

vagu©tim | Health Technologies

User Manual

Please ensure that you have read this user manual, before
using your Vagustim

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1. INTRODUCTION

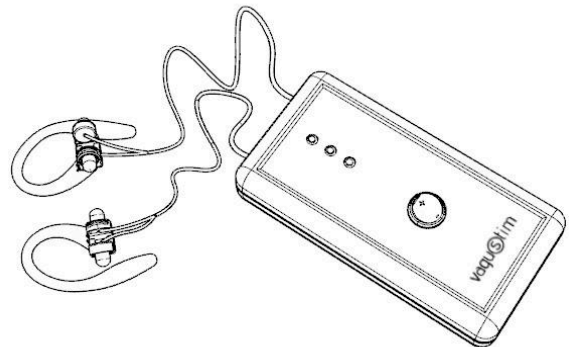
1.1. Product Description

Vagustim is a portable vagus nerve stimulator device that pairs (via Bluetooth®) and operates with mobile devices running on iOS and Android. Vagustim stimulates the auricular branch of the vagus nerve non-invasively and bilaterally. It consists of a stimulator and ear electrodes in size of Small, Medium, and Large. The stimulator generates electrical impulses. The ear electrode transfers the stimulation to the vagus nerve in both ears through the skin. Stimulation parameters are adjustable through the mobile application interface. The Mobile App can be downloaded from Apple's App Store and Google Play Store. The device is powered by a minimum of 2 pieces minimum 1500 mAh AA batteries.

1.2. What's in the Box

Your Vagustim box contains:

- Vagustim Stimulator
- Vagustim Ear electrodes (S, M, L sizes)
- Vagustim Conductive Gel/Paste
- Quick Start Guide
- User Manual



⚠ Caution: Please check to ensure that there is no visible damage on any of the components of the Vagustim. If the damage is present, do not use or attempt to repair the device, please contact the manufacturer directly.

1.3. Intended Use

The Vagustim is intended to be used as a non-invasive auricular vagus nerve stimulation.

1.4. Restrictions on Use and Contraindications

Vagustim is a multi-user device. The device can log the information and stimulation results that belong to each specific user.

Note :

- Ear electrodes must be cleaned before each usage.

Relative Contraindications for Vagustim

- Pregnant women should not use the device without a doctor's approval.
- Persons with active implants (e.g. implanted stimulators, or pacemakers) should not use the device without a doctor's approval.
- The electrodes should not be applied to sore or diseased skin.
- The device should not be used;
 - under the effects of sedative agents like alcohol or drugs
 - presence of wounds or infections in the ear
 - before bedtime in users with sleep apnea. Please ask your doctor when to stop using the device during the day.
 - if you have an ear implant,
 - if you have hypotension, bradycardia, hypoglycemia, without a doctor's approval
 - if you have hypotonic diseases, without a doctor's approval
 - if you have an implanted electronic device such as a pacemaker,
- Care should be taken in cases with high parasympathetic activity such as hypersomnia, vasovagal syncope, and allergies.
- Care should be taken in cases with low sympathetic activity
- Caution should be exercised when used with drugs or therapies that affect the autonomic nervous system.
- Situations where the increased cerebral activity is undesirable

Possible Side Effects

Common

- an itchy or burning sensation in the ear
- pressure marks in the ear
- redness in the ear (size of ear electrodes must be checked)
- feeling dizzy
- pain in the ear (size of ear electrodes and intensity of the current must be checked)

Rare

- tachycardia
- feeling distressed
- headache
- nausea

Very rare

- syncope

Side effects will generally subside soon after stimulation is stopped.

If you experience any long-lasting or severe side effects, please stop using and consult your doctor immediately.

Since the device may cause sedation and relaxation, care should be taken to use the device in situations that require attention.

2. SAFETY, WARNINGS, AND PRECAUTIONS

Important! Please adhere to the recommendations, warnings, and guidelines set out in this user manual as failure to comply may result in measurement errors, display of incorrect results, or harm to the user.

Warning! Use the device only for its intended purpose and as described in the instructions.

- The manufacturer is not responsible for any damage or harm to the device or user which has resulted from the user's failure to follow the warnings and guidelines given in this manual or other instructional materials provided with the device. Please note that a special WARNING should be given by handlers of the device to elderly, pediatric, or differently-abled users before the use of the device.
- Don't let your device drop, handle it improperly, or expose it to extreme temperatures or high humidity (use only at temperatures between 0 – 40°C, and at a relative humidity of less than 93 %).
- Use the ear electrodes only on intact skin.
- Keep water and other fluids away from the device.
- Do not drive or operate machinery while using the device. Do not engage in activities requiring your full attention.
- Avoid any active participation in road traffic while using the device.
- For health reasons, always clean your ear and the ear electrode before use.
- After use, please store the device in a designated storage box to protect it from damage or contamination.
- Please observe the information and instructions given by the manufacturer of the products you use for cleaning the ear and the ear electrode.
- Use the device only for its intended purpose and as described in the instructions.
- Contact your doctor, if a part of the electrode has gotten into the ear canal. Try not to remove it.

- Do not open or modify the device because of the danger of electric shock.
- Before using the device make sure that it is in proper condition. Never bring the ear electrode near your mouth or eyes.
- If you cannot stop stimulation using the stop function, unplug the ear electrode and contact customer support.
- If the device is exposed to intense heat or fire, the battery may explode or leak.
- Do not use the device outside the specified temperature range.
- Keep the device away from open fire, heaters, and other sources of heat.
- Do not use the device if it is getting unusually warm, as this indicates that the device is faulty.
- Regardless of the data presented on the Vagustim, if the user feels unwell, they should cease the use of the device.
- If any damage is present on the device or its components upon removal from packaging, do not use the device and return it to the supplier.
- Do not use Vagustim for any other purpose than its intended use. Vagustim is not recommended for children under the age of 5.
- Do not expose the device to liquids, prevent any liquids from entering the device. In the event of a liquid spill on or around Vagustim, immediately remove the battery and let the device dry thoroughly before use.
- The instrument may give inaccurate readings if operated in the presence of strong electromagnetic sources, such as electrosurgical equipment, or the presence of computed tomography (CT) equipment.
- To prevent damage to the Vagustim due to battery leakage or oxidation, remove the battery if the Vagustim device is not to be used or is to be stored for a long period.
- Dispose of the device and battery responsibly as required by local legislation.

- If a new user is to use the device, ensure that the device is cleaned (see Maintenance section of this manual) between each user. Also, ensure that you select the new user (or add a new user if that user does not already have an account) on the Vagustim App before performing a session with the device.
- The Vagustim must only be used with the original accessories specified and provided by the manufacturer. Use of other accessories that are not recommended by the manufacturer may cause inaccurate test readings, or damage/harm to the user and/or device.
- The user should be advised to report any adverse events immediately to the doctor. The user should also report such incidents to the manufacturer.
- Store and use the device as specified in this user manual as alternative methods or conditions of storage may affect device function and/or accuracy. Use only in specific environments/conditions (see Operating Environment) to avoid malfunction and/or display of incorrect results.
- All repairs, modifications, or reconfigurations must be performed only by the manufacturer. If the Vagustim is damaged or malfunctioning, contact the manufacturer or distributor if purchased from a reseller, directly to avoid incorrect measurements or potential harm. Do not attempt to repair the device yourself, an opened device casing will terminate the product warranty.
- Please follow all data security warnings and recommendations for the smart device used in conjunction with the Vagustim as per its manufacturer's instructions as the users' data recorded and stored on the Vagustim App, may otherwise be at risk. The user is encouraged to not share Vagustim App account information with unauthorized parties.

3. OPERATION

3.1. Operating Environment

The operating conditions for the Vagustim are specified as:

Temperature: +0°C to +40°C

Relative Humidity: 10% to 85%

The storage conditions for the Vagustim are specified as:

Temperature: -20°C to +60°C

Relative Humidity: 0% to 85%

Pressure: 500 hPa to 1060 hPa

The Vagustim should not be used in the presence of flammable liquids or detergents, nor the presence of inflammable anesthetic gases (oxygen or nitrogen). The device should not be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand, or any other chemical substances.

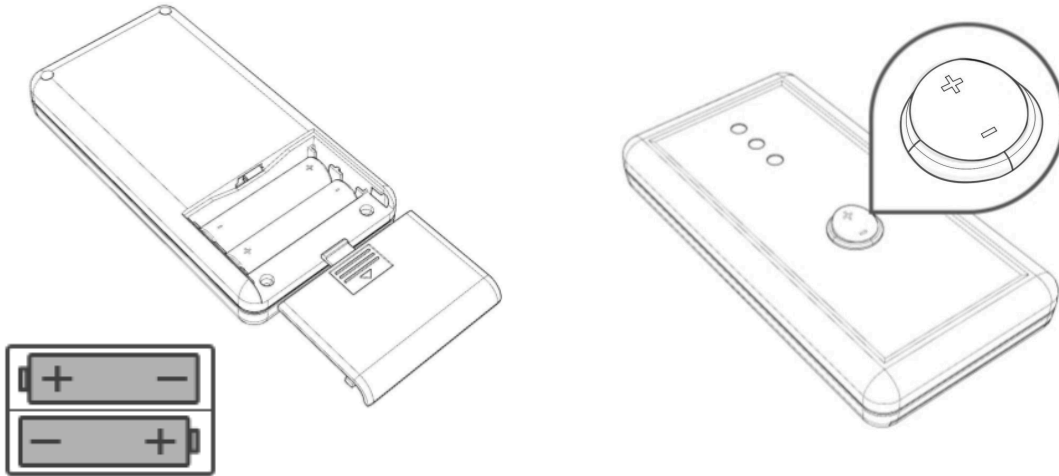
3.2. Setting Up Your Device

1. Download the Vagustim mobile application from the App Store, or Google Play Store, onto a smart device.

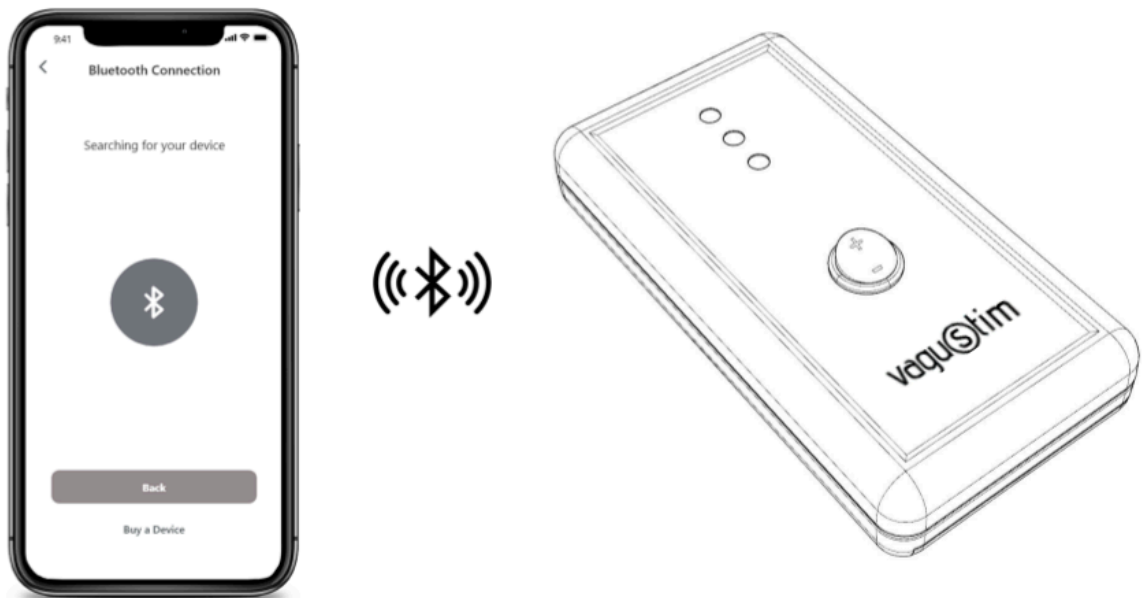


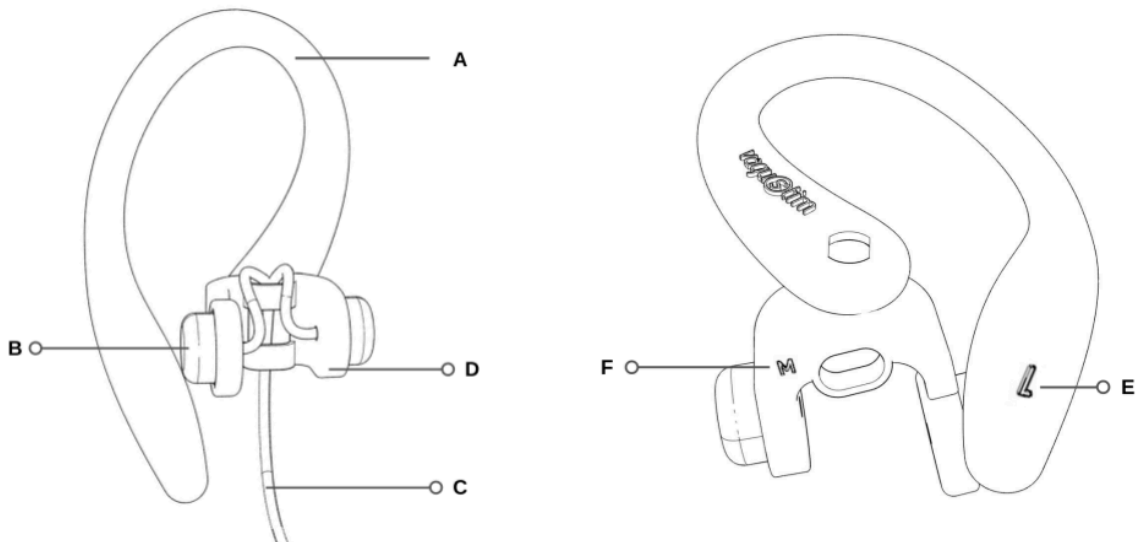
2. Follow the steps given in the app to create an account for a new user or log into an existing account.

3. Place the battery in the correct orientation and press the power button to switch the device on as shown.



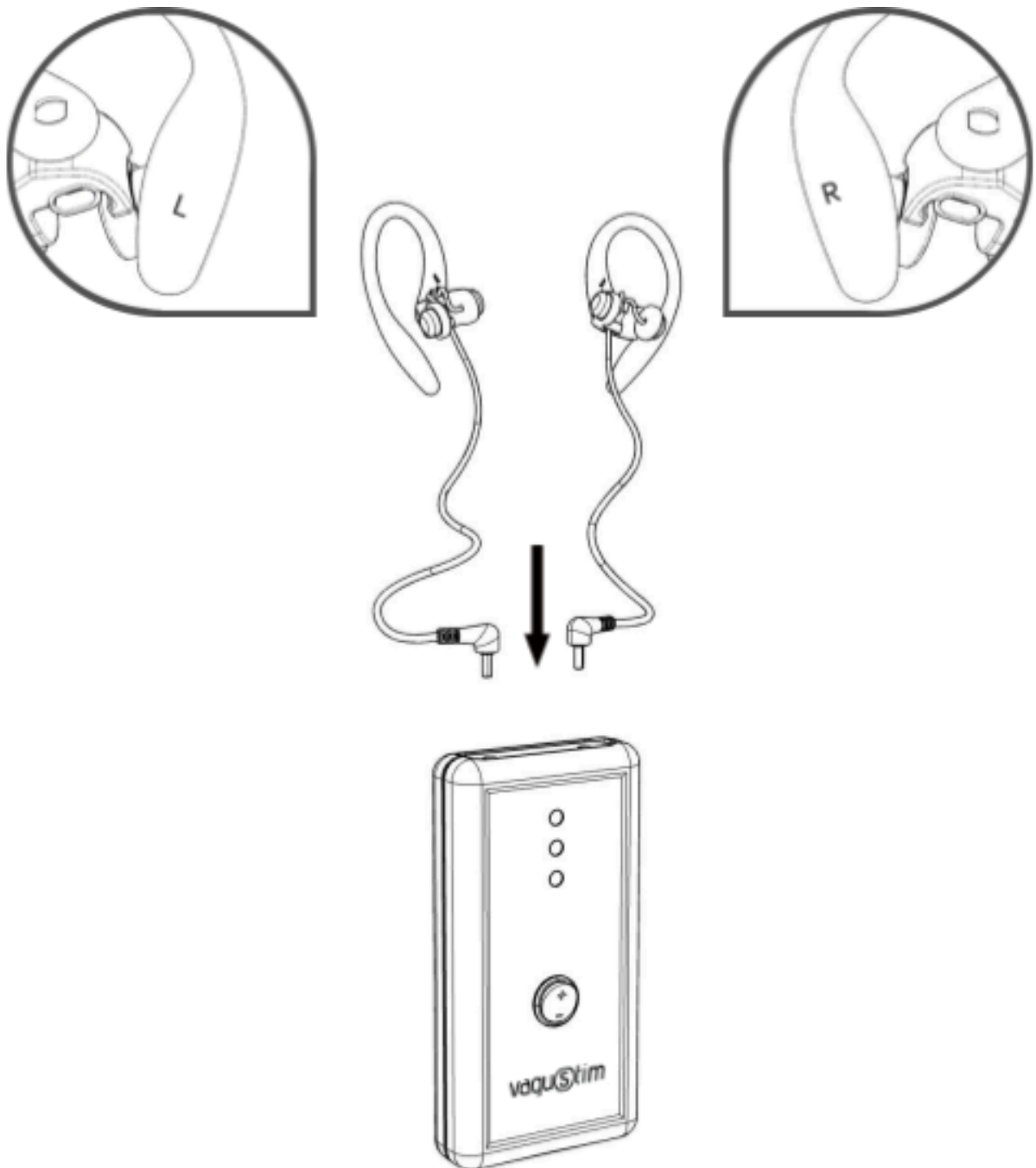
4. Pair the Vagustim mobile App and the Stimulator via Bluetooth to start the stimulation session.





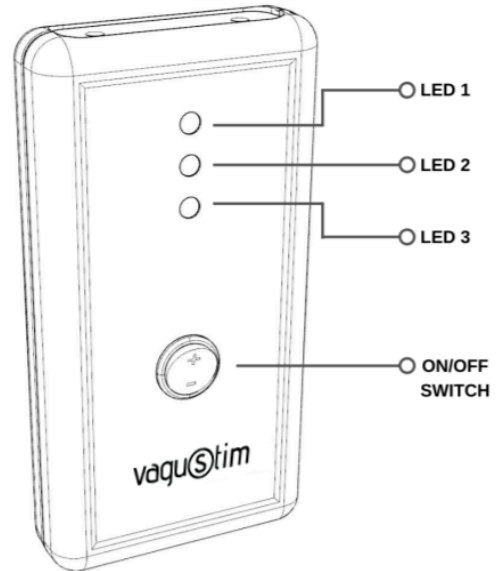
A. Hanger	The hanger holds the position of the ear electrodes stable.
B. Electrodes	The electrodes transfer electric impulses from the stimulator to the surface of the skin. If necessary, turn the electrodes sideways and to the rear.
C. Cable	The cable conducts the electric impulse from the stimulator to the ear electrode.
D. Plastic Part	This part ensures that the electrode is in full contact with your ear comfortably.
E. Side Sign	You can see the side (<i>Left or Right</i>) of the ear electrodes.
F. Size Sign	You can see the sizes (<i>Small, Medium, and Large</i>) of the ear electrodes

5. Connect the ear electrodes to the Stimulator. Make sure that the left and right ear electrodes are positioned correctly as shown in the image.



3.3. Device Indicators

There are 3 LEDs located in front of the device. These LEDs may be turned on or blinking in various colors and/or in various patterns. They indicate the current status of the device. Please see the following information for guidance on LED light indications.



LED Indication	Action/s
All LEDs are off.	The device is switched off.
LED number 1 is a constant white.	The device is switched on.
LED number 2 is flashing.	The device is searching for a Bluetooth® connection.
LED number 2 is constant blue.	Bluetooth® connection has been established.
LED number 3 is a constant green.	Stimulation has been started and in stimulation on period.
LED Number 3 is off.	The device is in off duration or stimulation has not been started yet.



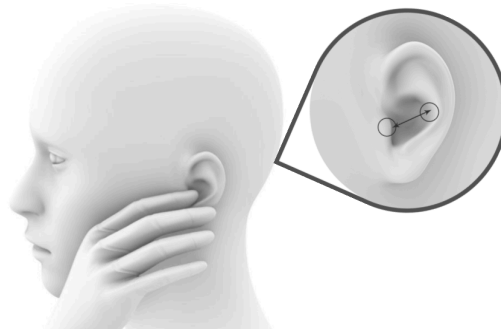
	Device State	LED1	LED2	LED3
1	Device OFF	OFF	OFF	OFF
2	Device ON	White	OFF	OFF
3	Bluetooth Search	White	Blue (Blinking)	OFF
4	Bluetooth Connected	White	Blue	OFF
5	Stimulation ON Period	White	Blue	Green
6	Stimulation OFF Period	White	Blue	OFF

3.4. Inserting the Ear Electrodes

1. Pour the conductive gel/paste on your finger.

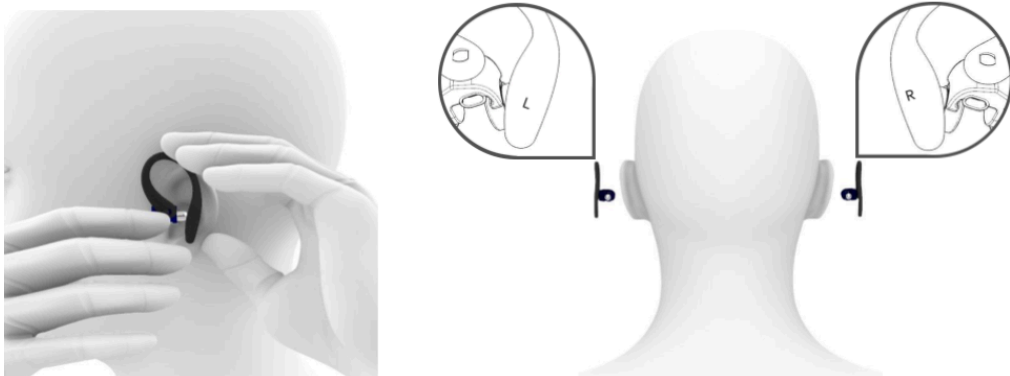


2. Apply the conductive gel/paste to both ears.

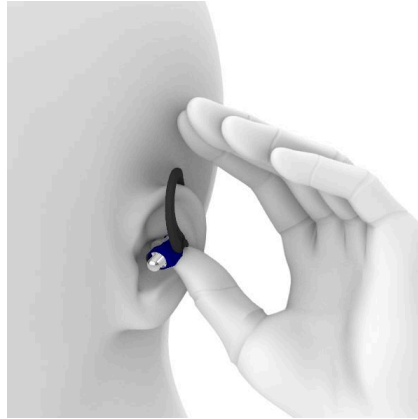


3. Place the Vagustim's ear electrodes in your ear.

- Make sure that the left and right electrodes are placed correctly.

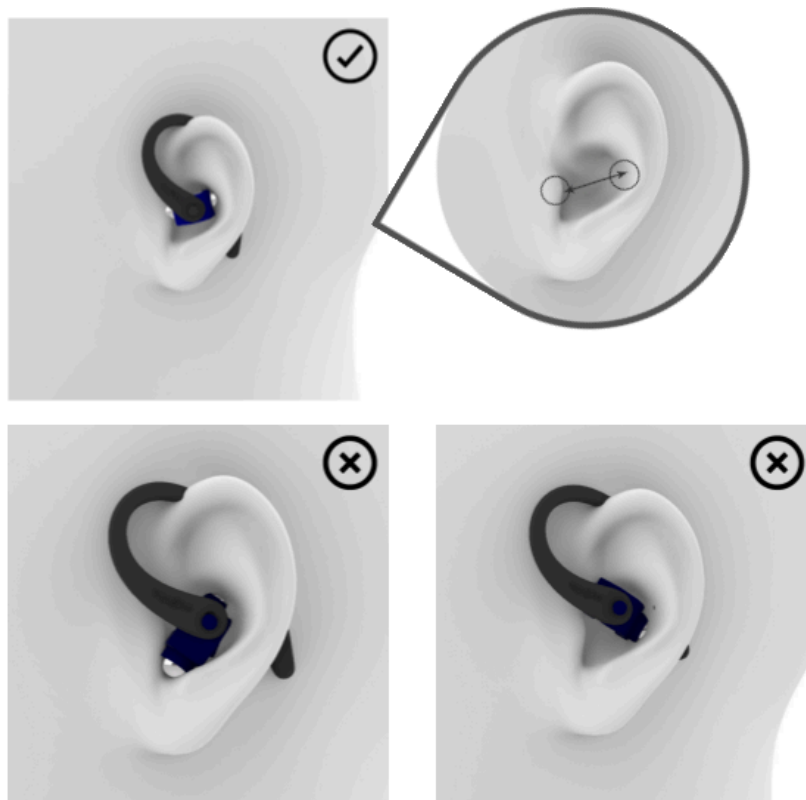


4. Adjust the position of the ear electrodes.



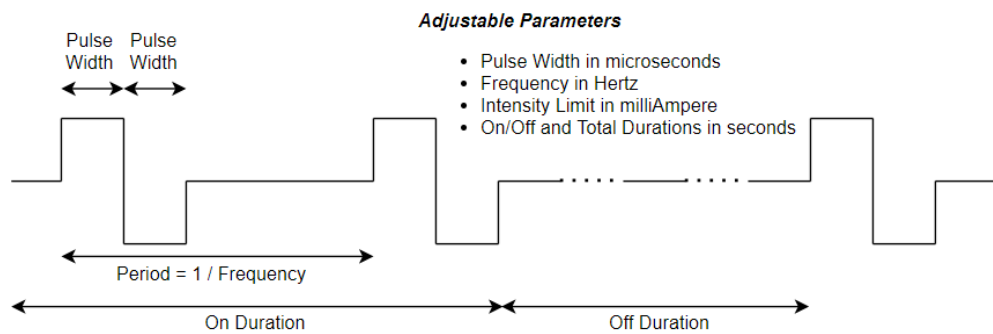
5. Make sure your ear electrodes are in contact with the indicated areas of the ear (Concha and Tragus).

- Check that BOTH electrodes are in contact with the skin and are well-positioned.
- Please note: Positioning can be difficult, depending on the size and shape of your ear.



4. STIMULATION PARAMETERS

4.1 Parameters of Waveform Generation



4.2 Setting Optimum Stimulation Intensity

1. **Start stimulation.**
2. Increase the intensity of the stimulation slowly, in steps of 0.1 mA, until you feel a prickling or tingling sensation. **The stimulation should be noticeable but not painful.**




As your sensitivity may vary daily or even during use, adjust the stimulation intensity as necessary for each session or even during the session.

4.3 Benefits and Outcomes of the VNS Stimulation

Continual and frequent daily usage of VNS is crucial to experiencing its potential benefits. Research indicates that individuals typically begin to notice improvements after 1 to 6 months of regular use.

5. SIGNS AND SYMBOLS

Please note the following labels, signs, and symbols provided for the safe use and storage of the Vagustim.

Markings	Descriptions
	<p>“Manufacturer” This symbol is accompanied by the name and the address of the manufacturer adjacent to the symbol</p>
	<p>The instruction manual/booklet must be read</p>
	<p>Disposal in Compliance with WEEE</p>

6. TECHNICAL FEATURES

Power Supply	2xAA Batteries
Dimensions	134 x 70 x 25 mm
Wireless connection	BLE 4.2
Pulse Width Interval	1 - 1000 microseconds
Frequency Interval	1 - 500 Hertz
On/Off Duration Interval	0 - 60 seconds

Total Stimulation Duration Interval	0 - 6 hours
Intensity Limit Interval	0.1 - 10 milliampere
Number of Outputs	2 - Right & Left
Type of Waveform	Biphasic Waveform

7. MAINTENANCE

Handle the Vagustim Stimulator and Vagustim Ear Electrodes with care. Do not use the device or its accessories if they are visibly damaged.

Store the Vagustim in dust-, dirt-, and moisture-free conditions. The pouch provided with the device may be used to keep the device protected. Before each use, always check that the device is free from contaminants and does not have any visible damage. After use by each new user, clean and disinfect the device according to the instructions given in this section.

Proper cleaning and disinfection of your Vagustim are important for the safe use of the device.

With regular cleaning, the physical build-up of contaminants on the device can be prevented. A cleaning process must always precede a disinfection process. Disinfection destroys any pathogens such as bacteria, viruses, or other microorganisms that might still be present on device surfaces after an initial cleaning process. Regular, thorough cleaning and disinfection of the device protect both handlers and users of the device from the potential transmission of infections resulting from contact with the device. Handlers and users of the device should be sure to wash hands with soap before and after each use of the device.

7.1. Cleaning

Important!: The Vagustim Ear Electrodes must be cleaned before each use.

1. Wash Hands

Before beginning the cleaning procedure, wash your hands thoroughly with soap and water.

2. Cleaning the Ears and Ear Electrodes

Warning! It is essential to clean the ear and the ear electrode before use.

- a. Using a standard alcohol swab with 70% isopropyl alcohol (available in any pharmacy), clean the ears where the electrode comes into contact with the skin.
- b. Use another standard alcohol swab to clean the ear electrode. Wipe all accessible surfaces of the electrodes, using moderate pressure.

3. Wash Hands

Wash hands thoroughly after performing a cleaning and disinfection procedure, and before handling the cleaned and disinfected components again for packing and storage.

7.2. Vagustim Ear Electrodes

Vagustim may be used by multiple users, however, the cleaning and disinfection procedure described for the device must be performed between each new user.

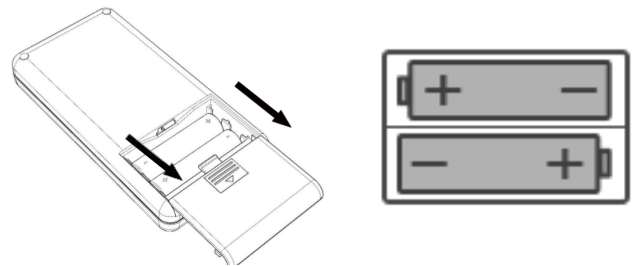
To purchase a new electrode, you can contact your local distributors, if there is no local distributor or you can not reach them, you can reach Vagustim at <https://www.vagustim.io>

7.3. Battery

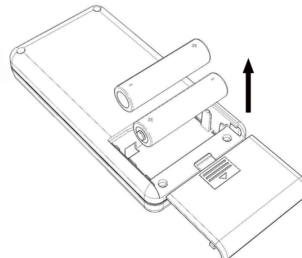
The Vagustim device is suitable to work with 2 pieces of AA batteries a minimum of 1500 mAh. The battery charge level is continuously monitored by the device. When the device's battery charge level is low, the device will not turn on. The battery of the device should be removed if the device is not going to be used for more than a week.

Instructions for battery replacement

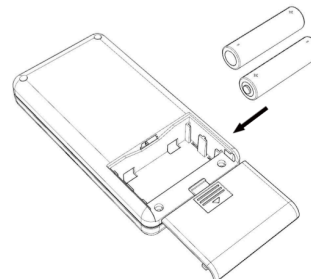
1. Remove the battery cover



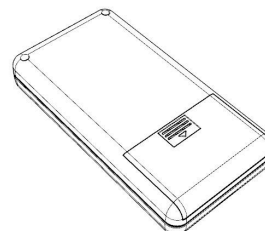
2. Remove the empty battery.



3. Place the new battery in the correct orientation.



4. Close the battery cover.



7.4 Vagustim Gel/Paste

Vagustim Gel/Paste is designed to enhance conductivity on the ear's skin, ensuring even stimulation during Vagus Nerve Stimulation (VNS) sessions. This gel/paste is a standard, water-based ultrasound gel/paste, tailored for optimal performance with your device.

Ensure to apply the Vagustim Gel/Paste to the stimulation area. Proper application is crucial for effective stimulation. Should you run out of Vagustim Gel/Paste, please contact Vagustim to place an order for more. Keeping a sufficient supply on hand will ensure uninterrupted therapy sessions.

7.5 Disposal of Vagustim

This product is not to be discarded as regular household waste but should be discarded as electronic waste in accordance with local regulations and returned to a collection point of recycling for electric and electronic devices.

The used battery should be disposed of in designated battery recycling containers in accordance with local laws and regulations.

8. TROUBLESHOOTING

Problem	Cause	Solution
The device is not turning on	Multiple possible causes	Check battery orientation and correct polarities
		Remove the batteries, wait 30 seconds, and reinstall it
		2 pieces of AA batteries a minimum of 1500 mAh
		Check that the battery cap is in the lock position, or if it is broken, contact the manufacturer
Vagustim can not connect to a smart device via Bluetooth	The smart device is out of range	Bring your smart device closer to the Vagustim device and restart it
	Bluetooth and location services are disabled	Enable Bluetooth and the location of your smart device
	Bluetooth connection not working properly	Your smart device will need Bluetooth version 4.0 or higher. Find and select your Vagustim device from the list of scanned devices.

Device is disconnected during test	The device is turned off accidentally or due to rough handling during use	Switch the device on again and proceed with a new test
	BLE connection dropped	Reconnect the device and proceed with a new test
Device is not responding to switch	Device error	Remove the battery, wait 30 seconds, and reinstall it
Stimulation does not cause any feelings in the ears	Loose contact, wrong intensity setting, or cable error	Remove ear clips from your ear and put gel/paste on your thumb and index fingers, hold metal electrodes with those two fingers, and increase the intensity limit on the mobile application until feelings occur.

For any other technical queries please e-mail info@vagustim.io

9. ORDERABLE ACCESSORIES

1. Vagustim Stimulator
2. Vagustim Ear Electrodes
3. Vagustim Gel / Paste

To purchase these accessories, you can contact your local distributors, if there is no local distributor or you can not reach them, you can reach Vagustim at www.vagustim.io

10. TERMS OF WARRANTY

Vagustim, together with any accessories provided, is guaranteed for 24 months, effective from the date of purchase, upon the provision of an invoice or sales receipt.

The user is responsible for checking the product for damaged or missing components at the time of purchase or delivery, and claims must be made in writing to the manufacturer.

The customer must return goods for replacement or repair at the customer's expense to the authorized supplier or manufacturer.

Please provide the returned product with a clear written explanation of the fault or problem. This warranty does not apply, at the discretion of the manufacturer, in the following cases:

- Improper installation or operation of the device
- Use of the product for purposes other than those specified in this user manual
- Damage due to failure to follow instructions
- Damage due to unauthorized repair, modification, or reconfiguration performed on the device
- Damage caused by fall, hit, lack of proper care or maintenance

- Damage caused by abnormal physical or electrical stress or defects of the main electric supply (battery cell) or equipment

11. MANUFACTURER INFORMATION

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