might be the problem?

Any running device stops for 2 reasons:

1. The device stops automatically when the total daily session time is over. (it can be 120/160/240 minutes depending on therapy) At 00:00 midnight, the device resets and the new day cycle begins.
2- When the headphone indicator turns red (See QUESTION 2), after a while, there will be a very weak warning sound signal and the device will turn itself off in 1 Minute to save the remaining duration.

QUESTION 3: What is the working principle of Blue Led lights?

The total daily therapy time of the device is represented by 16 blue LED lights. In standard 4 hours (240 minutes) application, after every 15 minutes, in accelerated special mode (if advised by the physician (160 minutes), an LED light turns off at the end of every 10 minutes. When the total daily therapy time is complete, all blue lights will be off and the device will turn off.

During a session you start before 12 am, the device is not reset at 12 am, and this reset process happens when the device is turned on and off after the session is over.

QUESTION 2: The electrode indicator shows red light, what could be the reason?

1.The properly placed electrode glows green light.

2.The electrode may fully or partially separated from the contact site, or it is not positioned correctly.

3.There may be earwax or gel residue that is not cleaned well in the ear that interferes the electrical conduction.

4. A sufficent amount of cream may not have been applied.

5. The cream may have dried in the jar.

6. Silicone pad may need to be renewed.

7. The electrode may be damaged.

Preparing the Electrode

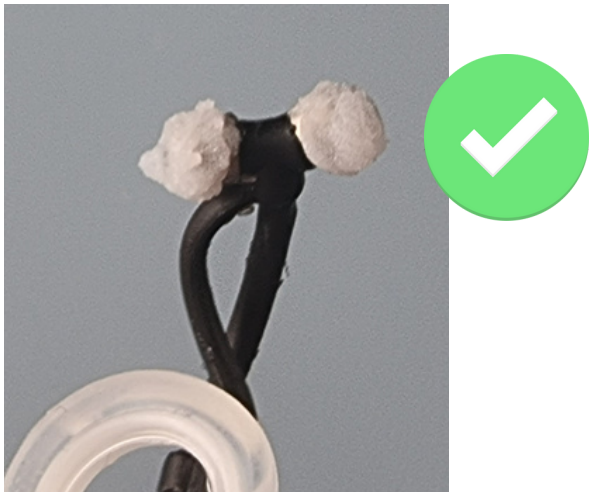
Electrode Usage

Before Electrode Plugging:

- Clean the ear with wet tissue.
- Insert the pads.

While applying the cream

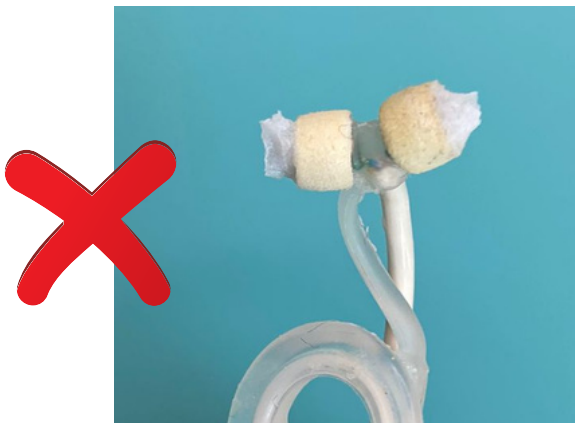
- Cream should not be applied to the black plastic area in the middle of the metal heads, to prevent any short circuit.



- If pads are used, the whole pad and the metal tip on the bass should be covered with the cream. For the option without pads, all the metal caps must be covered with the cream.

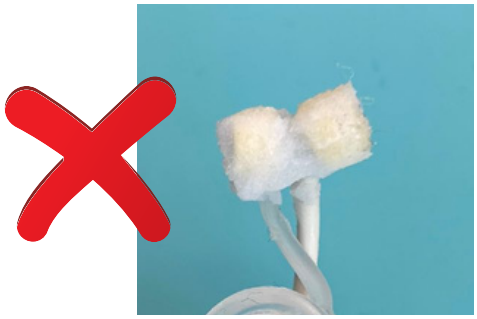
- The pads should never touch each other.

- Pads should not be used for more than 1 day. Cream remainings adversely affect the delivery of the current.



- Try to place the electrode on the ear with single move to prevent the spread of the cream in the ear concha.

- If the cream is too slight, it will cause irritation and burning towards the end of the therapy due to absorption by the skin.



- At the end of the therapy, the electrode heads and pad should be cleaned and made ready for the next use.

- IMPORTANT: Do not use any heavy chemicals such as disinfectant for metal cleaning to prevent corrosion.

Device Usage

QUESTION 4: Why does the device continue to work without a red light warning even though it is not in the ear?

The dried cream left over from previous sessions on the pad or electrode metal is perceived as skin resistance and the device can't detect disconnection from the ear. In such a case:

1. Pads may need to be renewed.

2. The cream used may have dried out (refresh the small jar)

3. The relevant receptor of the electrode may be damaged (the electrode should be renewed)

QUESTION 6: Is there any radiation damage if the device comes into contact with the head and chest area?

There is no health risk ,as evidenced by RF tests, in the contact of the chest or head area with the device. The low currents, do not create any radioactive risk.

However, avoid keeping the device in high magnetic and radiation areas such as microwave, radio, telephone for a long time.

QUESTION 5: Why do I feel less vibration after a while?

There are pain nerves around the point where the vagus nerve is stimulated. A patient who has just started therapy can clearly feel the vibration at 1000 mA, but after a certain period of time, the pain will be tolerated by the nerves, and begin to feel the vibration less.
If there is no vibration:
1. Electrodes are not placed in correct contact.

2. A sufficient amount of cream may not have been applied.

4. The cream in the jar may have dried.

5. Silicone pad replacement may be required.

6. If there is no tingling, there may be a short circuit (Question-16)

7. Electrodes may be damaged.

Application Usage

QUESTION 7: Why am I having trouble connecting on my phone to tVNS?

Phone brand, memory, RAM or Android/iTunes version affects connection performance.

Phones with higher memory and RAM, and the latest versions, contain less problems.

- If your phone's memory is too full, optimize it.
- Clear cookies, temporary files from phone maintenance section.
- Try turning the device and phone on and off and reconnecting.
- If you frequently change the phone you use with tVNS, the only way to solve the Bluetooth pairing problem is to uninstall the application from the phone and install it from the beginning.

QUESTION 8: If I delete the application and reinstall it, shall I lose the old data?

tVNS session information (date, time, mA) is recorded to the device. For this reason, you can see the details of all sessions from the time of production of the device to the present on all phones where the application is installed.

The fields where the seizure and personal information are entered are recorded by the phone. Therefore, if you are going to delete and reinstall the application, we recommend that you make a backup beforehand.

QUESTION 9: What should I pay attention to when deleting and reinstalling the application?

- Before deleting the application, click the "SHARE" icon in the upper right corner and select one of the options and keep a backup of the data.
- Delete the app
- Delete the "tVNS Next Gen" device from the list of defined devices in the Bluetooth connection tab of your phone
- Reinstall the application and complete the pairing steps.

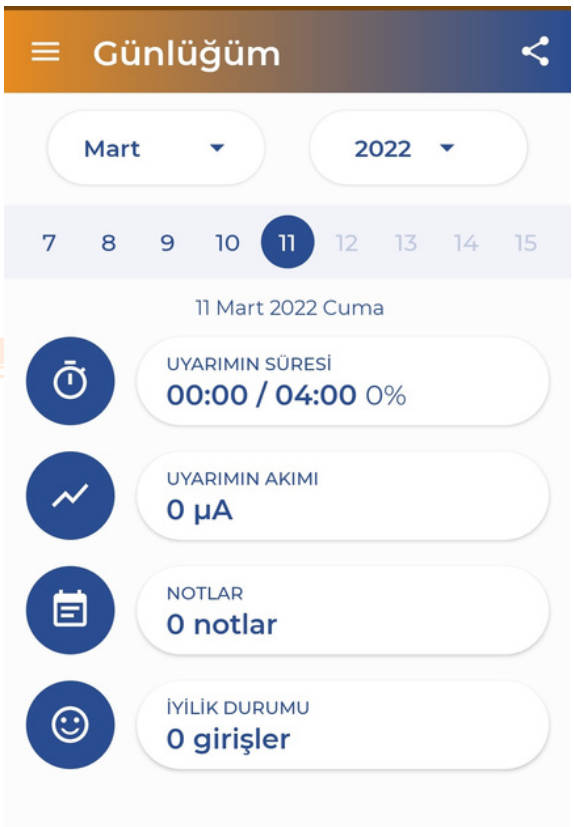
Application Usage

QUESTION 10: Can I use the application on more than one phone?

fI these phones are in the same environment at the same time, you may experience freezing or confusion in further connections.

For this reason, we recommend that you specify a main phone for tVNS, and turn off the Bluetooth of other paired devices.

If a new phone is to be paired, the device must be turned off, the bluetooth mode of the previously paired device must be turned off and , the device must be turned on and paired.



QUESTION 12: Where can I access daily information?

You can access the alert time, alert current, and notes for each day from the "Daily Notes" tab of the app.

Electrode Usage

QUESTION 12: How often should the electrode be changed?

Electrode life depends mainly on usage:

- How much wear and tear during use (electrode life will be shorter in mobile children)
- How carefully preserved outside and in the box
- It varies depending on whether the device is entrusted to a caregiver other than parental supervision.

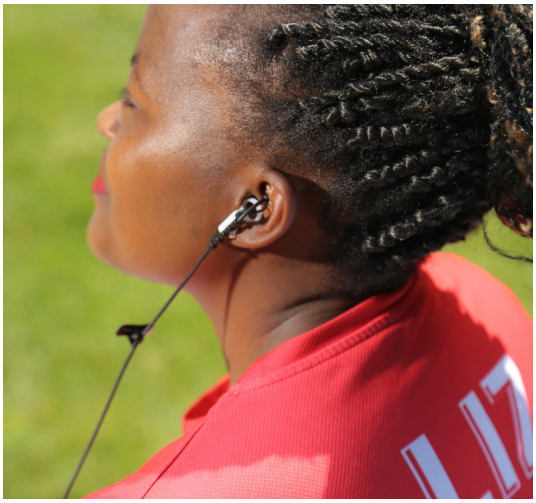
For this reason, it is very important to periodically control the headphones by the parent. If you see a decrease or complete loss of current, it is likely that the headphones are damaged. If there is no decrease in current, you can continue to use it.

Our R&D center recommends that earphones used up to 4 hours a day be replaced once a year. If there is a visible kink or current decrease in the cable, it must be replaced. The lifespan of the earphones depends on usage.

Our recommendation is use carefully and checking frequently.

QUESTION 13: The electrode is damaged/broken, is it possible to repair it?

Any physical damage, cable bend or breakage that may occur in the device or the headset contains a risk in terms of medical device safety regulation, so it is not possible to repair it.



Cream and Pad Usage

QUESTION 14: What is the function of the cream in therapy?

The cream ensures the transmission of electric current throughout the session and prevents skin irritation during application.
It is one of the most important factors in the effectiveness of therapy, and its use is mandatory in every session.
There are fundamental differences in this sense in creams and gels produced around the world:

DRYING STATUS OF THE CREAM

- While the creams in standard EEG shots continue to function with minimum contact with air under the pad, since tVNS is exposed to direct air contact throughout the therapy session, drying of the cream means that the current you will receive from a certain part of the session decreases and you cannot get efficiency from the treatment.

- **SENSITIVITY PERFORMANCE ON THE SKIN**

it should not cause irritation since the electrode is a chemical that contacts the skin with the heated electrodes for 4 hours a day.

For this reason, using the therapy with the right cream and renewing the cream after the drying period is one of the main factors for the success of the treatment.

QUESTION 15: Can I use the device with different creams?

Germany R&D has been testing gels and creams with various ingredients for 12 years. As a result of these tests, it was approved for only a 50gr portion of a cream specially developed for "long shot EEGs" and which does not cause irritation.

It has been proven by tests that 50 g is the right portion for the use of tVNS, the cream dries out after 3-4 months after the box is opened and the efficiency drops very much.

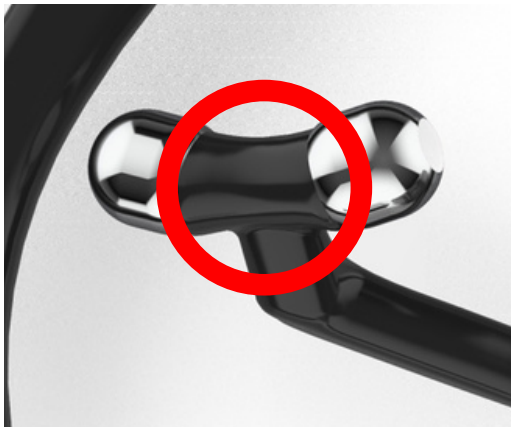
Using the right cream is one of the main factors that determine the therapy performance. For this reason, creams with untested drying speed or large weights are not recommended, and if used, correct therapy cannot be guided due to the risk of device effectiveness.

Cream and Pad Usage

QUESTION 16: What precautions should we take to prevent the cream from drying out?

- Do not use from the large jar each time, this will speed up drying. You can put it in the small jar supplied with the device with the help of a spatula or knife from the top and use it by putting it little by little without pushing it to the bottom.

- Do not expose the cream to sunlight. Do not store in very cold places, too close to heaters or heaters.



QUESTION 17: Can I apply the cream with my hand?

Due to the consistency of the cream, it is not very easy to apply. However, it is very advantageous in that it does not spread as in the cream and does not have the risk of short circuit.
Legacy electrodes are a little easier by design when it comes to applying cream.

You can apply it to the electrode heads

- by dipping it on the tiny jar.
- With the help of a hygienic ear stick or a small spatula

With your hand disinfected with alcohol or cologne

QUESTION 18: What is a SHORT CIRCUIT, how can it be prevented?

Applying the cream to the black plastic area in the figure, or spreading it too much in the ear during placement in the ear will cause the circuit to be completed before the current can pass into the SHORT CIRCUIT.

The vibration cannot be felt and therapy is not applied.

A warning that can detect a short circuit in the device is not technically possible. For this reason, the contamination of the cream must be checked in every session.

Cream and Pad Usage

QUESTION 19: What is the function of PAD in therapy?

The pad provides a gentler delivery of current to the ear without sacrificing conductivity and is optional to use.

Its advantages are:

- It provides protection for sensitive skin by preventing direct skin contact of the ear electrode.
- It provides a tighter attachment in the concha canal by increasing the diameter at the tip of the metal electrode heads.
- It ensures that the earphones contact the right points in the ears where the concha canal is wide considering that the ear anatomy varies greatly from person to person.

Therefore;
It is mandatary

- In order to prevent the risk of hook hanging in the air when using the hook earphones,
- For extremely sensitive skin
- People with wide concha canal (for all types of earphones)

QUESTION 20: What should I pay attention to when using the pads?

- The circumference of the pad should be covered with plenty of cream.
- The cream on it should be cleaned with wet wipes and paper towels at the end of each session for the next session and made ready for the next session.

Even if the cream is cleaned, the pads should be discarded at the end of each day and the next day should be started with a new pad, as the cream that remains in the pores and dries out will prevent the succesful therapy.

QUESTION 21: Can I use the pads by washing them?

We strongly do not recommend washing the pads. The risk in washing is that the cream residue will dry in the pores and form a layer.
This can cause the following situations:

- Dry cream reduces transmission. It does not stimulate, but causes low vibration and inadequate therapy.
- You can completely block the transmission, you may encounter a red warning.
- If the electrode disconnects from the ear, it does not give a red warning as it will perceive the dried cream as ear resistance.

Charging the Device

QUESTION 22: What should I pay attention to for the charging performance of the device?

1. The charging time of the device should not exceed 3-4 hours, it is not recommended to charge it at night and leave it until the morning.

2. Always charge the device in the "Surge Protected Socket".

3. The device should be charged with its own charger (or original Samsung charger.)

4. The percentage indicator in the app and how full the battery is in reality may not exactly match.

It should be based on the indicator on the device.

QUESTION 23: Even though I keep the device charged for a long time, the battery indicator does not progress, the charge is not completed?

Long charging durations may damage the charger or battery.

The charging problems that may be experienced may depend on the device as well as the CHARGER.

To understand this, try charging it with the original (Samsung, Apple, Huawei) phone charger and the supplied charging cable (or USB-B type) cable. if it is charging then the problem is in the charger.

If it still does not charge, there may be a malfunction in the device battery.

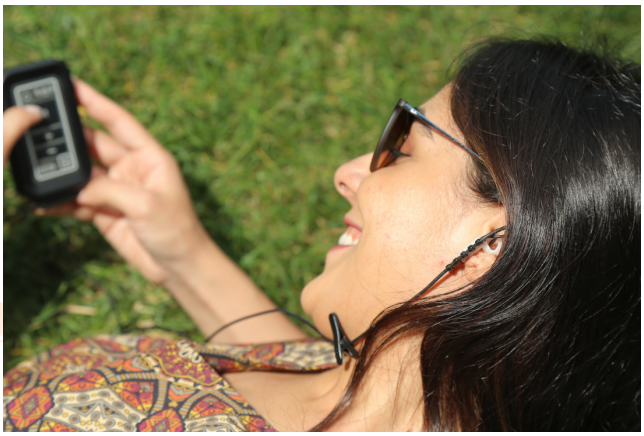
tVNS Therapy Process

QUESTION 24: How soon can I get results from the treatment?

The duration of action of vagal nerve stimulation and the results vary according to the age of the patient, the diagnosis, and the pace of therapy.

Sometimes the effects can be seen in the first days, while it can take 3 months on average and in some cases 7-8 months.

It has been proven by clinical studies that the effectiveness increases over time.



QUESTION 25: Is the increase in sleep normal when the tVNS current dose is increased?

Some patients may experience increased sleepiness with dose increases. This is a temporary situation and the effect decreases with adaptation.
Due to the relaxing effect of tVNS, the sessions are planned according to the sleep routine during the day.

QUESTION 26: How is the therapy schedule planned?

Therapy timeline and intensity plans are made individually.

- The patient's age and perception status,
- Seizure intensity and distribution,
- Meal and sleep schedule
- Presence of autism, mental retardation or pain tolerance.

An initial protocol is applied according to the parameters.
Updates are made based on progress.

QUESTION 27: Is there any problem if we have a lot of delays on the proposed therapy schedule?

It is necessary to use the therapy sessions in their planned hours

Irregular use in patients with epilepsy who have frequent seizures adversely affects the effectiveness of therapy and may reduce the seizure prevention effect of therapy.

Non-continuous clock shifts (1-2 hours) do not cause any problems in uses other than epilepsy and in patients with a low frequency of seizures.

SORU 28: Does having a problem in the ear nerves prevent using the device?

Having problems with the auditory nerves or using a hearing aid is not a problem for the treatment of tVNS.

QUESTION 29: How much minimum time, we should have between 2 consecutive sessions?

There is an average of 5-8 hours between sessions. However, there is no harm in having 2-3 hours for mandatory individual changes.

QUESTION 30: How often is the tVNS intensity dose increased?

The tVNS mA level and the increase plan are decided according to the patient's tolerance and the short-term results of the therapy.

Normally, 100 mA is increased in 7 days initially.

tVNS Therapy Process

QUESTION 31:Does the use of tVNS cause wheezing, sputum or increased secretion?

TVNS does not cause an increase in secretion. On the contrary, due to its positive effects on inflammation, it may cause a decrease in secretion over time.

In therapies started in winter months, various symptoms can be confused with the effects of tvns due to the widespread infection.

Since the presence of infection can cause an increase in seizures, it can be difficult to decide on issues such as an increase in ampere.

QUESTION 32: What should I do if I experience ear irritation?

If there is irritation in the ear, right ear stimulation can be given until the rash is completely healed.

QUESTION 33: What is the effect of the use of tVNS on perception and concentration?

tVNS provides great benefits on perception, concentration and motor development by supporting the increase in neural plasticity in the brain.

For this reason, the effects of the use of sessions on neural plasticity when the learning processes of the brain are active, such as special education, rehabilitation, walking and swallowing therapies, have been scientifically proven.

tVNS Therapy Process

QUESTION 34: From what age can tVNS be used?

It can be used from newborns with the approval of a doctor. Since tVNS is a treatment that does not require surgical intervention and drug use.

QUESTION 35: Can tVNS be used in case of hydrocephalus and cerebral shunt?

Cerebral shunt is not a barrier to use of tVNS. It is used in many pediatric and adult patients.

QUESTION 36: Can tVNS be used in the case of cardiac, respiratory diseases and pacemaker?

Since tVNS is a non-invasive treatment, it can be used safely in patients with a pacemaker with the approval of a doctor.

While in cervical (neck region) stimulation, swallowing, respiratory and cardiac side effects can be seen, these side effects are not seen when vagus is stimulated by ear. One of the biggest advantages of tVNS is that it does not pose a risk for respiratory and chronic heart diseases. Therefore, it does not pose any risk in conditions such as chronic cardiac diseases, respiratory problems, asthma and bradycardia..

tVNS Therapy Process

QUESTION 37: Does the usage of tVNS cause an increase in seizures?

In some cases (about 1 in 25 patients), the use of tVNS may initially cause a slight increase in seizures.

One reason is that the device is new to the daily routine and can cause stress during the orientation period. Another reason is that some epilepsy patients are more sensitive to vagal stimulation. There is no differentiation of this condition based on known age or seizure type.

In such a situation, the mA levels are reduced, the adaptation period is extended for the patient to get used to the vagal stimulation, and the mA increase rate is slowed down..

The patient can tolerate it in an average of 2-8 weeks.

QUESTION 38: How many mA can be reached in a tVNS session?

The device gives current in the range of 100-5000 mA. Direct current means that the vibration is felt as much as possible, but at a level that does not hurt.

QUESTION 39: Does tvNS have an effect on feeding routines?

tVNS can cause nausea at a rate of 1-2%. In case of such a situation, it is recommended to set a minimum of 1 hour between meal and session times. This side effect is mostly temporary and disappears within 4-8 weeks.

If vagal nerve stimulation causes a rare condition such as decreased appetite, it is recommended not to schedule a session within the 2 hour period before meals.