# Instruction for Using the VGuard System for Patients

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# Transcutaneous Vagus Nerve Stimulation System

## Table of Contents

# 1. INTRODUCTION

## 1.1. Description of the document

This document is part of the technical documentation for the VGuard product developed and maintained by the manufacturer. It contains instructions for the patient's use of the product.

## 1.2. Brief Description of the System

The VGuard system provides non-invasive transcutaneous vagus nerve stimulation applied to the surface of the ear canal (aVNS). The main purpose of using the VGuard system is to treat cognitive disorders in the course of mild cognitive impairment (MCI) and Alzheimer's disease. VGuard activates selected structures of the central nervous system by stimulating branches of the vagus nerve located in the ear canal of the left ear with a series of alternating direct current pulses delivered during sleep, implemented by a set of self-adhesive electrodes attached to the skin of a single ear.

## 1.3. Availability of the VGuard System user manual

The user manual is provided to all users along with the VGuard System in a paper format. Additionally, the manual is accessible on the manufacturer's website at www.neuromedical.pl/user-manuals

Users of the VGuard System can also receive a paper version of the manual free of charge within 7 working days from the date of request. To do so, please send a message to office@neuromedical.pl.

## 1.4. Explanations of warnings

DANGER! - Danger indicates a hazardous situation that, if not avoided, will result in death or serious injury.

⚠ WARNING! - Warning signifies a hazardous situation that may result in death or serious injury if not avoided.

CAUTION! - Caution denotes a hazardous situation that may result in minor injury if not avoided.

NOTICE! - Notice indicates potential threats that may cause material or environmental damage.

 INFORMATION - Signifies helpful tips regarding a specific sequence of actions

### 1.5. Description of Product Functions

The VGuard system provides the following functionalities:

- night stimulation of the vagus nerve branch located in the left auricle;
- supervising VGuard devices and their use in a web application intended for technical staff and medical staff.

## 2. SAFETY

### 2.1. Intended use of the product

The VGuard system is intended for the treatment of memory disorders in the course of mild cognitive impairment (MCI) and Alzheimer's disease.

The VGuard system activates selected structures of the central nervous system by stimulating branches of the vagus nerve located in the left ear canal with a series of alternating direct current pulses delivered during sleep, implemented by a set of self-adhesive electrodes appropriately positioned in the patient's left ear.

### 2.2. Method of Using VGuard

The VGuard system is intended for the treatment of cognitive disorders through nightly sessions of vagus nerve stimulation, conducted for the duration and frequency prescribed by the doctor. VGuard stimulation is performed independently at the patient's home.

Throughout the treatment period, the patient must remain under the appropriate supervision of a doctor.

Any changes to stimulation parameters can only be made by modifying the settings of the VGuard stimulator, done exclusively and directly by authorized personnel (doctor or technician)

### 2.3. Indications for Using VGuard

- Adult patients diagnosed with amnestic and non-amnestic MCI.
- Adult patients diagnosed with Alzheimer's disease in the mild and moderate stages of dementia.

### 2.4. Contraindications for Using VGuard

- ⚠The VGuard system is not intended for users with implanted electronic devices (such as pacemakers, brain stimulators for DBS - deep brain stimulation, cochlear implants, etc.).
- ⚠ The VGuard system is not intended for users with bone-joint prostheses of the head and cervical spine (excluding dental prostheses).

## 2.5. Possible Adverse Effects of Using VGuard

- Irritation of the skin around the ear at the stimulation site
- Headache
- Sleep disturbances

CAUTION!

In case of any adverse effects, technical issues, or any medical incidents, immediate contact with the attending physician is necessary.

## 2.6. Limitations Regarding the Use of VGuard

- The VGuard system is designed for vagus nerve stimulation during sleep. Achieving the planned therapeutic effect relies on the patient's peaceful sleep during stimulation. VGuard is not intended for daytime stimulation outside of the patient's sleep.
- The VGuard system is designed for stimulation of the left ear, meaning the electrodes should be placed on the patient's left ear. VGuard is intended for stimulation of adult patients only. The device and therapy are not intended for use in children.
- The use of the VGuard device can only be prescribed by a doctor, and the course of treatment requires periodic medical supervision. Before issuing the device for independent use by the patient, medical personnel must calibrate the stimulation amplitude to set the threshold value at which the patient does not feel the stimulation current
- To set the threshold value, the technical panel of the device must be accessed on the base station screen. Access to the technical panel is limited to technicians, service personnel, or medical staff responsible for the care of the user.

## 2.7. Requirements for VGuard users

The intended user of the VGuard system is a patient qualified by a doctor. VGuard is intended for the treatment of patients exhibiting symptoms of moderate cognitive impairment (MCI) and Alzheimer's disease.

The patient or their caregiver should be trained by the VGuard system operator during the initial issuance of the device for independent use.

The operators of the VGuard System are:

- A doctor who prescribes therapy to the patient using the VGuard system and then monitors its progress.
- A technician/doctor who installs the VGuard system, sets the prescribed stimulation current amplitude value, and conducts training for the patient.

Operators of the VGuard System should be trained by an authorized representative of the manufacturer in the operation of the system and the supervision of therapy effectiveness.

## 2.8. Warnings and recommendations regarding the use of VGuard

- **Carefully read the user manual provided by the manufacturer** before the first use of the VGuard stimulator and follow its instructions to ensure proper and safe usage.

- Do not use the electrodes in areas not intended for their use. **VGuard is intended solely for transcutaneous stimulation of the vagus nerve branch in the left ear canal**.
- **Apply the electrodes only to undamaged skin surfaces**. When stimulating, skin damage areas may lead to irritation at the electrode contact site. Do not use the VGuard device in cases of alcohol and/or drug (or other psychoactive substances) dependence.
- The VGuard device may only be recommended by a doctor, and the course of treatment requires periodic medical supervision.
- **Only use the original dedicated power supply provided in the VGuard kit to power the VGuard system base station.**
- The VGuard stimulator is a medical device powered by a lithium polymer battery installed inside the stimulator. The VGuard charger, included as part of the system, is used to charge the stimulator's battery.
- **Do not use any other induction charger to charge the stimulator's battery. This may damage the stimulator.**
- Do not use the stimulator in a manner inconsistent with the manufacturer's instructions.
- Do not exceed the recommended usage times for the VGuard stimulator.
- Do not place the VGuard stimulator on the head using any fasteners other than the special VGuard headband provided with the system to the patient.
- Do not connect the VGuard stimulator to the patient's ears using any electrodes other than the original self-adhesive VGuard electrodes.
- Do not connect the base station to any power source other than the household electric network.
- Do not disassemble or repair any VGuard system device independently. In case of problems, consult the manufacturer or technical service appropriate to the place of therapy.
- Do not use the VGuard device or any of its accessories after the expiration date (expiration date on the labels of individual system components).
- Do not expose the VGuard system devices in temperatures: lower than 5°C or higher than 35°C.
- Do not leave the device in direct sunlight.

# 3. System description

## 3.1. Introduction

The VGuard system provides non-invasive transcutaneous stimulation of the vagus nerve applied to the surface of the ear canal (aVNS). The primary goal of using the VGuard system is to treat cognitive disorders in the course of mild cognitive impairment (MCI) and Alzheimer's disease. VGuard activates selected structures of the central nervous system by stimulating branches of the vagus nerve with a series of alternating direct current pulses delivered during sleep, implemented by a set of self-adhesive electrodes attached to the skin of a single ear.

The VGuard system is intended for aVNS treatment sessions performed independently by the patient at home. Throughout the treatment period, the patient must remain under the appropriate supervision of a doctor. **The VGuard transcutaneous vagus nerve stimulation system** consists of:

- VGuard transcutaneous Vagus nerve stimulator (ST);
- VGuard Base Station (BS);
- VGuard Wireless Power Transmitter.

The VGuard system is used with the following accessories:

- VGuard Electrodes;
- VGuard Head band (different sizes available);
- VGuard Web application.

The VGuard base station is powered by dedicated external power supply, delivered with the system .

(See Figure 1. below)

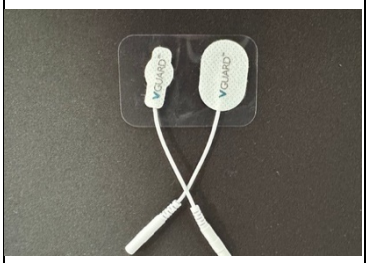
Fig. 1. VGuard System (from left to right) - 1. Headband, 2. Electrodes, 3. Stimulator, 4. Base Station, 5. Charger, 6. Power Supply

| System / system's element | Basic UDI-DI |
|---|---|
| VGuard – Transcutaneous Vagus Nerve Stimulation System | 5905567895AVTS-SYS-VGBC |
| Vguard Stimulator | 5905567895AVTS-VGStG5 |
| Vguard Base Station | 5905567895AVTS-VGBsEG |
| Vguard Electrodes | 5905567895AVTS-VGElEB |
| Vguard HeadBand | 5905567895AVTS-VGHbDY |

| | |
|---|---|
| Wireless charger | 5905567895A VTS-VGWpt |
| Dedicated Power Supply | ---------- |

## 3.2. Intended use of VGuard system components

| System elements | Intended use |
|---|---|
| Vguard Stimulator  | The main purpose of the VGuard stimulator is to treat memory disorders in the course of mild cognitive impairment (MCI) and Alzheimer's disease. The VGuard stimulator activates selected structures of the central nervous system by stimulating branches of the vagus nerve located in the left ear canal with a series of alternating direct current pulses delivered during sleep, implemented by a set of self-adhesive electrodes attached to the skin of a single ear. |
| Vguard Base Station  | The VGuard Base Station performs the following functions in the VGuard System:<br>• user interface (user: Patient and/or Care giver, and Physician/technician);<br>• control and management of Stimulator work;<br>• communication interface between the VGuard Stimulator and the Web Application.<br><br>The purpose of the Base Station usage includes:<br>• User interface for patient/caregiver:<br>  ○ starting a stimulation session;<br>  ○ stopping the stimulation session;<br>  ○ presentation of information for the patient about electrodes contact with the skin – only showing if there is no correct contact with the skin, including comment suggesting patient action;<br>  ○ presentation of information about battery state of charge and charging, including comment suggesting patient action;<br>• user interface for Physician/technician:<br>  ○ setting the amplitude of the stimulation current;<br>• communication between the Stimulator and Base Station:<br>  ○ receiving reports from the Stimulator and storing them in the memory of the Base Station;<br>  ○ receiving information about the stimulator battery charge level;<br>  ○ uploading a new firmware version for updating the stimulator software |

| | |
|---|---|
| | ○ sending stimulation parameters from the Base Station to the Stimulator<br>• supplying the wireless charging transmitter (utilizing for the stimulator battery charging) with DC voltage;<br>• downloading the new version of the Stimulator software from the portable memory device in process of stimulator firmware update.<br>• In the area of communication between the Base Station and the Web Application:<br>○ Sending reports about device (stimulator) to the web application |
| Wireless charger<br>  | The VGuard wireless charger is an inductive charger designed to charge the battery in the VGuard stimulator.<br>To function properly, it should be connected to the base station. |
| VGuard Electrodes<br>  | VGuard Electrodes intended for VGuard transcutaneous vagus nerve stimulation system.<br>VGuard electrodes are non-active devices designed to transfer the electrical energy of the stimulating wave produced by the VGuard transcutaneous vagus stimulator to the branch of the vagus nerve located in left ear auricle, to stimulate it.<br>The transfer of energy from the VGuard transcutaneous vagus stimulator to vagus nerve takes place due to current flow through ear auricle tissues as the result of stimulating wave flow between the electrodes glued to the surface of the skin on opposite sides of the auricle. |
| Vguard HeadBand<br>  | VGuard Headband intended for VGuard transcutaneous vagus nerve stimulation system.<br>The VGuard Headband is designed to comfortably and stably hold the VGuard transcutaneous vagus stimulator on the patient's forehead while sleeping. It is also used to hold the wires connecting the stimulator with the electrodes attached to the surface of the left ear auricle. |

| | |
|---|---|
| Power Supply  | The dedicated external power supply is used to power the Base Station during its operation. It is delivered together with VGuard system. |

# 4. PRODUCT OPERATION CHARACTERISTIC

## 4.1. Requirements for using the VGuard Stimulator

The VGuard stimulator is intended for self-use by the patient at home. Prior to issuing the device, training will be conducted on its usage. Training will be provided during the therapy initiation visit by a doctor or trained technician. During this visit, an individual stimulation current amplitude value (below the sensation threshold) will be set to ensure user comfort during sleep.

## 4.2. Stimulator

The main component of the VGuard system is the Stimulator. It is a miniature generator of stimulating current pulses powered by a rechargeable lithium-polymer battery integrated inside the device.

Fig. 2. VGuard Stimulator

The VGuard stimulator activates selected structures of the central nervous system by stimulating branches of the vagus nerve located in the left ear canal with a series of alternating direct current pulses delivered during sleep. This stimulation is implemented by a set of self-adhesive electrodes attached to the skin of the left ear. The electrodes are connected to the headband, and the headband is connected to the stimulator via a Pogo-Pin connector located on the front panel. The housing of the stimulator has gentle grooves on the side walls, allowing for easy mounting of the stimulator in the holder on the front part of the headband.

The stimulator is a generator of direct current stimulation pulses controlled by a microcontroller circuit. The parameters of the stimulating wave are transmitted to the stimulator by the base station. The stimulator communicates with the base station via Bluetooth Low Energy signal. The stimulator is powered by a Li-Po battery, charged wirelessly by the charger, which is part of the Base Station equipment.

The stimulator is a non-disassemblable device.

**The patient's operation of the device involves:**

- Mounting the charged stimulator in the headband.
- Placing the stimulator on the inductive charger during battery charging.
- Using a piece of dry cloth to wipe the housing when it is dirty. Do not use any cleaning agents or water to clean it.

### 4.2.1. Stimulation Pulse Wave Specifications

The Vguard stimulator generates a wave of pairs of rectangular direct current pulses, repeated cyclically according to a specified pulse wave frequency. The pulses have a controlled current amplitude and pulse duration. The pulse pairs are bipolar in nature.

VGuard Stimulator pulse waveform specifications:

- maximum direct current (DC) of a single pulse (P-Amp): 2 [mA]
- maximum duration of a single direct current (DC) pulse: 2 [ms]
- pulse wave frequencies: 25 [Hz]
- maximum authorised resistance at electrode to electrode: 10 [KΩ]

## 4.3. VGuard Headband

For stable and comfortable maintenance of the Stimulator on the patient's head, a textile headband equipped with a frame for mounting the Stimulator has been prepared. The headband features Velcro-fastened tabs at the back, allowing the Headband to be securely fastened in a manner that is stable and does not cause discomfort to the patient during wearing and sleep. Inside the headband, wires are routed connecting the frame socket to the electrode tips. The wires are terminated with a connector for connection to the socket on the electrodes. Figure 4 below illustrates the method of mounting the stimulator in the headband frame and the headband with the stimulator correctly mounted and without the stimulator.

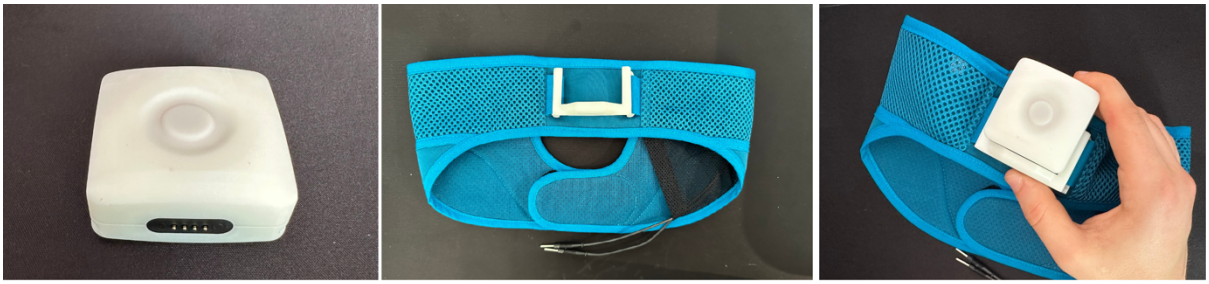


Fig. 3. Ilustration of the method of mounting the stimulator in the headband frame and the headband with the stimulator correctly mounted and without the stimulator

The headband is available in three sizes (S, M, L).

Fig.4. The headband correctly positioned on the patient's head.

## 4.4. VGuard Electrodes

The self-adhesive electrodes are used to deliver stimulating current to the patient's tissues. Two specially designed electrodes with a hydrogel coating enable overnight contact with the skin while maintaining the required level of electrical conductivity between the device and the user's body. The stimulating current generated by the stimulator, flowing between the electrodes placed in the appropriate area of the ear canal, stimulates the Vagus nerve.

Along with the VGuard system, two types of electrodes are provided:

- Internal (smaller) with dimensions of 28mm x 12mm
- External (larger) with dimensions of 30mm x 20mm; (see Figure 5)

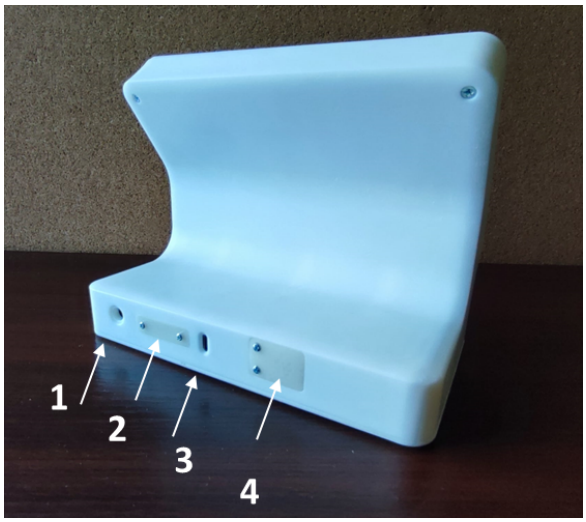

Fig. 5. VGuard Electrodes (from left to right) - 1. Larger electrode (outside the ear canal); 2. Smaller electrode (inside the ear)

The VGuard electrodes are intended for single use. New electrodes should be applied for each new stimulation session. In case of poor contact of the electrodes with the skin despite attempts to improve it, the electrodes should be replaced with new ones.

## 4.5. Base Station

The VGuard Base Station is a medical device that performs the following functions within the VGuard system:

- Provides separate user interfaces for:
  - Patient
  - Technician/Doctor
- Collects data on the operation and technical condition of the Stimulator;
- Powers the inductive charger for charging the Stimulator's battery.


a )


b)

Fig. 6. Base Station: a) front view; b) rear view: 1 - DC 5V socket; 3 - USB-C socket for powering the inductive charger. Under the covers are: 2 - SIM card slot; 4 - USB-A connector.

The built-in connectors are technical connectors available for technical service. The SIM card slot is used for inserting a GSM communication module card; The USB-A socket is used to connect external memory (USB flash drive) for updating the software of the station or stimulator.

On the front of the Base Station is a 7" diagonal IPS display with a touchscreen, serving as the User Interface.

The DC 5V socket is used to connect the Base Station to the DC 5V output plug of the AC/DC medical power supply, included as an accessory to the base station.

## 4.6. Base Station display

The base station display functions as a touchscreen, serving the following purposes:

- Presents graphical and textual information on the screen.
- Identifies screen touches, triggering the desired action.

The display does not use sound alarms in Patient mode. It turns on when power is connected to the base station (DC, 5V). The display dims after 30 seconds of properly initiated stimulation.

The display lights up automatically when an alarm related to the operation of the stimulator or ongoing stimulation occurs, presenting graphical information about the alarm.

## 4.7. Symbols on the Base Station screen

| Symbol | Meaning |
|---|---|
| Top of the screen | |
|  | Logo |
|  | Battery Level in the VGuard Stimulator (value in %) |

| | |
|---|---|
|  | GSM Signal (optional) |
|  | Bleutooth Signal |
| Middle of the screen | |
|  | Correct stimulation |
|  | Measurement of electrode resistance |
|  | ERROR! |
|  | ERROR! Electorde resistance out of the correct measurement – no conatct |
|  | ERROR! No Bluetooth connection |
|  | ERROR! Battery Critically Low |
|  | ERROR! Critical System Error |
|  | Charging Battery in Progress |
| Bottom of the screen | |
|  | Start Stimulation |
|  | End Stimulation |
|  | Stimulator Name |

The symbols presented in the table are displayed on the screen in various configurations, depending on the situation during the stimulation session. Details are presented in the section on the course of stimulation.

## 4.8. Power supply of the base station

The AC/DC power supply 5V, 5A is used to power the base station, which is included as an accessory of the base station (fig. 7). The power supply has two plugs: a power plug with two pins (without a grounding socket) for connection to the household 230V, 50Hz power socket, and a concentric plug 5.5 x 2.1 mm for insertion into the DC 5V socket in the base station. The power supply is equipped with a diode indicator to signal when it is operational.

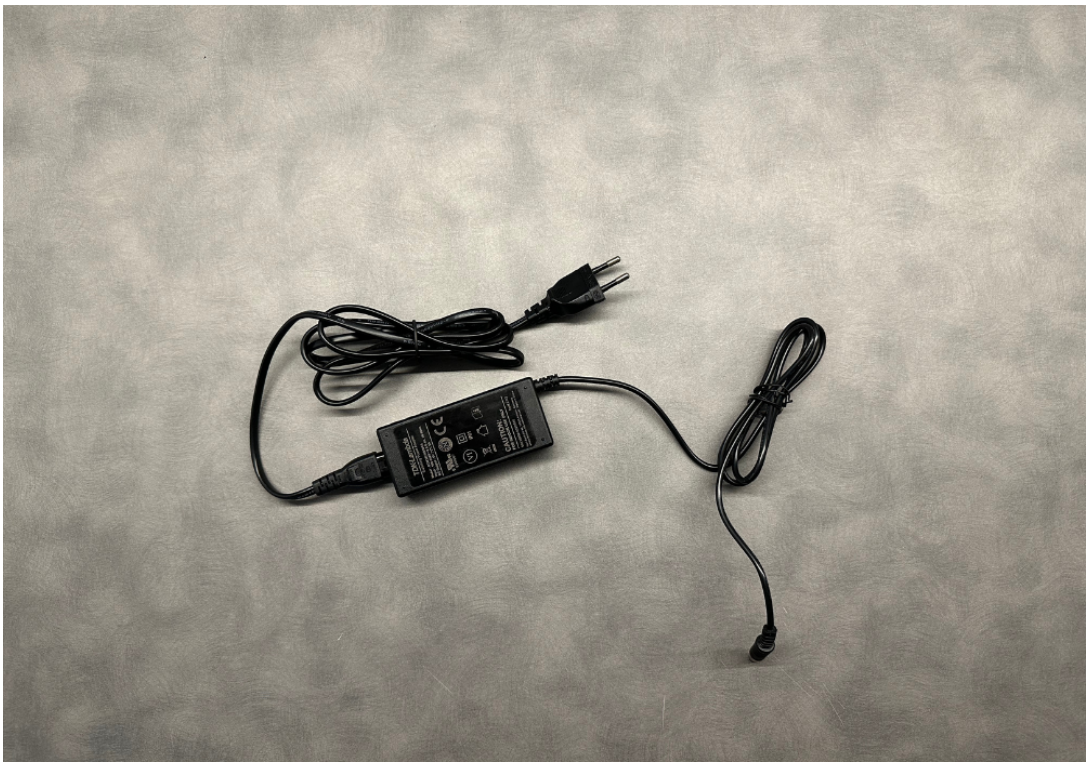


Fig. 7. Power supply dedicated for Base Station

## 4.9. Wireless charger

The wireless charger, which is an accessory to the base station, is used to charge the Stimulator's battery. The charger is connected to the USB-C socket of the base station. The charger housing is equipped with a positioning and stabilizing frame that magnetically holds the stimulator on the charger during charging (Fig. 8).

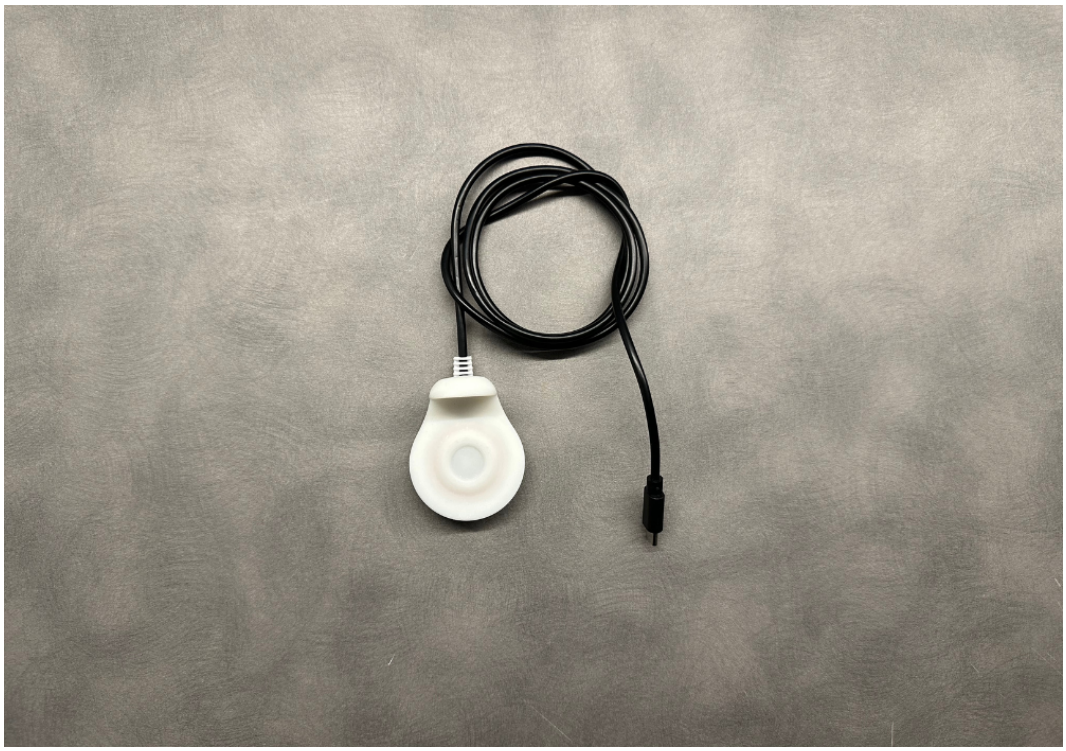


Fig.8. Wireless charger VGuard

# 5. DEVICE PREPARATION

## 5.1. Unpacking the device

Unpack all VGuard system devices from the packaging. You should have:

- Stimulator
- Stimulator Strap
- Set of electrodes
- Base Station
- Base Station Power Supply
- Wireless Charger

Ensure that all items are present in the packaging and are in good condition.

CAUTION!

1. If any element of the VGuard system is found damaged, do not attempt to use it. Contact your doctor or technician.
2. Pay special attention to the Stimulator. Check for any signs of damage, such as housing leaks or other mechanical damage.
3. Similarly, check the base station.

## 5.2. Connecting the base station

Place the base station in a convenient location for you to observe and operate it before bedtime (for example, on a table or nightstand near the bed).

Connect the base station to a power source (wall socket nearby) using the provided AC power adapter (see Fig. 9).

Fig. 9. Connecting the Power to the Base Station

Make sure that the base station is properly connected to the electrical network.
The base station will turn on automatically after being connected to the power supply. This may take several seconds.
After the base station is powered on, the welcome screen will appear on the display (Fig. 10).

ATTENTION! Before the first stimulation, place the stimulator on the wireless charger and leave it for at least an hour to charge.

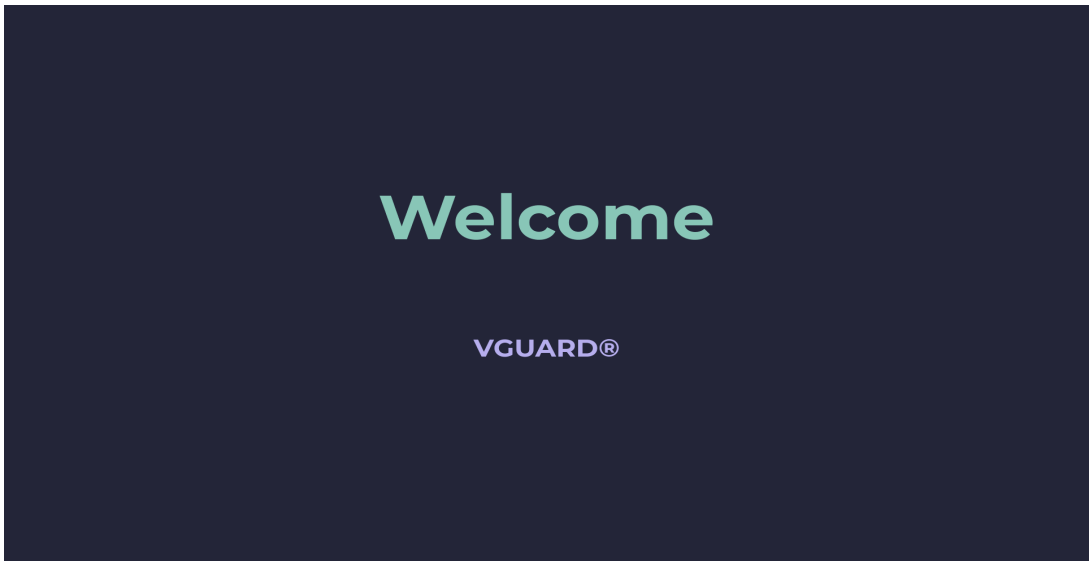



Fig. 10. The welcome screen of the Base Station

## 5.3. Prepare the stimulator for first use

1. Connect the wireless charger to the base station (Fig. 11). Plug the USB-C connector of the charger into the USB-C port on the bottom rear panel of the Base Station.

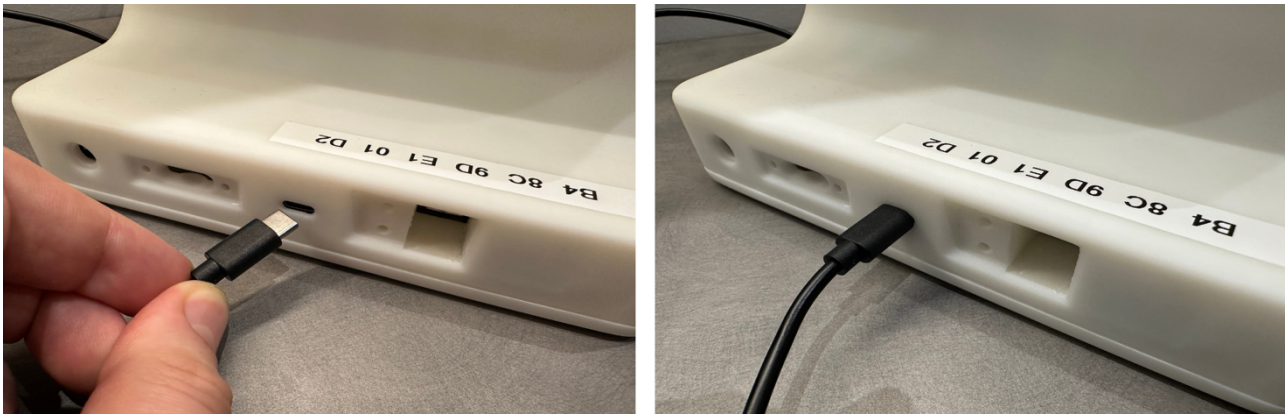


Fig.11. Proper connection of the wireless charger to the base station.

2. Umieść stymulator na ładowarce indukcyjnej, zbliżając do siebie wyprofilowane powierzchnie kontaktu ładowarki i stymulatora oraz stykając ze sobą magnesy) (Fig.12.).

Fig.12. Correct way of charging

3. The battery charging will start automatically. The battery charging icon will appear on the base station screen.
4. If the battery is low (single battery charge indicator in orange colour = 10% energy or double battery charge indicator in yellow colour < 35% energy), charge the battery to full.

**Battery status:**

- The green colour indicates the battery status between 75% and 100%

- The yellow colour indicates the battery status between 35% and 75%

- The orange colour with an exclamation mark indicates that the battery level is equal to or less than 10%, and stimulation cannot be started. The stimulator needs to be charged.

- The lightning bolt icon, regardless of the battery status, indicates the charging process. It is not possible to use the device while it is charging.

INFORMATION! The charger can be permanently connected to the base station; there is no need to disconnect it after the battery is fully charged.

# 6. CONDUCTIONG STIMULATION SESSION

## 6.1. Preparing the ear skin and applying the electrodes

Before applying the VGuard stimulator electrodes, ensure that the area of skin where the electrodes will be placed is clean and dry. Remove any skincare products from the skin surface on both sides of the earlobe that may interfere with electrode adhesion. Gently affix the electrodes to the skin of the left ear, ensuring they are in the designated positions. Place the smaller electrode near the entrance of the ear canal in the left ear (see diagram below). Direct the electrode wire downwards towards the neck.

Meanwhile, affix the second, larger electrode to the back of the left earlobe, opposite the smaller electrode placed in the ear canal recess. Route the wire of the larger electrode downwards behind the ear (Fig.13).

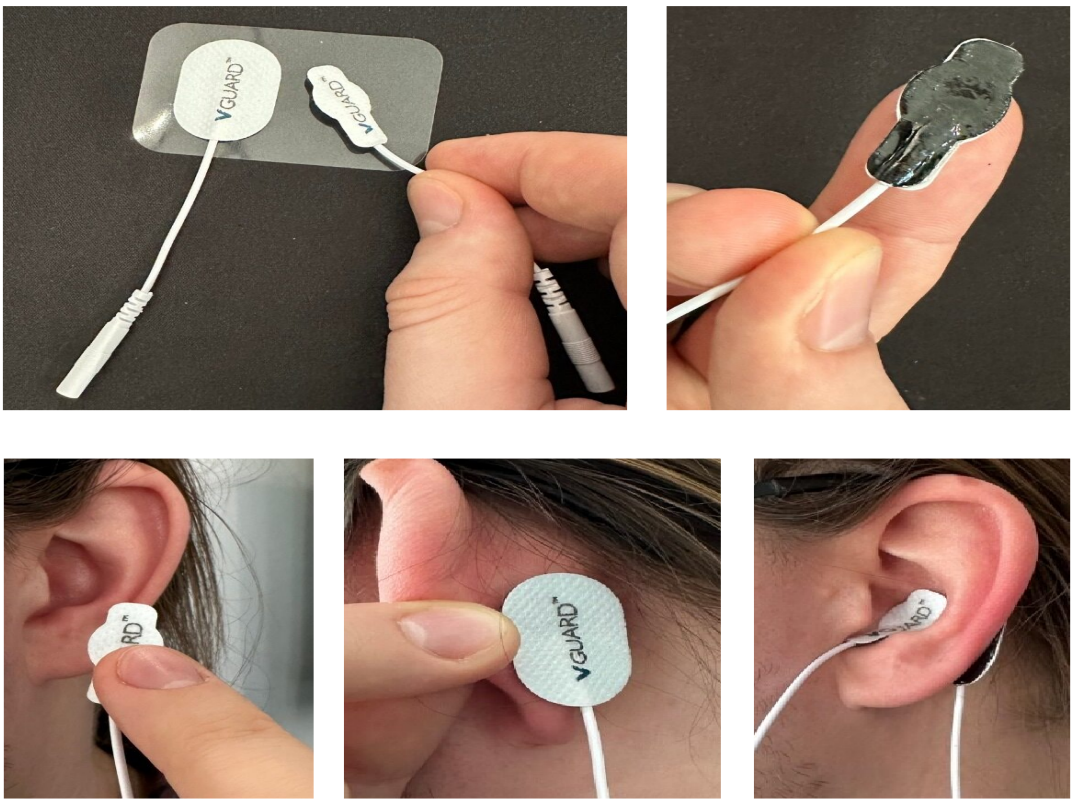



Fig.13. Proper electrode placement

INFORMATION! Proper electrode placement ensures effective stimulation of the auricular branch of the vagus nerve.

## 6.2. Mounting the stimulator on the headband

The stimulator is connected to the headband using a mechanical fastening. To ensure proper device operation, the VGuard stimulator can only be inserted into the mount in one correct way (Fig. 14).

When inserting the stimulator, always make sure that the charging area of the device is on the opposite side from the headband (Fig. 14). Slide the stimulator into the mounting guides on the headband until the magnetic latch engages the stimulator with the headband. Finally, check that the stimulator does not protrude spontaneously from the headband.

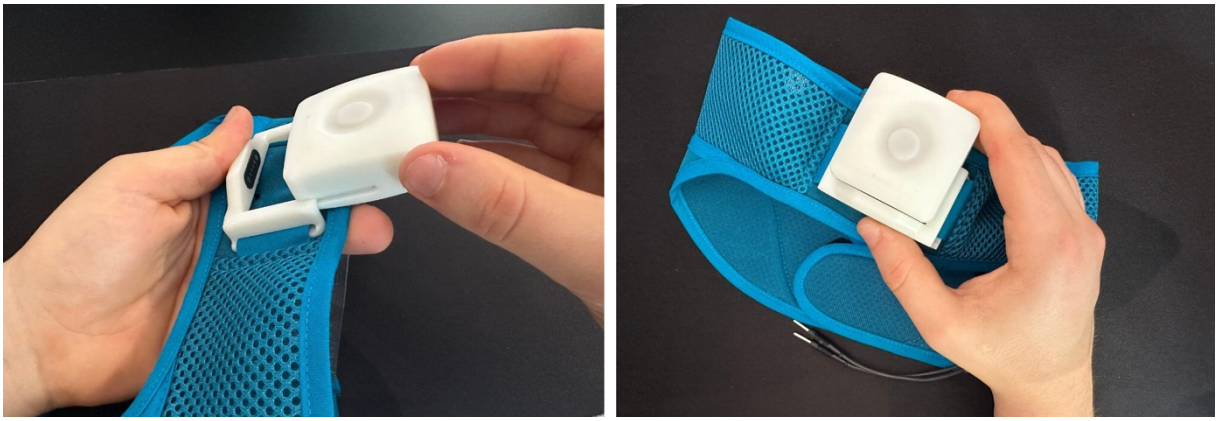


Fig. 14. The stimulator correctly placed in the headband.

## 6.3. Putting on the headband

Put on the headband with the stimulator (Fig. 15), adjust the fastening at the back of your head so that the headband does not slide or cause discomfort.

Ensure that the stimulator is securely attached to the headband and the electrodes are properly adhered to the skin.

Fig. 15. Placement of the Headband with the Stimulator on the Head

Connect the headband wires to the wires attached to the electrodes. The order or orientation of the wires does not matter (Fig 16).

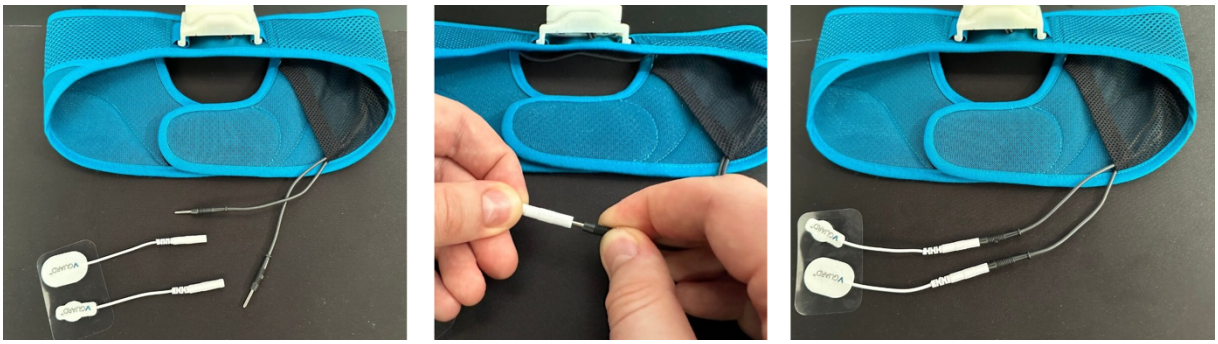


Fig. 16. Proper connection of the electrodes to the headband.

## 6.4. Starting the stimulation.

Press the START button on the base station to activate the stimulator (Fig. 17). After pressing the START button, the device will begin checking whether the electrodes have been properly connected, which will take at least 10 seconds. If this process takes longer, it may indicate poor electrode contact with the skin - in which case, you can improve the electrode contact by pressing them with your finger.

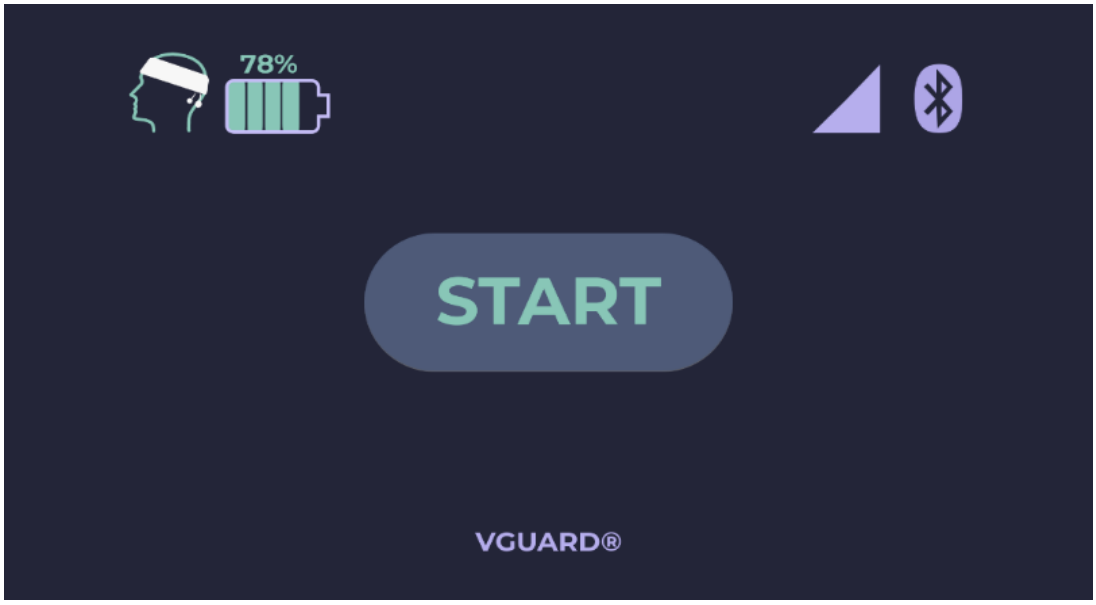



Fig. 17. Stimulator ready for activation

After pressing the START Stimulation button, the Resistance Check screen will appear on the display (Fig. 18).

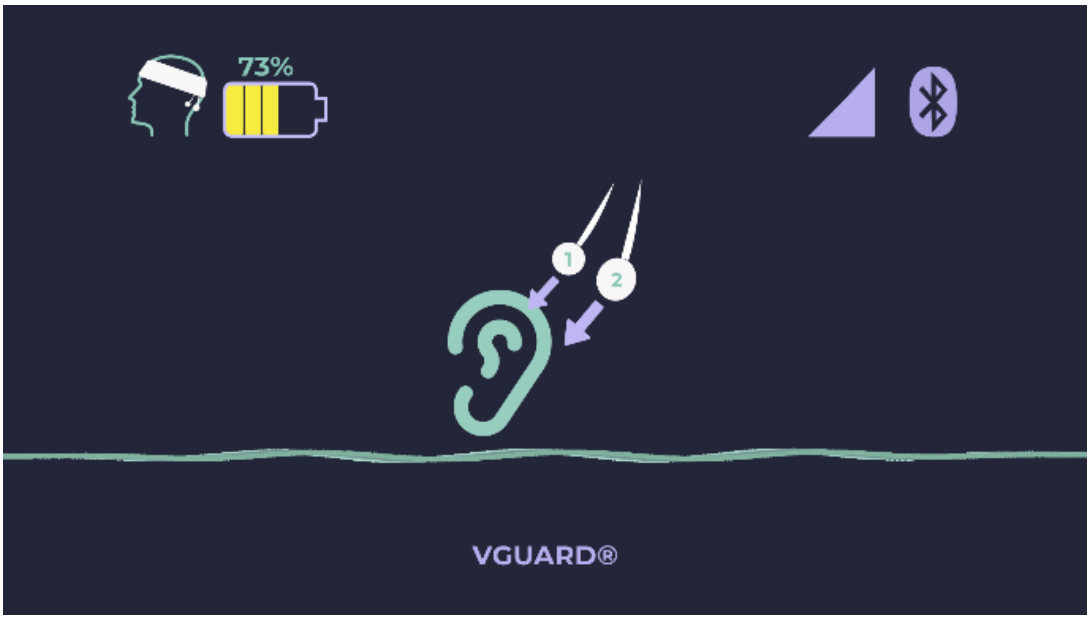



Fig. 18. Resistance Test Screen

The stimulator will wait for 2 minutes for at least 10 seconds stable resistance measurement with the correct value for. If it does not achieve this state within the first two minutes, it will stop the stimulation attempt and return to the initial screen, waiting for the START stimulation word to be pressed again.(Fig. 17).

When the animation of the wave appears on the screen, it means that the stimulator has started its operation correctly (Fig.19). From this moment, the device operates fully automatically and does not require user attention, and the display screen of the base station will turn off after 5 minutes of inactivity on the touch screen.
The device will shut down automatically after completing the stimulation cycle.

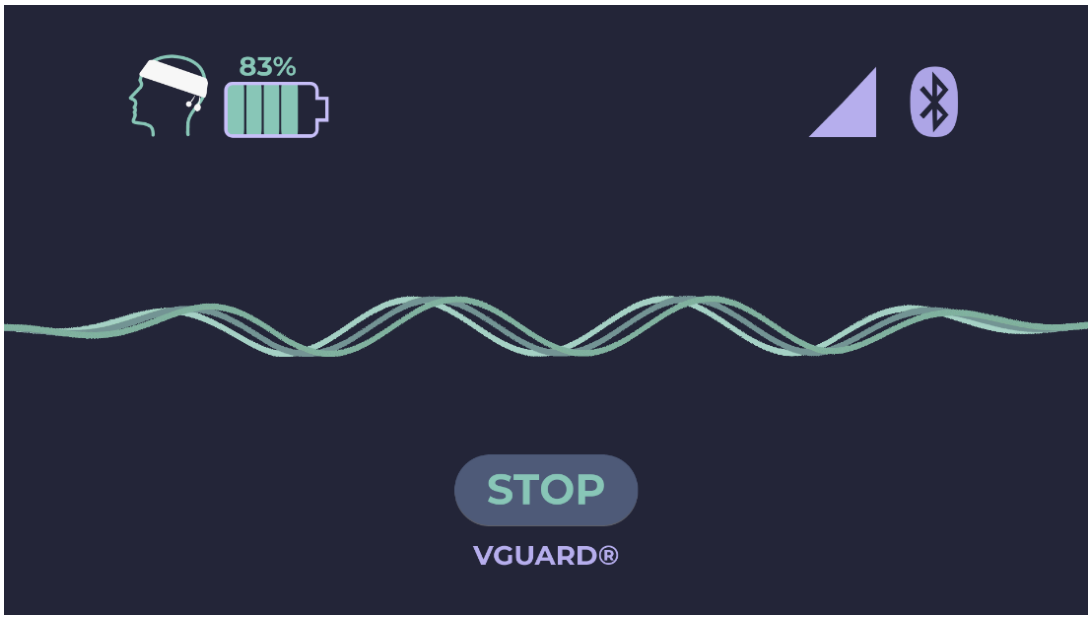



Fig.19. Stimulation in progress.

## 6.5. Ending stimulation process

If you want to stop the stimulator during stimulation, press the STOP button on the base station. This will halt the stimulator's operation.

Halting the stimulation with the STOP button means the current stimulation session will be permanently ended. You can resume the stimulation in the next session.

## 6.6. Removing the stimulator after stimulation

After the stimulation cycle is completed, carefully remove the device from the head. Follow these steps:

1. Disconnect the electrodes from the connecting wires in the headband with the stimulator.
2. Ensure that the stimulator is properly disconnected from the electrodes on the head.
3. Remove the headband along with the stimulator.
4. Check the battery level of the stimulator.
5. If the battery level is low (below 25% of full capacity), remove the stimulator from the headband and connect it to the charger according to the procedure described in section 6.3.

The manufacturer recommends charging the stimulator after each stimulation cycle.

Additional information:

The base station screen will automatically turn off after 5 minutes of inactivity.

To wake up the screen, you can touch the screen anywhere.

If a message appears indicating a low battery level in the stimulator, it is necessary to place the stimulator on the charging station. A low battery level (below 25%) prevents stimulation from starting.

The manufacturer recommends charging the stimulator after each stimulation cycle.

# 7. ERRORS DURING STIMULATION

## 7.1. Resistance Error

The stimulator continuously monitors the resistance between the electrodes during the stimulation session. In case of identifying resistance outside the correct range (too low resistance = electrode short circuit or too high resistance = partial or complete detachment of electrodes), the flow of stimulation current to the electrodes is suspended.

An error screen for resistance appears on the Base Station display (Figure 20).

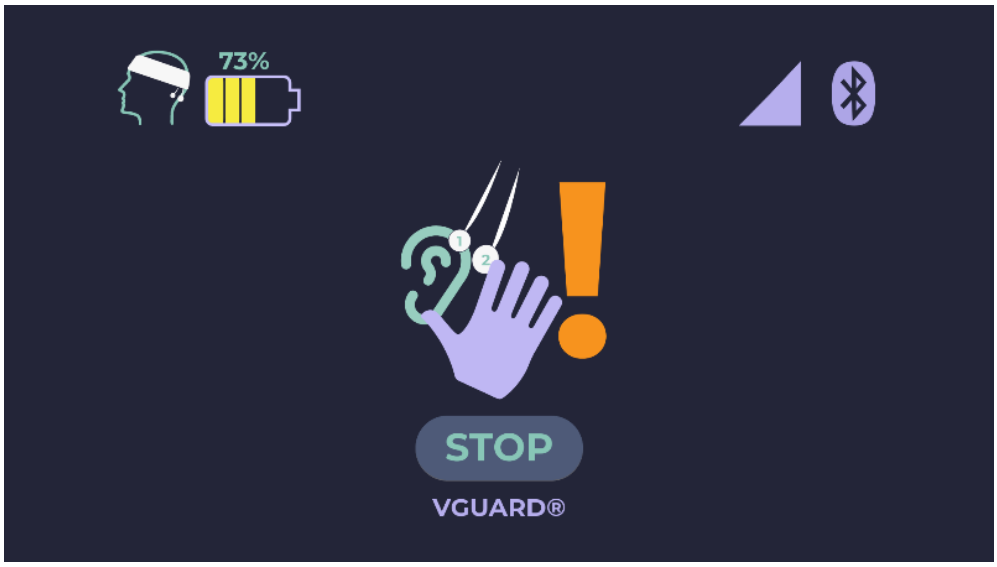



Fig.20 ERROR! Resistance between electrodes out of range.

The error notification is silent to avoid disturbing the patient. The flow of stimulation current is halted until the resistance value between the electrodes returns to normal.

Whether the user is awake, electrodes should be adjusted. Once the resistance returns to the correct range, the stimulator will resume the current flow to the electrodes, continuing the stimulation from the current point in its path until the end. The display will return to the correct Stimulation Screen (Figure 19).

If the session reaches its planned end time and the resistance has not improved, the current stimulation session will end, and the stimulator will stop working. The Stimulator Screen (Figure 19) will appear on the display, indicating the readiness of the stimulator to start a new session.

## 7.2. Low Battery Error.

The stimulator is equipped with an independent microprocessor-based battery charging controller. Regardless of the current operation state of the stimulator, the battery level is monitored. When the battery level drops to 10% of its capacity, the stimulator's operation will be interrupted, and the screen will display the "CRITICALLY LOW BATTERY LEVEL" screen (Fig. 21). Stimulation will be halted, and the current session will be terminated.

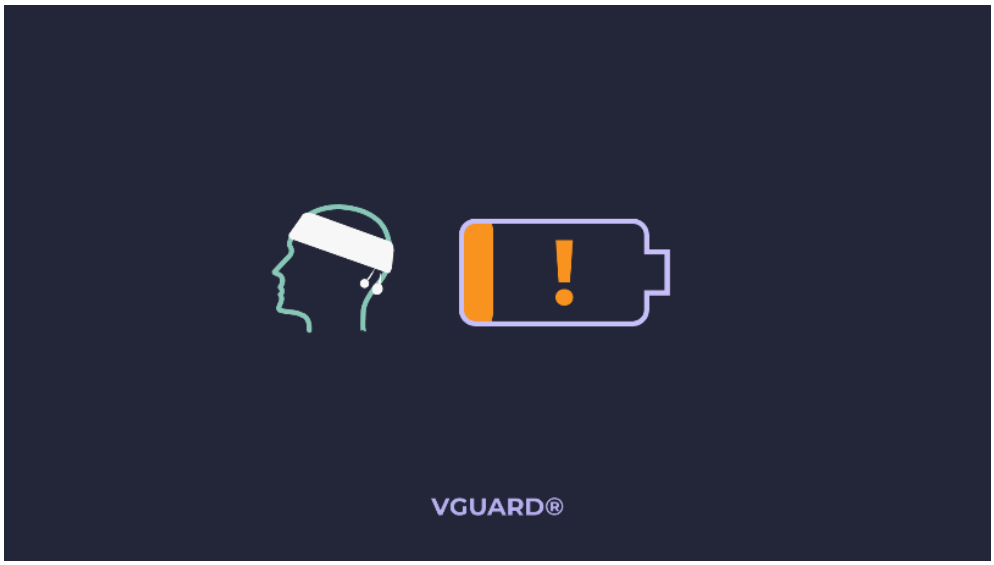



Fig. 21. ERROR! Critically low battery level.

Disconnect the stimulator from the headband as soon as possible and connect it to the wireless charger to recharge the battery.

Charging the battery to above 25% of its full capacity will enable the stimulator to be used in the next stimulation session.

## 7.3. Error of lack of communication between the stimulator and the Base Station

In case a message indicating a lack of Bluetooth range (Fig. 22) appears, it is necessary to place the stimulator near the base station or on the charging station and leave it in the charger for at least 15 minutes.


Fig. 22 ERROR! No Bluetooth connection with base station

# 8. ADDITIONAL ACCESSORIES OF THE VGUARD SYSTEM

The **VGuard transcutaneous vagus nerve stimulation system** consists of the **VGuard stimulator**, the VGuard Base Station and the VGuard Wireless Charger

with accessories:

- VGuard electrodes;
- VGuard headband (available sizes: S, M, L);
- VGuard web application

The system comes with a dedicated power supply for the Base Station.

# 9. CLEANING AND MAINTANCE

Maintenance and Storage

***VGuard Stimulator***

Maintaining the VGuard Stimulator during its use involves keeping the battery level adequate. The battery level of the stimulator is constantly displayed in the upper left corner of the Base Station screen when it is powered on and has Bluetooth connection with the Stimulator (icons in the upper right corner of the Base Station screen).

During regular use of the VGuard Stimulator (conducting regular night stimulations), ensure that the battery is charged to a minimum of 25% before starting a session.

***Charging the VGuard Stimulator Battery***

The Inductive Charger is used to charge the VGuard Stimulator battery. To charge the battery, follow the procedures described in Section 6.3.

If the device needs to be discontinued for an extended period, it is recommended to charge the Stimulator battery to a minimum of 60% electrical capacity (the charging indicator is on the left). This is to maintain a sufficient energy level in the battery throughout its storage period.

CLEANING

***VGuard Stimulator and Base Station***

The Stimulator and Base Station can be cleaned with a dry, soft cloth. Exercise caution when cleaning plastic components to avoid damaging the plug on the side of the stimulator.

For the headband, hand washing in water up to 35 degrees Celsius without cleaning agents is recommended. Do not use the headband until it is completely dry.

If the headband wires are damaged, further use of the headband is impossible, and it should be replaced.

Both the headband and electrodes can be disposed of in mixed waste.

# 10. TECHNICAL SUPPORT

## 10.1. Contact information

**Neuromedical Sp. z o.o.**
ul. Natolin 15,
92-701 Natolin, Polska
office@neuromedical.pl

## 10.2. Reporting serious medical incidents

Each serious incident related to the VGuard System must be reported promptly to the manufacturer at office@neuromedical.pl and to the competent authority of the Member State where the user or patient resides.

**A serious incident** means an incident that directly or indirectly led to, could have led to, or may lead to any of the following events:

a) the death of a patient, user, or other person;
b) temporary or permanent serious deterioration in the health of a patient, user, or other person;
c) a serious threat to public health.

**An incident** means any malfunction or deterioration in the properties or performance, including user error resulting from ergonomic features, of a product available on the market, as well as any deficiencies in the information provided by the manufacturer and any adverse events.

# 11. WARRANTY TERMS

Please read all instructions before using the device. Please keep the receipt or invoice as proof of purchase and purchase date. The receipt or invoice must be presented when making any warranty claims during the warranty period. Any warranty claim without proof of purchase is invalid. Your device is covered by a two-year (2-year) warranty from the date of purchase.

This warranty covers material or manufacturing defects that occur during normal use; defective devices meeting these criteria will be replaced free of charge.

The warranty does NOT cover defects or damage resulting from misuse or failure to follow user instructions. The warranty becomes void if the device is opened, tampered with, used with parts or accessories from brands other than Neuromedical Sp. z o.o., or if repairs are carried out by unauthorized persons.

Accessories and consumables are excluded from any warranty. These items include:

- Electrodes (except for missing from the packaging or if damaged)
- Headband (except for missing from the packaging or if damaged)

For support inquiries, please contact us by email or find contact information below in the instructions. This warranty applies only in Europe.

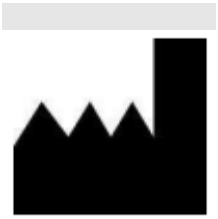
**Neuromedical Sp. z o.o.**
ul. Natolin 15,
92-701 Natolin, Polska
office@neuromedical.pl

## Description of used symbols

| | | | |
|---|---|---|---|
|  | VGuard system manufacturer |  | Medical Device |
|  | Date of manufacture of the device |  | Unique device identification code |
|  | European compatibility |  | Please refer to the instructions for use |
|  | Warning |  | Read instruction |

## Contact with manufacture

VGuard - Transcutaneous vagus nerve stimulation system



**Neuromedical Sp. z o.o.**
ul. Natolin 15,
92-701 Natolin, Polska
email: **office@neuromedical.pl**
neuromedical.pl

The user manual pertains to the VGuard System. It contains detailed information regarding operation, safety, precautions, indications, and contraindications necessary for the use of the product by the Patient.

VERSION OF THE USER MANUAL INTENDED FOR THE EUROPEAN UNION MARKET - COUNTRY: POLAND