

vagu©tim | Health Technologies

# User Manual

Welcome to Vagustim

Before using your Vagustim stimulator, ear electrodes, and mobile application, please ensure that you have read this user manual, labels, and information on the product.

## CONTENTS

<b>1. INTRODUCTION</b>	<b>3</b>
1.1. PRODUCT DESCRIPTION	3
1.2. WHAT'S IN THE BOX	3
1.3. INTENDED USE	3
1.4. RESTRICTIONS ON USE AND CONTRAINDICATION	3
<b>2. SAFETY, WARNINGS, AND PRECAUTIONS</b>	<b>5</b>
<b>3. OPERATION</b>	<b>7</b>
3.1. OPERATING ENVIRONMENT	7
3.2. SETTING UP YOUR DEVICE	7
3.3. DEVICE INDICATORS	11
3.4. INSERTING THE EAR ELECTRODES	13
<b>4. ADJUSTABLE STIMULATION PARAMETERS</b>	<b>15</b>
4.1 PARAMETERS OF WAVEFORM GENERATION	15
4.2 SETTING OPTIMUM STIMULATION INTENSITY	15
<b>5. SIGNS AND SYMBOLS</b>	<b>15</b>
<b>6. TECHNICAL FEATURES</b>	<b>16</b>
<b>7. MAINTENANCE</b>	<b>16</b>
7.1. CLEANING	17
7.2. VAGUSTIM EAR ELECTRODES	17
7.3. BATTERY	18
7.4. DISPOSAL OF VAGUSTIM	19
<b>8. TROUBLESHOOTING</b>	<b>19</b>
<b>9. ORDERABLE ACCESSORIES</b>	<b>20</b>
<b>10. TERMS OF WARRANTY</b>	<b>20</b>
<b>11. MANUFACTURER INFORMATION</b>	<b>21</b>

## 1. INTRODUCTION

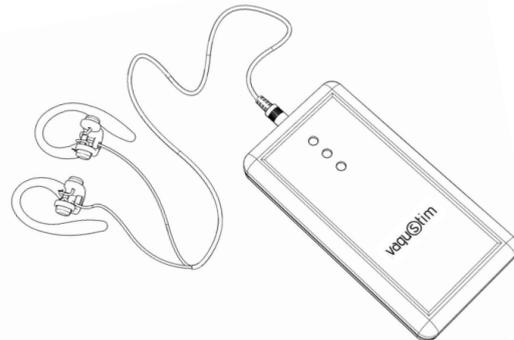
### 1.1. PRODUCT DESCRIPTION

Vagustim is a portable vagus nerve stimulator device that pairs (via Bluetooth®) and operates with mobile devices whose mobile application is running on both iOS and Android. Vagustim stimulates the auricular branch of the vagus nerve non-invasively and bilaterally. The system consists of three units, the stimulator, ear electrodes, and mobile application running on Android and iOS devices. The stimulator generates stimuli in the form of electrical voltage or current pulses. The stimuli is transferred to each ear electrode via separate cables. The ear electrodes apply the stimuli generated by the stimulator to the vagus nerve in both ears non-invasively through electrical contact, transcutaneously. The app can be downloaded on the Apple App Store and Google Play Store. The device is powered by 2xAA batteries.

### 1.2. WHAT'S IN THE BOX

Your Vagustim device box contains:

- Vagustim stimulator
- Vagustim ear electrodes



**⚠ 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 stimulator is intended to be used as a non-invasive auricular vagus nerve stimulation. See the “4. Adjustable Stimulation Parameters” section for more information about stimulation parameters.

### 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. For each new user, a new user account must be created on the Vagustim app, so that each user's personal information and test results can be stored and logged, separately.

### Relative Contraindications for Vagustim

- Pregnant women should not use the device.
- Persons with active implants (e.g. cochlear implants, vagus nerve stimulators, or pacemakers) should not use the device.
- 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,
  - if you have hypotonic diseases,
  - if you have implanted electronic devices such as pacemakers,
- 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 has stopped.

If you experience any long-lasting or severe side effects, please stop the treatment 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.

**Please ask the user if they have or suspect having any of the conditions above before the use of the Vagustim.**

---

## 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 %).
- Do not wear the device on unprotected skins; this may cause skin irritation.
- 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 are not able to stop treatment by 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 of time.
- Dispose of the device and/or device 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

Vagustim is designed for use in a clinical setting, by more than one user.

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 stimulator should not be used in the presence of flammable liquids or detergents, nor in 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.

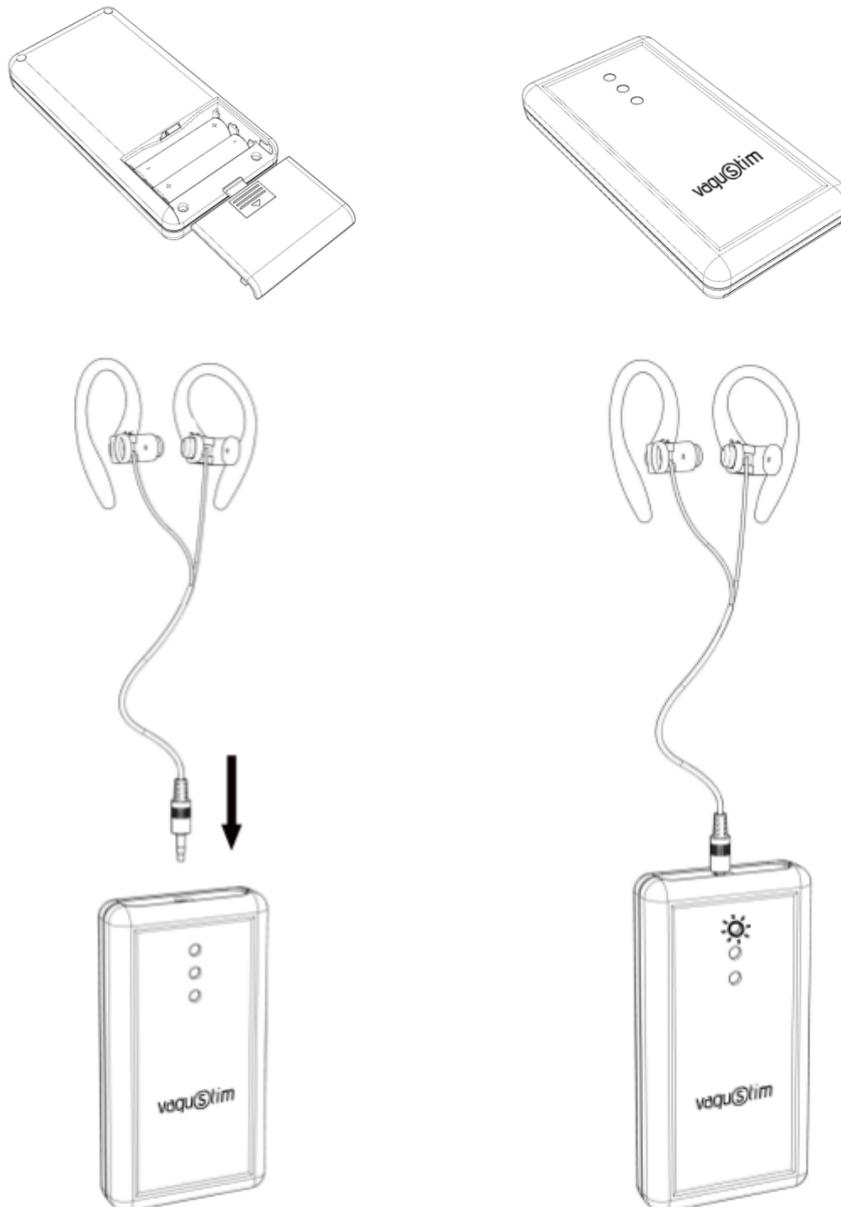
#### 3.2. SETTING UP YOUR DEVICE

1. Download the Vagustim app from the Apple App Store or Google Play Store onto a smart device.
-

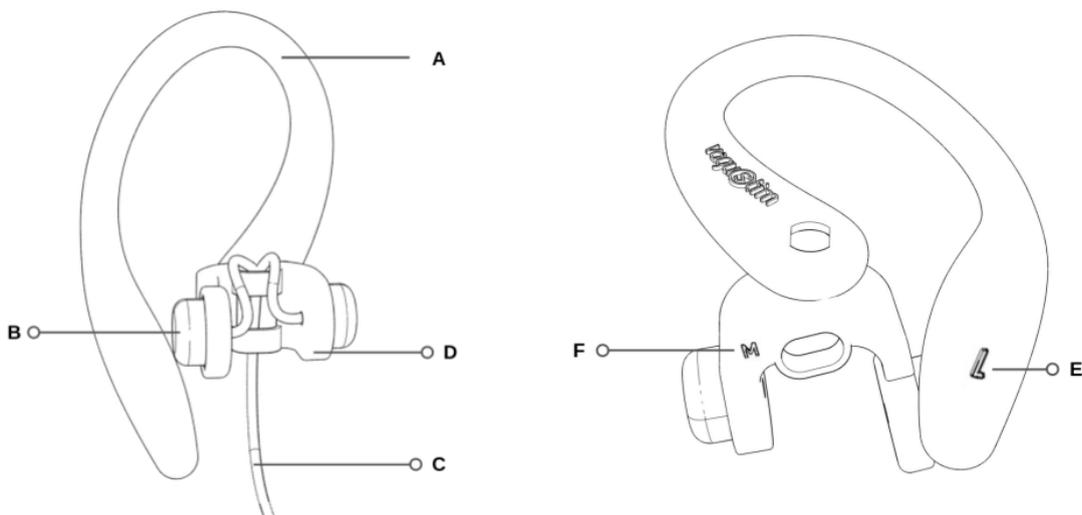
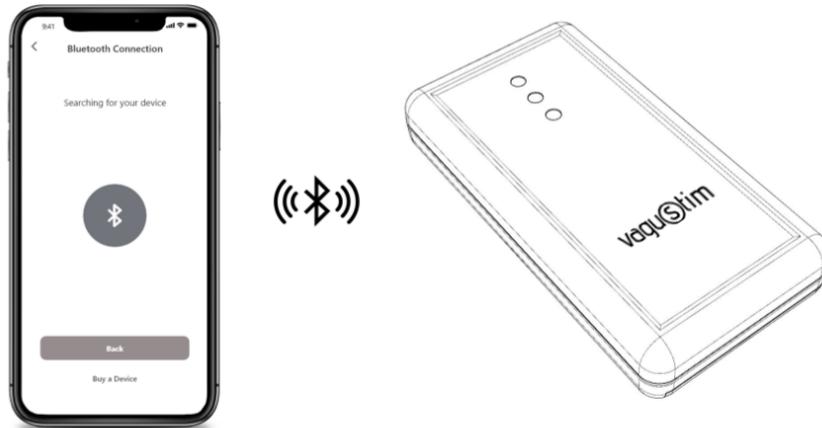


2. Follow the steps given in the app to create an account for a new user or login into an existing account.

3. Place the batteries in the correct orientation and plug them into the ear electrodes connector to turn on the device

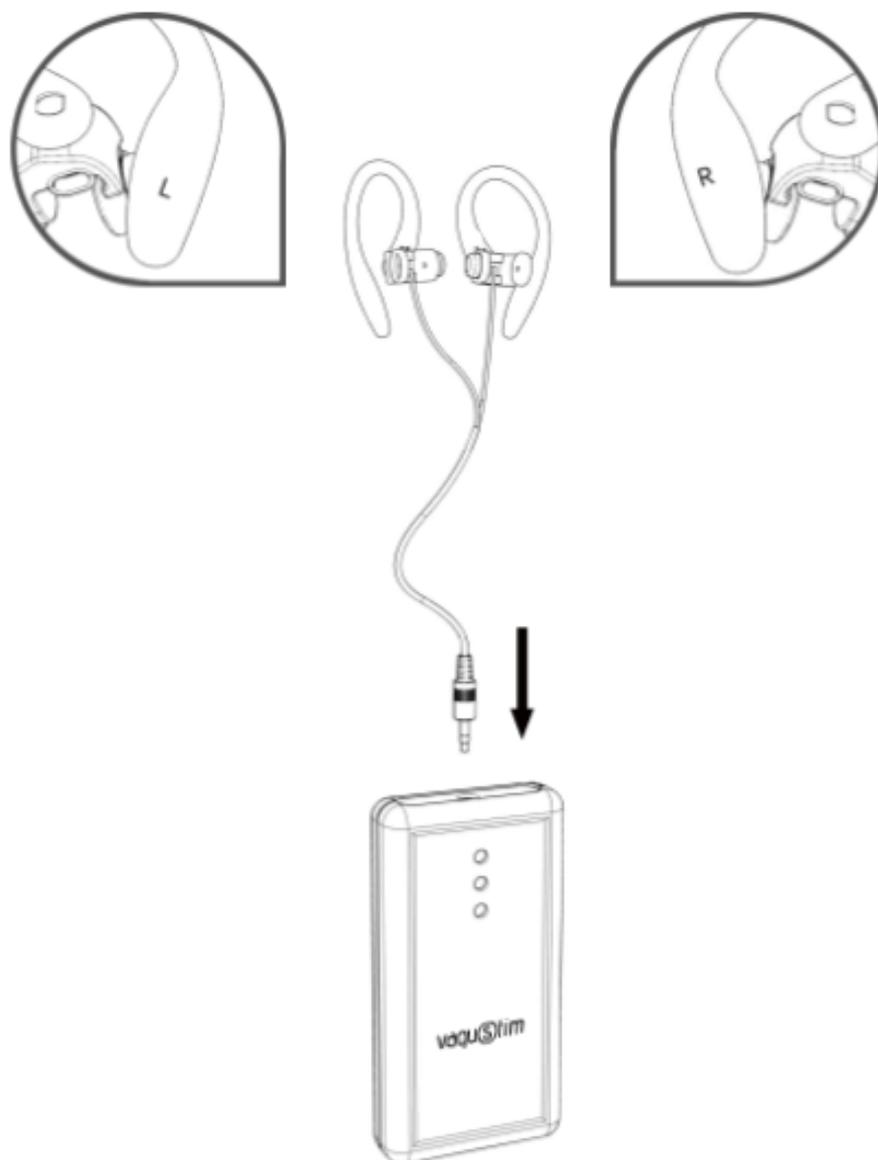


4. Enable Bluetooth and location permissions on the smart device and pair the Vagustim Stimulator with the smart device, following the instructions on the app.



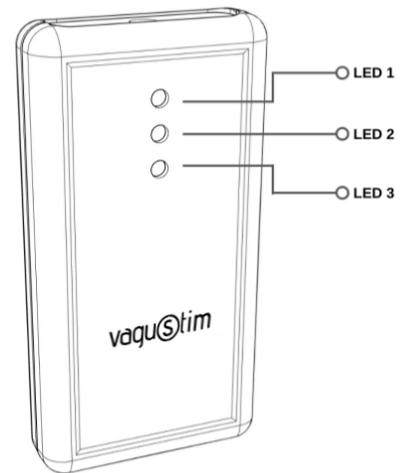
A. Hanger	The hanger holds the position of the ear electrodes stable.
B. Metal Probes	The electrodes transmit electrical stimuli from the stimulator to the ears.
C. Cable	The cable transfers the electrical impulse generated by the stimulator to the metal probes.
D. Plastic Part	This part ensures that the electrode is in full contact with the ears comfortably.
E. Side Sign	Left and Right side indicators
F. Size Sign	Size indicators ( <i>Small, Medium, and Large</i> ) of the ear electrodes

5. Plug the ear electrodes into the stimulator module. Make sure that the left and right ear electrodes are positioned correctly as shown in the image.

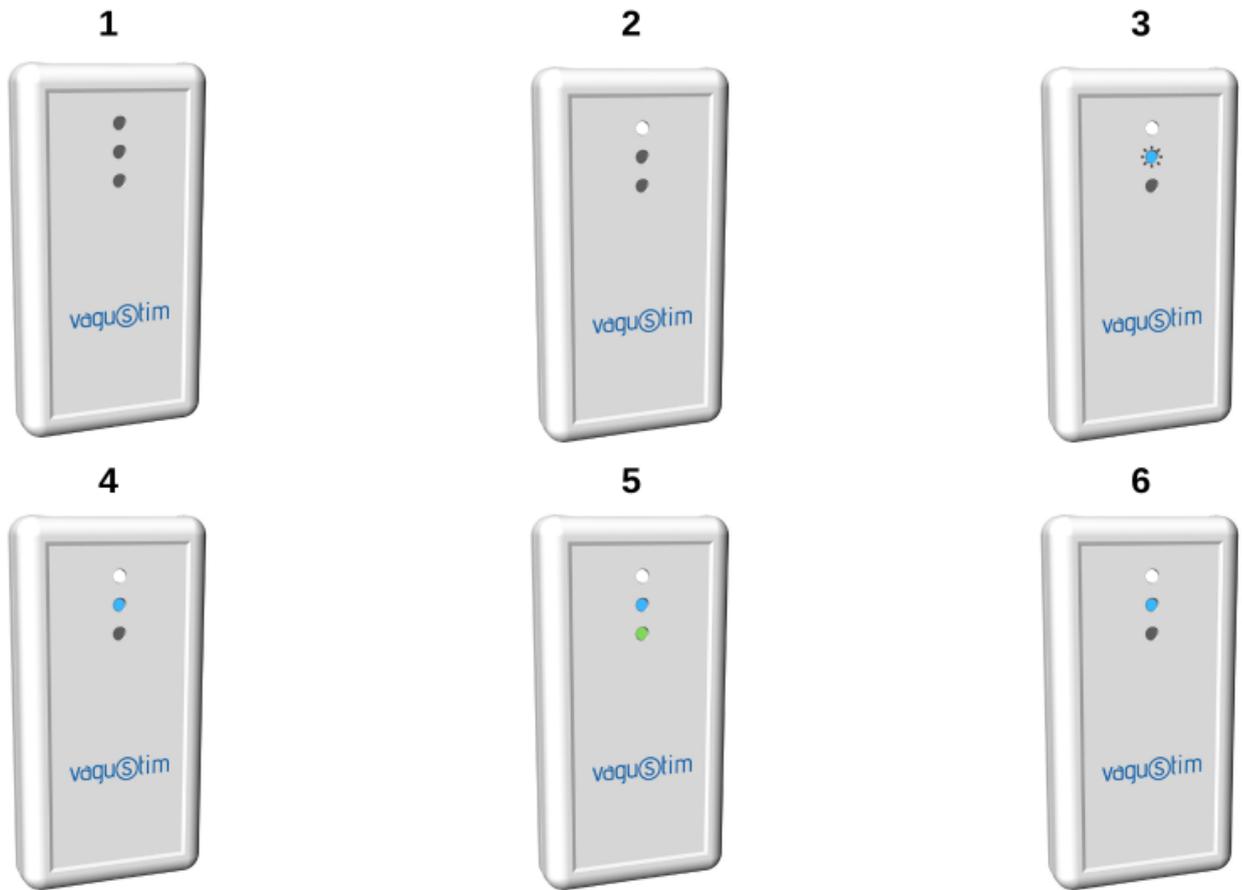


### 3.3. DEVICE INDICATORS

There are 3 LEDs located in front of the device. These LEDs may be turned on or blinking 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 a constant blue.	Bluetooth® connection has been established.
LED number 3 is a constant green.	Stimulation has been started and has been in stimulation for a period.
LED number 3 is off.	The device is in off duration or stimulation has not been started yet.



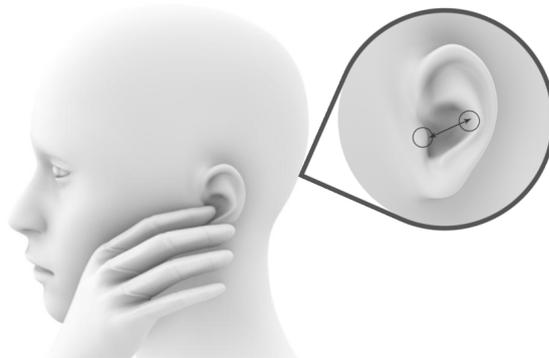
	Device State	LED1	LED2	LED3
1	Device OFF	OFF	OFF	OFF
2	Device ON	White	OFF	OFF
3	Bluetooth Search	White	Blue (Blinking)	OFF
4	Bluetooth Connected	White	Blue	OFF
5	Stimulation ON Period	White	Blue	Green
6	Stimulation OFF Period	White	Blue	OFF

### 3.4. INSERTING THE EAR ELECTRODES

1. Wet your finger with the conductive gel.

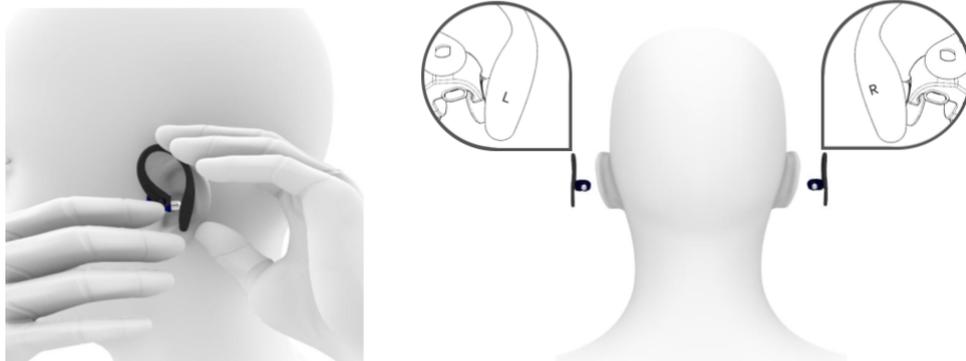


2. Apply the conductive gel to both ears.

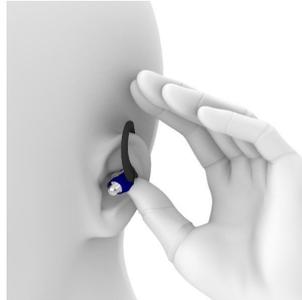


3. Place the Vagustim's ear electrodes in your ear.

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

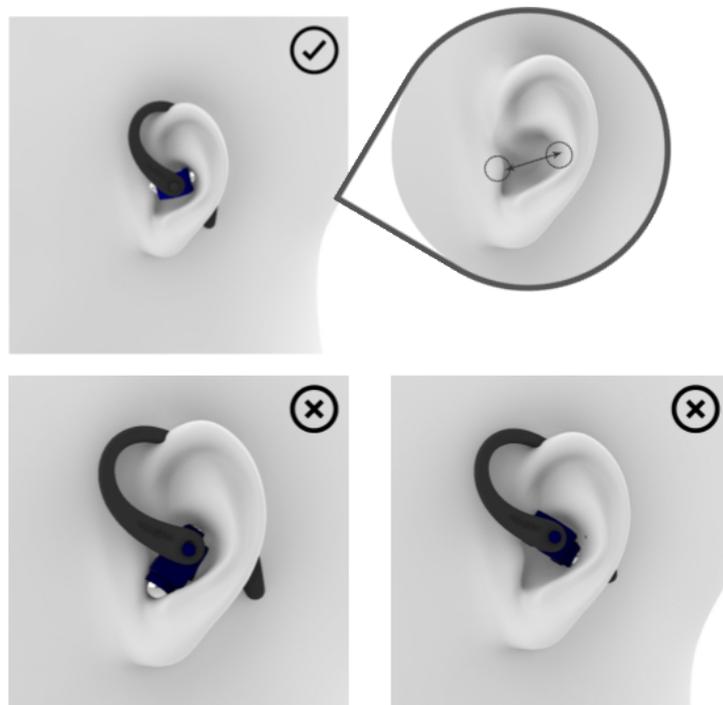


4. Adjust the position of the ear electrodes for a comfortable fit.



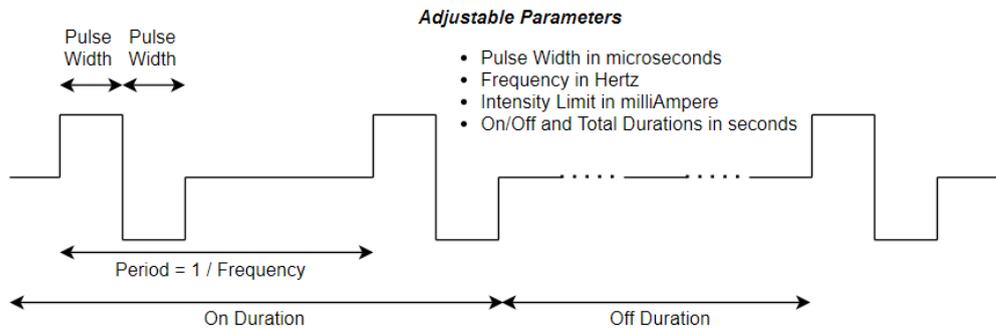
5. Make sure your ear electrodes are in contact with the indicated areas of the ear (Concha and Tragus) to which you have applied the gel earlier.

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



## 4. ADJUSTABLE 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.

The current intensity for vagus nerve stimulation must be adjustable. Since the parameters such as skin resistance vary from person to person and affect electrical conductivity, there is no single signal intensity suitable for everyone. That’s why once the user starts the stimulation, the signal intensity will need to be increased for each ear until the patient starts to feel the sensation. The maximum level of intensity is 5 mA for safety.

## 5. SIGNS AND SYMBOLS

Please note the following label, 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	2 x AA Batteries
Dimensions	134 mm x 70 mm x 25 mm
Wireless connection	Bluetooth Low Energy 4.2
Pulse Width Interval	50 - 1000 microseconds
Frequency Interval	1 Hz - 500 Hz
On/Off Duration Interval	0 - 60 seconds
Total Stimulation Duration Interval	0 - 6 hours
Intensity Limit Interval	0 - 5 mA with a step size of 0.1 mA
Number of Outputs	2 - Right & Left
Waveform	Symmetrical Biphasic Rectangular 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.

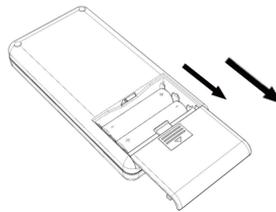
To purchase a new electrode, you can contact your local distributors, if there is no local distributor or you can not reach them, you can reach Vagustim at <https://www.vagustim.io>

### 7.3. Battery

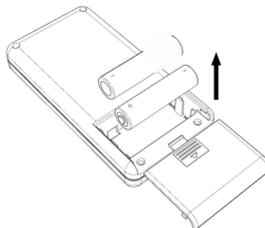
The Vagustim stimulator is powered by 2 disposable Alkaline batteries. The battery charge level is continuously monitored by the device. When the device's battery charge level is low, the device will not turn on. The battery of the device should be removed if the device is not going to be used for more than a week.

#### Instructions for battery replacement

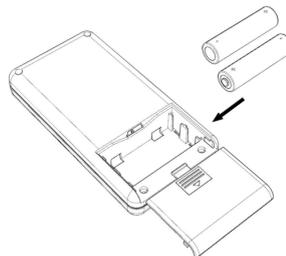
1. Remove the battery cover



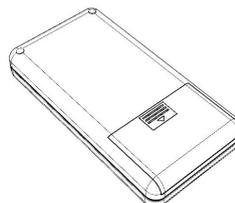
2. Remove the empty battery.



3. Place the new battery in the correct orientation.



4. Close the battery cover.



### 7.4 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 AA batteries, wait 30 seconds and reinstall it
		Replace AA batteries with a new one (AA batteries with at least 1500 mAh capacity are recommended such as Duracell or GP)
		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 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 among 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 on the ears	Loose contact, wrong intensity setting, or cable error	Remove ear clips from your ear and put gel 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](mailto:info@vagustim.io)**

---

## 9. ORDERABLE ACCESSORIES

1. Vagustim Stimulator
2. Vagustim Ear Electrodes

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](http://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 damage 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 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 of equipment

## 11. MANUFACTURER INFORMATION

**Name:** Vagustim Health Technologies

**Sales Office:** 44 Tehama St. 94105 San Francisco, CA

**R&D Manufacturing Office:** Resitpasa Mah. Katar Cad. Arı 4 Teknokent Sarıyer İstanbul Türkiye

**E-mail:** [info@vagustim.io](mailto:info@vagustim.io)

**Web:** <https://vagustim.io/>