

tVNS[®] E

INSTRUCTIONS FOR USE



tVNS**TECHNOLOGIES**
smart | neuro | therapy

Valid for **tVNS® E**

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Reprint, also in part,
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1. INTRODUCTION

1.1 INTENDED USE

tVNS[®] E is a non-invasive device for the transcutaneous stimulation of the auricular branch of the vagus nerve at the cymba concha of the left ear.

Detailed explanation: **tVNS[®] E** generates electrical impulses that are introduced into the body at the point of contact between the electrode and the auricle. These impulses innervate the auricular branch of the vagus nerve in the auricle.

1.2 WHAT IS **tVNS[®] E** AND HOW DOES **tVNS[®] E** WORK?

The autonomic nervous system (ANS) via its sympathetic and parasympathetic divisions influences the function of numerous organs, glands and involuntary muscles throughout the body. A major component of the parasympathetic nervous system is the vagus nerve. A branch of the vagus nerve supplies the cymba conchae. Here it is possible to stimulate that branch through the skin by applying electrodes. Imbalances in the activity of the constituent parts of the ANS have been linked with several clinical disorders. In general, the reported imbalance involves relatively higher sympathetic activity associated with a paucity of parasympathetic activity. By activating the vagus nerve through electrical stimulation, the imbalance shall be rebalanced.

IMPORTANT:

Treatment with **tVNS[®] E** must be carried out under medical supervision.

Please note:

Treatment with **tVNS[®] E** is not an acute treatment. Even if you respond to the treatment, the effect is usually only noticeable after a delay of a few weeks to months.

Therefore, you should adhere to the daily stimulation recommendation of 4 hours, especially in the first few months. Only then can you tell whether the treatment with **tVNS[®] E** has a positive effect on the course of your disease.

1.3 INTENDED PATIENT POPULATION

tVNS[®] E is intended for all patients of the age of 18 or above.

There is no limitation with regard to gender, skin, weight, height, BMI, ethnicity or any other known parameter.

1.4 MEDICAL CONDITIONS AND MEDICAL INDICATIONS

tVNS[®] E is indicated for patients suffering from depression, epilepsy, chronic migraines and Prader-Willi-Syndrome.

1.5 CLINICAL BENEFITS TO BE EXPECTED

Epilepsies:

Reduction of seizure frequency over a period of 28 days during intervention compared to pre-intervention phase of a minimum 25% after a treatment period of 20 weeks.

Depression:

Reduction of depression-specific HAMD score of minimum 2-3 points in adult patients when used in parallel with psychopharmacological and psychotherapy treatments after a treatment period of 9 weeks.

Prader-Willi-Syndrome:

Reduction of mean number of outbursts per day compared to mean number of outbursts per day in a pre-intervention phase of minimum 50% after a treatment period of 12 months.

Chronic Migraines:

Reduction of the frequency of days with migraine of 50% after a treatment period of 12 weeks.

1.6 INTENDED USER

The patient is intended to be the operator of the device.

The applicability of the of treatment with **tvNS[®]** shall be determined in consultation with a physician.

The use of the device is then performed by the patient himself.

No special training is required prior to use.

2. SAFETY

2.1 SAFETY INFORMATION

- The patient is intended to be the operator of the device.
- Do not drop the device or the electrode, do not handle the device or electrode improperly and do not expose the device or the electrode to extreme temperatures or high humidity (only use at temperatures between 5°C and 40°C and a relative humidity below 93%).
- Do not wear the stimulator on bare skin. Skin irritation may occur.
- Contact your doctor if you notice unusual reddening or rashes at the contact points of the ear electrode or if you are allergic to metals, certain plastics (see chapter 8.1) or preservatives (see label of electrode cream).
- Only use the ear electrode on intact skin.
- Keep water or other liquids away from the device.
- Keep **tVNS[®] E** and all accessories away from pets.
- Do not operate vehicles or machines during use. Do not partake in activities that require your full attention.
- Do not actively participate in traffic while using the device.
- Service and maintenance must not be carried out while the device is in use.
- Only use the ear electrode in the designated ear.
- While wearing the ear electrode, hearing may be slightly impaired on the ear on which the electrode is worn.
- For hygienic reasons, clean the ear electrode and the ear before each use (see chapter 6.2), as well as the stimulator once a day (see chapter 9.1).

- Place the device in the designated storage box to protect it from damage and contamination after use. The device is not protected against dust and lint, especially when the ear electrode is not connected. Always connect the ear electrode immediately after removing it from the storage box.
- Only clean the device when the electrode is attached.
- Observe the instructions and information provided by the manufacturers of the products you use to clean the ear and the ear electrode (e.g. alcohol pads).
- The electrode pads are for single use only. Discard them after use.

2.2 WARNINGS

IMPORTANT:

Before using the device, read the instructions for use carefully.

- **WARNING:** Only use accessories approved by the manufacturer for use with **tvNS[®] E**.
- **WARNING:** Only use the device for its intended purpose. A therapeutic efficacy cannot be guaranteed.
- **WARNING:** It cannot be ruled out that treatment with **tvNS[®]** has an impact on the cardiac system. Patients with cardiac arrhythmias must therefore consult their doctor to clarify whether **tvNS[®]** treatment is suitable for them.
- **WARNING:** The user must be able to optimally adjust the stimulation strength.
- **WARNING:** The device may only be used by a single patient.
- **WARNING:** Please make sure that the cable does not wrap around your neck and restrict breathing. Risk of strangulation.

- **WARNING:** Do not leave **tVNS® E** and its accessories near children unsupervised. Risk of choking and suffocation from small parts that can be swallowed or inhaled!
- **WARNING:** The device must not be modified or opened. Risk of electric shock!
- **WARNING:** Before using the device and the electrode, make sure that they are in good working condition. If liquid has entered the device or is leaking from the device, do not use the device under any circumstances. Risk of electric shock!
- **WARNING:** Never let the electrodes come near your mouth or eyes.
- **WARNING:** The electrodes can reach a temperature of 43°C. This is not dangerous during normal use. Contact customer service if the temperature is too high or you perceive the temperature as disturbing.
- **WARNING:** The device must not be connected to other devices during stimulation with the ear electrode. The ear electrode is an applied part according to IEC60601-1 type BF.
- **WARNING:** Do not use the device if it is malfunctioning or has been damaged.
- **WARNING:** If you cannot end a treatment with the **STOP** function as usual, unplug the ear electrode and contact customer service.
- **WARNING:** Do not try to repair the device yourself. Contact customer service.
- **WARNING:** If the device is exposed to extreme heat or fire, the battery in the device may explode or leak.
- **WARNING:** Do not operate the device outside of the specified temperature range.

- **WARNING:** Keep the device away from open flames, radiators or other sources of heat.
- **WARNING:** Do not keep the device in a car in the summer.
- **WARNING:** Do not use the device if the device becomes noticeably warm. This indicates that the device is defective.
- **WARNING:** Do not use the device while sleeping.

 **WARNING:**

Simultaneous connection of the patient to a high-frequency surgical device can result in burns under the electrodes.

 **WARNING:**

tVNS[®] E is not intended to be used in the vicinity of devices that emit strong electromagnetic or ionizing radiation (e.g. microwave, X-ray machine, MRT). Operation near a shortwave or microwave device can cause fluctuations in the output values. Portable and mobile HF communication devices can also affect **tVNS[®] E**.

2.3 CONTRAINDICATIONS

The device should not be used in the following cases:

- Pregnant women should not use the device.
- People with active implants (e.g. cochlear implant, implanted vagus nerve stimulator, cardiac pacemaker) should not use **tVNS® E**.
- People with cerebral shunts (e.g. for the treatment of hydrocephalus) should not use the device.
- Electrodes should not be attached to sore or diseased skin areas.

2.4 SIDE EFFECTS

When using **tVNS®** treatment, the following stimulation-dependent side effects can occur: headaches, dizziness, voice alteration/hoarseness, drowsiness, transient subjective hearing impairment, stinging sensation, prickling sensation, burning sensation, unpleasantness, vertigo, fatigue, paresthesia, pruritus, erythema/skin redness, scabs, ulcers, skin wounds, numbness, general pain, ear pain, neck pain, chest pain, face contraction, neck contraction, vomiting, nausea, anxiety attacks, dysesthesia, dyspnoe, arrhythmia, diarrhea, vestibular neuronitis.

As with other drug or neurostimulation therapies, **tVNS®** treatment can lead to a preliminary increase in epileptic seizures in epilepsy patients or depression in depression patients.

Usually these side effects subside after the stimulation has ended. If long-lasting or severe side effects occur, please contact your doctor.

2.5 EXTERNAL DEVICES

Do not connect any external devices to **tvNS® E** that are not specified in these instructions for use.

Compliance with the requirements of IEC 60601-1 is not guaranteed if external devices other than those specified by the manufacturer are connected to the device.

3. INCLUDED COMPONENTS

1. tVNS[®] E Stimulator
2. Ear electrode with cable clip (either Legacy Electrode including Silicone Rings or Hook electrode)
3. Storage case
4. Charger with micro-USB connector
5. Electrode cream
6. Electrode pads (for single use)

⚠ IMPORTANT:

Before using the device, check whether all the components listed above are included with your delivery. If any components are missing, contact customer service.

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4. OVERVIEW OF YOUR DEVICE

4.1 STIMULATOR



1 ON/OFF button	Turn stimulator on and off
2 START/STOP button	Start and stop the stimulation
3 Control buttons	Control the stimulation strength
4 Battery indicator	Indicates battery capacity Red: Battery empty Yellow: Current capacity
5 Keylock	Lock and unlock buttons
6 Progress indicator	Remaining stimulation duration Stimulation intensity (when +/- is pressed)
7 Micro-USB plug	Connection for charger

4.2 CONNECTIVITY INDICATOR



Ear Electrode
left/right/both

Green: Active stimulation
Red: Contact problem

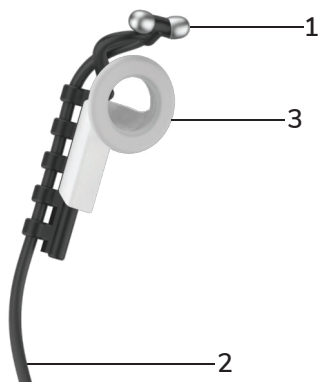
Exclamation mark

Permanently yellow: active treatment in the stimulation phase (ON phase)

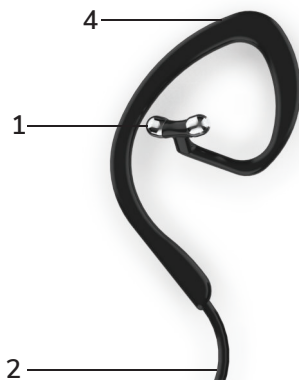
Blinking yellow: active treatment in the pause phase (OFF phase)

Permanently red: Defective device – stop using the device and contact customer service

4.3 EAR ELECTRODE



Legacy Electrode



Hook Electrode

Your device either includes a legacy electrode (left) or a hook electrode (right). The legacy electrode is placed inside of your ear canal, while the hook electrode is placed behind the auricle.

1 Electrodes	The electrodes transmit the electrical impulse from the stimulator to the surface of the skin.
2 Cable	The cable conducts the electrical impulse from the stimulator to the electrodes of the ear electrode.
3 Ear Plug	The ear plug is placed inside of the ear canal like an earphone. It is used to position the ear electrode.
4 Ear Hook	The ear hook is placed behind the auricle. It is used to position the ear electrode.

5. BEFORE FIRST USE

Charge the device fully before using it for the first time. You can check the charge status using the battery indicator.

The device is pre-configured and can be used immediately.

⚠ IMPORTANT:

Allow the device to reach the ambient temperature for operation (approx. 20 °C) for about an hour, if it has previously been transported or stored under very hot or cold conditions.

5.1 ADJUSTING THE ELECTRODE

Confirm whether you are using an electrode for your left ear, right ear, or both ears.

If you are using a legacy electrode, place the ear plug inside your ear canal in the corresponding ear and insert the electrodes into the cymba conchae (marked orange in the illustration). If it does not fit well, adjust the ear plug by sliding it up or down.

If you are using a hook electrode, place the ear hook behind the corresponding ear and insert the electrodes into the cymba conchae (marked orange in the illustration). If it does not fit well, remove the electrode and bend the ear hook in the appropriate places to ensure an optimal fit.

Confirm that the electrodes are in the correct ear.



5.2 USING THE APP

An app (**tVNS**[®] Patient) for your mobile phone is available to document your stimulation results. It is not necessary for a successful treatment, but it helps you and your doctor to monitor the progress of the treatment.

1. 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.
2. Pair your device with the app by switching on your device and pressing the — button and the **START / STOP** button at the same time.
3. Under **Configuration**, select the indication for which you are using the device.

6. HOW TO USE tVNS[®] E

IMPORTANT:

The user must be able to:

- recognize and interpret the display
- optimally adjust the stimulation strength.

6.1 DURATION AND FREQUENCY OF APPLICATION

Treatment with tVNS[®] E is carried out independently by the patient. The recommended daily stimulation dose is 4 hours, of which at least one hour should be carried out continuously.

If the daily stimulation dose is exceeded, the displayed stimulation duration will remain at 100%. The daily stimulation dose is reset to the starting value every day at midnight.

6.2 CLEAN EAR AND EAR ELECTRODE

! IMPORTANT:

Cleaning the ear and the ear electrode before using the device is essential.

Procedure

1. Clean the ear at the orange-marked spot, which will later also be the location of the electrode (illustration on the right). Use commercially available alcohol swabs with 70% isopropyl alcohol. You can purchase these in our online shop or at a pharmacy.
2. Clean the ear electrode with a commercially available alcohol swab.



! IMPORTANT:

Do not wipe the cleaned area dry.

6.3 CONNECT EAR ELECTRODE TO THE DEVICE

Procedure

1. Connect the ear electrode to the stimulator. The cable must point to the left (see figure below).
2. Make sure that it clicks into place.



6.4 USING THE EAR ELECTRODE

Before you can start the stimulation, you must put on the ear electrode.

Wet the electrode contacts individually with electrode cream. Then place the electrode in your ear. The contacts must be inserted into the cymba conchae as described in chapter 6.2.

Make sure that you insert the electrode into the correct ear.

6.5 TURN ON THE DEVICE

Hold the **ON/OFF** button down for approximately two seconds. The stimulator will turn on.

6.6 START THE STIMULATION

Press the **START/STOP** button once. The stimulation will start.

Requirements

- You have properly cleaned the contact points (see chapter 6.2).
- The ear electrode is connected to the device (see chapter 6.3).
- You have put on the ear electrode correctly (see chapter 6.4).

6.7 STIMULATION PROGRAM

Stimulation with **tVNS® E** is carried out with a preset stimulation program that the user cannot change. The program consists of an "ON phase" and an "OFF phase". **tVNS® E** automatically switches the stimulation on for 28 seconds and off for 32 seconds.

The "ON phase" is indicated by a permanently lit yellow exclamation mark symbol, while the "OFF phase" is indicated by a flashing yellow exclamation mark symbol.

6.8 SET STIMULATION INTENSITY

You can adjust the intensity of the pulses during stimulation, and before the stimulation starts, if an electrode is connected. The minimum stimulation intensity is 0.1 mA (Milliampere), the maximum stimulation intensity is 5.0 mA.

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 increasing or decreasing the stimulation intensity, the LED ring will indicate the set intensity. As the intensity increases, more ring segments will be illuminated.

Segment 1: Always illuminated

Segments 2-15: illuminate step-by-step between 0.1 mA and 3.5 mA

Segment 16: illuminates between 3.5 mA and 5.0 mA

If the **+** or **-** buttons are not pressed for more than 3 seconds, the LED ring will indicate the remaining stimulation duration.

When the device starts, the current is always set to the minimum current value. Set the stimulation strength with the + and - buttons.

If you have only paused the treatment, the current value set last is saved and automatically set again when you start it. This may take a few seconds, as the power is slowly increased.

The stimulation intensity can also be set during the “OFF phase” (see chapter 6.7).

⚠ IMPORTANT:

To ensure optimal stimulation, the stimulation strength should be set to an intensity that causes you to feel a tingling or pulsing sensation at the stimulation location (see chapter 6.8.1).

6.8.1 SETTING THE OPTIMAL STIMULATION INTENSITY

Procedure

1. Start the stimulation.
2. 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.

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.

If it is not possible for you to set the optimal stimulation strength during stimulation, please check the stimulation strength and the position of the ear electrode (see chapter 6.9). Please also check whether your skin is intact at the electrode's location.

6.9 CHECK THE POSITION OF THE EAR ELECTRODE

If the ear electrode loses contact with the skin or if the skin resistance is too high, a signal tone will ring. The sound can be switched off in the app.

To ensure an optimal stimulation, do the following:

- Correct the fit of the ear electrode (see chapter 6.4).
- If it is not possible to resolve the error message by correcting the fit of the ear electrode, use the supplied electrode cream as described in chapter 6.9.1.

6.9.1 USING THE ELECTRODE CREAM

A jar of electrode cream is included with your delivery to support the conductivity of the electrode. If you experience contact problems, please use the electrode cream as follows:

1. (Optional) Fill some electrode cream into the provided travel jar.
2. Push the electrode heads into the cream one at a time.
3. Insert the electrode immediately. Do not let the cream dry first.

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 cream between the electrode heads. In this case, dry the ear electrode, e.g. with a cloth, and repeat steps 1–3.

Please inform yourself about the ingredients of the electrode cream. You can find these on the label of the jar.

 **IMPORTANT:**

If you have an intolerance towards any of the ingredients, you should not use the product.

6.9.2 USING THE ELECTRODE PADS

If contact problems persist despite using the electrode cream, please use the included electrode pads as follows:

1. Place an electrode pad on each electrode head. Be careful not to damage the electrode pads.
2. Push the electrode heads including the electrode pads into the electrode cream jar individually (as described in chapter 6.9.1.) The electrode pads must be completely covered with the cream.
3. Put on the ear electrode immediately.

 **IMPORTANT:**

Place the electrode pads on the electrodes only so far that the metal is covered. The electrode pads must **not** touch each other.

 **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 cream between the electrode heads. In this case, dry the ear electrode, e.g. with a cloth, and repeat steps 1–3.

 **IMPORTANT:**

The electrode pads are intended for single use only and must be disposed after use.

6.10 ACTIVATE/DEACTIVATE THE KEYLOCK

The keylock prevents the stimulation from being accidentally interrupted or for settings to be changed during stimulation.

The keylock is not automatically activated. It can be activated or deactivated by pressing the keylock button for longer than 1 second.

When activating the keylock, you will hear a buzzer sound and the LED ring will be illuminated briefly (0.5 s).

When deactivating the keylock, you will hear a buzzer sound and all LEDs (LED ring, as well as battery, electrode and status LEDs) will be illuminated.

6.11 STOP THE STIMULATION

Requirements

- The stimulation is running.
- You may have to deactivate the keylock (see chapter 6.10).

Procedure

Press the **STOP** button. The stimulation will stop.

6.12 TURN OFF THE DEVICE

You can turn off the device at any time using the **ON / OFF** button.

IMPORTANT:

When the ear electrode is disconnected from the stimulator, the stimulation will stop automatically.

6.13 STIMULATION HISTORY

The stimulation history shows the stimulation sessions carried out over the last few days and months and is saved as a percentage in relation to the preset stimulation time. Stimulation sessions that start before midnight and go beyond are fully counted in the history for the previous day.

You need the app for your mobile phone to display the stimulation history.

7. FURTHER HANDLING

7.1 WHERE TO PUT **tVNS® E** DURING USE?

You have several options to comfortably wear **tVNS® E** during use.

If you want to use **tVNS® E** discreetly during the day, the length of the cable allows you to run the cable under your clothing and carry the device in a trouser or breast pocket.

When inserting the device into your trouser pockets or the like, make sure that the plug connection between the stimulator and the ear electrode is not loosened and that the keylock is activated.

In order to provide additional support for the ear electrode, you can attach the cable to your clothing using the included cable clip (see chapter 7.1.1).

Alternatively, you can use the included device clip to attach the stimulator to a belt or a bag (see chapter 7.1.2).

7.1.1 ATTACH THE CABLE CLIP

1. Press the cable clip together until the front opens up.
2. Insert a piece of fabric from your clothing into the front of the cable clip.
3. Release the cable clip. The cable clip will now adhere to your clothing.

7.1.2 USING THE DEVICE CLIP

The device clip can clip onto the device's housing in two directions, with the electrode connector pointing upwards or downwards.

Select the clip position that suits you and click the clip audibly into place. Check that the clip is properly in place.

Attach the stimulator to your belt or bag. Make sure that the device cannot accidentally fall out.

7.2 CHARGE THE DEVICE

tVNS[®] E is powered by a built-in lithium polymer battery. This battery must be charged if necessary.

The current charge status of the rechargeable battery is shown on the battery indicator (see chapter 4.1).

IMPORTANT:

Before charging the device, you must remove the ear electrode from the device. Only use the supplied charger to charge the battery.

Procedure

1. Connect the charger to the device (see illustration in chapter 4.1).
2. Plug the charger into a power socket.
3. The charging process is indicated by the battery indicator flashing. The battery is fully charged when all LEDs light up yellow.
4. Remove the charging cable from the device.

7.3 SET THE TIME

Procedure

The device has an internal clock.

If you use the device without the app, setting the time correctly is not necessary.

If you use the device with the app, the internal clock is automatically synchronized as soon as the device is connected to your smartphone via Bluetooth.

7.4 WHEN TO STOP USING THE EAR ELECTRODE

WARNING: Stop using the electrode when:

- the attached cable shows signs of damage (open spots, brittle cable(s)/insulation)
- the electrodes heat up too much (possible cable fault)
- the electrodes have broken off and/or are only partially attached to the ear hook
- the ear hook is fragile and/or is only held in place by the cable
- the connection to the stimulator has been broken or it has become unstable (it can be moved with bare fingers)
- you see signs of material wear

If one or more of these cases occurs, stop using the product and contact customer service.

8. TECHNICAL DATA

8.1 TECHNICAL SPECIFICATIONS AND PRODUCT INFORMATION

Parameter	Feature
Measurements of device	100 mm (L) x 60 mm (W) x 20 mm (H)
Weight	115g
Power supply	Internal, permanently installed Li-Polymer battery with 4.2 V, rechargeable
Power consumption	< 500 mA DC
Operating time	> 2 days
Standby time	> 3 months
Charging time	< 3 h
Degree of protection	IP22; Protection from water spray less than 15° from vertical (only applicable when the electrode plug is plugged in)
Operating conditions	Temperature range: +5°C to +40°C, Humidity: 15 - 93 %, non-condensing, 700 - 1060 hPa
Storage and transport conditions	Temperature range: -10°C to +50°C, Humidity: 0 - 93 %, non-condensing, 700 - 1060 hPa

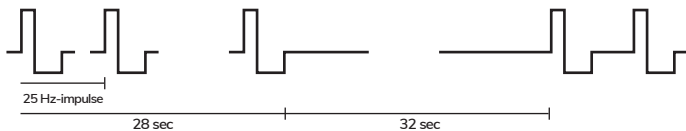
Parameter	Feature
Charger	Charger with micro-USB connector (EU 220V, US 110V)
Product Classification	Class IIa according to 2017/745 (MDR)

8.2 IMPULSE PARAMETERS

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, 32sec off
Impulse frequency: 25 Hz

The device delivers the current strength desired by the patient, regardless of the skin resistance, up to a maximum value of 18 kOhm without a direct current component. The maximum pulse voltage at the electrodes can be up to 90 V.



The device continuously monitors the patient's impedance to determine whether the electrode is making good contact. For this purpose, pulses with a very small current of 0.1 mA and at a rate of 1 Hz are emitted when no stimulation is active.

8.3 ACCESSORIES

tVNS® E may only be used with the following original accessories from tVNS Technologies GmbH:

Ear Electrode for **tVNS® E** (included in delivery)

Charger for **tVNS® E** (included in delivery)

8.4 CONSUMABLES

tVNS® E may be used with the following electrode cream:

tVNS® Electrode Cream

LABEL SYMBOLS EXPLANATION



Pay attention to accompanying documents!



Medical Device



Before using the product you must read the instructions for use.

IP22

Protection class and degree of protection of the housing for contact and foreign body protection and water protection (only applicable when the electrode plug is plugged in).



Manufacturer



Serial number of the device



Follow the instructions for use!



Not suitable for children under three years of age.



Device complies with 2017/745 (MDR)



Protect from heat and direct sunlight.



Date of manufacture of the product.



Store in a dry place.



This product must not be disposed of with household waste; it must be taken to a collection point for electrical and electronic equipment.



Type BF applied part. The product provides protection against electric shock if the leakage current is reliable.

9. MAINTENANCE

9.1 CLEANING

Clean **tvNS® E** and the ear electrode with a slightly damp cloth or cotton swab. Use commercially available alcohol wipes with 70% isopropyl alcohol. Clean the device carefully. Do not use abrasives or abrasive cloths.

 **IMPORTANT:**

Do not immerse the device or electrodes in water or other liquids. Clean the ear electrode and the auricle before each use. Use commercially available alcohol swabs with 70% isopropyl alcohol.

9.2 MAINTENANCE

The device is maintenance-free.

The operating life of **tvNS® E** including accessories is at least 2 years. Please note the best-before dates of the consumables.

10. INFORMATION ABOUT DISPOSAL

This product must not be disposed of with household waste; it must be taken to a collection point for electrical and electronic equipment.

11. TROUBLESHOOTING

Error	Potential cause	Solution
The device cannot be switched on.	The battery is empty.	Charge the device (see chapter 7.2).
	The device is malfunctioning.	Stop using the device and contact customer service.
Ear symbol shows an error (red light)	Electrodes are too dry.	Moisten the electrodes again (see chapter 6.9.1).
The device does not respond.	The key lock is activated.	Deactivate the key lock (see chapter 6.10).
	The device is malfunctioning.	Stop using the device and contact customer service.
The stimulation intensity does not change.	The button is malfunctioning.	Stop using the device and contact customer service.
	The device is currently in the "OFF phase".	Wait until the device is in the "ON phase" again. Setting the stimulation strength is now possible.

Error	Potential cause	Solution
No stimulation history available.	You have not stimulated for a sufficient amount of time.	You can only see the stimulation history once you have stimulated for a day.
The device does not charge.	The charger cannot be connected.	Remove the plug of the ear electrode and plug in the charging cable.
	Wrong plug.	Check that the charging cable is in the correct plug. (see chapter 4.1).
	Wrong charger.	Use the charger supplied by the manufacturer.
	The charger is malfunctioning.	Contact customer service.
	The device is malfunctioning.	Stop using the device and contact customer service.
The ear electrode causes tenderness.	The electrode does not fit properly.	Adjust the electrode's fit (see chapter 5.1).

Error	Potential cause	Solution
Stimulation is not possible.	The electrode does not fit properly.	Adjust the electrode's fit (see chapter 5.1).
	The electrode is not attached to the device.	Check if the electrode is properly attached to the device (see chapter 6.3).
	The charger is connected.	To enable stimulation, the charging cable must be removed and the electrode must be connected.
	The device is malfunctioning.	Stop using the device and contact customer service.
Exclamation mark symbol shows an error (red light)	The device is malfunctioning.	Stop using the device and contact customer service.

In the event of malfunctions and technical questions, you can contact customer service at the following address:

tVNS Technologies GmbH

Wetterkreuz 5

91058 Erlangen

Germany

support@t-vns.com

www.t-vns.com

 **IMPORTANT:**

In the event of serious incidents in connection with the use of the product, you must inform the manufacturer

be-on-market GmbH, Lilienstr. 33, D-91244 Reichenschwand
and the responsible authority.

12. ELECTROMAGNETIC COMPATIBILITY

Medical electrical devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC). They must be installed and used in accordance with the EMC information contained in the accompanying documents.

The device is intended for use in the areas of domestic healthcare and in medical facilities. It has been tested for operation in residential areas and buildings that are used for residential purposes and are connected to a public supply network.

Warnings:

WARNING:

The use of this device next to other devices or with other devices in a stacked form should be avoided, as this could result in incorrect operation. If use in the manner described above is necessary, this device and the other devices should be observed to ensure that they are working properly.

WARNING:

Portable RF communications equipment (including peripheral devices such as antenna cables and external antennas) should be used no closer than 30 cm to any part of **tvNS® E**, including cables specified by the manufacturer. Otherwise, the performance of this device may be negatively impacted.

 **WARNING:**

The use of accessories, converters and cables that are not specified or provided by the manufacturer of this device can lead to increased electromagnetic emissions or decreased electromagnetic immunity of this device and to improper operation.

 **NOTE:**

The electromagnetic compatibility was tested in accordance with the information in IEC 60601-1-2 with the test setup according to IEC 60601-2-10. No special precautions are necessary for compliance with the technical specifications and safety over the expected service life. The stimulation frequency and the max. current levels are not influenced by electromagnetic fields.

Electromagnetic emissions

tVNS® E is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.

Emission Measurements	Correspondence	Electromagnetic Environmental Guidelines
RF emissions according to CISPR 11	Group 1 Class B	tVNS® E uses RF energy only for its internal function. Therefore, its RF emissions are very low and it is unlikely that nearby electronic devices will be disturbed.
Emission of harmonics according to IEC 61000-3-2	Not applicable	tVNS® E is intended for use in all facilities including residential areas and those that are directly connected to a public supply network that also supplies buildings that are used for residential purposes.

Electromagnetic immunity

tVNS® E is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.

Immunity Tests	IEC 60601- Test Levels	Match Levels
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV Contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air discharge	± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV Contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air discharge
Radiated HF interference according to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m
Rapid transient electrical disturbances / burst according to IEC 61000-4-4	± 2 kV 100 kHz spike frequency (Exception: Patient lines)	± 2 kV 100 kHz spike frequency
Surge voltages according to IEC 61000-4-5	± 0.5 kV, ± 1 kV line to line ± 0.5 kV, ± 1 kV, ± 2 kV line to ground	± 0.5 kV, ± 1 kV line to line ± 0.5 kV, ± 1 kV, ± 2 kV line to ground
Conducted disturbances, induced by high-frequency fields according to IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in the ISM- and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz to 80 MHz 6 V in the ISM- and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Magnetic field at the supply frequency (50 Hz / 60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m 50 Hz/60 Hz
Voltage dips, short-term interruptions and voltage fluctuations according to IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles Single phase at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° und 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles Single phase at 0° 0 % UT; 250/300 cycles

Mobile RF Communications Equipment

Test frequency in MHz	Frequency band in MHz ^{a)}	Radio service ^{a)}	Modulation ^{a)}	Maximum power in W	Distance in m	Immunity test level in V / m
385	380 to 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460 FRS460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
810	800 to 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1900	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse modulation ^{b)} 18 Hz	2	0.3	28
1845						
1970						
	2400 to 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5500						
5785						

a) For some radio services, only the frequencies for the uplink have been included in the table.

b) The RF carrier must be modulated with a square wave signal with a 50% duty cycle.

c) As an alternative to frequency modulation (FM), a pulse modulation with 50% duty cycle with 18 Hz can be used, since this would represent the worst case, even if not the actual modulation.



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