

# USER'S GUIDE

## EVANES (taVNS) device by Salustim

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Content

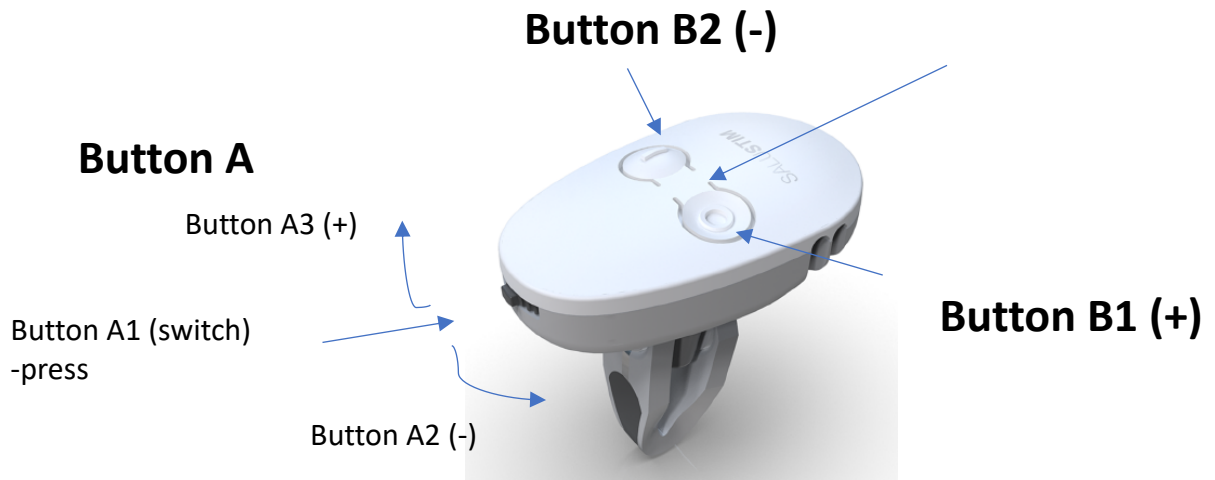
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# 1. QUICK GUIDE

Product pictures

## The EAR UNIT



### Buttons B1 and B2:



B2 : Reduce stimulation current.



B1: START and increase stimulation current.  
Reset, when pressing 10 sec

## The CHARGER UNIT



## Preparation

- Set the electrode unit to the taVNS device with two snap connectors.
- Connect the charger to USB power source +5 VDC using USB C -connector and cable (not included in the package).
- Set the device into the charger for charging.
- Close the charging box. The LED will start to blink every 5 seconds.
- Charging will take 2-3 hours. When the device is charged the LED blink every two seconds.

## Setting into the ear

- Take the device from the charger.
- Set the device into your ear.
- To improve the skin contact the black electrode areas can be slightly wet by water.
- The device can be placed 1-5 minutes with the skin contact before starting (it helps to stabilize the contact and your skin will be accustomed to the device and electrode).

## Starting treatment

- Press button B1 for starting.  
LED starts to blink every second.
- The device will start to give audio instructions:
  - “Start by setting audio volume”. “Slide Button A up or down”.
  - You will hear “ocean wave sound”.
- Adjust the volume.
- When the audio has been set or after 10 seconds the program proceeds:
  - “Checking skin contact”, “Set your device into your ear “
- It will take 3-5 minutes. The device will check that the contact is good and stable. Be patient this will ensure good and reliable treatment.
- When the contact is ok. The program proceeds.
  - “Contact is good”.
  - “Treatment starts. Automatic control of treatment level or press B1 or B2 for manual setting”
    - If you don't press anything (recommended) the device will set safe stimulation treatment current level (1.8mA).
    - If you want lower treatment level, press B2 ( (-) button, higher button) to reduce level, 1 press means -0.2 mA.
    - If you want higher treatment level, press B1 ( (+) button, lower button) to increase level , 1 press means +0.1 mA.
    - Automatic mode: LED blinks 2 times then 6 seconds OFF,  
(XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX)
    - Manual mode: LED blinks 3 times then 6 seconds OFF  
(XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX)

## Treatment

- When the treatment has been set , after 10 seconds from the last button pressing, the program proceeds.
- The device indicates the treatment parameters. Two numbers are said three times as follows:
  - “020 – 180”, “022 – 179”, “018 – 180”
  - These are telling the voltage and current levels of the treatment stimulation.
- After 10minutes the device informs:
  - “10 minutes done”, “020 – 180”, “022 – 179”, “018 – 180”
- After 20minutes the device informs:

- “ 20 minutes done” , “ 020 – 180” , “ 022 – 179” , “ 018 – 180”
- This will be repeated until 60 minutes done if not stopped earlier.
- After 60 minutes:
  - “ 60 minutes done. Treatment is ready”. The device stops and goes to standby.
- You can do another 60 minutes period during the next 24 hours.
- The device will enable maximum 120 minutes treatment per successive 24 hours.

## 2. PACKAGE CONTENT

The product package **EVANES by SaluStim** consists of :

- the Ear Unit
- the Charger Unit
- changeable Electrodes available with sizes Small (S) and Large (L)
- User instructions
- Package

## 3. EVANES by SALUSTIM

### Background and treatment description

SALUSTIM EVANES device is the first tVNS stimulator to be used in user’s ear.

The product SALUSTIM EVANES is designed to manage and reduce stress of a person. The device enhances and stimulates human body by activating parasympathetic tonus. The device uses two parallel stimulation methods which can be used together. First it can stimulate electrically transcutaneous vagus nerve branch located on the outer ear (taVNS). The non-invasive electrodes on the outer cover of the device are placed against the skin of the outer ear channel.

A stimulation period is typically 5-60 minutes switched periodically on and off. The stimulation period can be repeated 1-3 times per day and continue over 1-90 days.

Second it can give breathing pace guidance through an audio tone. The device indicates in and out breathing phases with a separate audio tones at a suitable frequency. It is known that breathing at low rate 10-12 seconds per one breathing cycle activates vagus nerve which enhance parasympathetic tone, improves HRV, and reduces stress.

A stimulation of vagus nerve is known to affect positively to person’s health. It has been reported and validated to:

- increase parasympathetic activity, and/or reduce sympathetic activity
- increase heart rate variability,
- reduce effect of tinnitus, and relieve tinnitus caused stress
- reduce stress
- improve sleep and sleep measures
- improve cognitive skill
- reduce burden of atrial fibrillation (i.e. length and frequency of AF periods)

When used, device provides audio based breathing pace guidance that is set to nominal 10s cycle, consisting of 2,5s “inhalation cycle” and subsequent 7,5s “exhalation cycle”.

Electrical stimulation is synchronized with breathing pace guidance, so that electrical stimulation is on for first 5s of the “exhalation cycle”.

## Intended Purpose

The intended use of the product SALUSTIM EVANES is for :

- the treatment of mental stress and treatment of tinnitus-related mental stress (TRMS)
  - by means of reducing the sympathetic prevalence and/or increasing the parasympathetic activity in generally stressed individuals
- the treatment of pain, insomnia, anxiety, and burn out
  - by means of reducing the sympathetic prevalence and/or increasing the parasympathetic activity associated with the disorders
- the treatment of tinnitus by means of reducing the annoyance and loudness of tinnitus by allowing the habituation to take place

## Intended User Group

The targeted user group is 15 years and older. The target users are having a normal hearing capability (for audio instructions) and having normal cognitive skills for operating a smart phone or corresponding electrical device.

A typical user is keen on her/his health and wellness. The user is intended to improve his/her wellness, reducing stress level, enhancing relaxation. The user may also be keen to improve or strengthen his/her cognitive skills and learning ability. The user may suffer from stress, sleep problems, tinnitus or other health problem which cause stress.

The users excluded:

- users using pacemaker or other stimulator or implanted electrical devices
- users being impaired to use and control electrical device (such as a mobile device or similar)
- users being impaired with sensation of pain
- users being impaired with hearing
- users having heart health issues must consult their medical doctor before use.

## Intended Use Environment

Intended use environment for device is normal home, an office and out-hospital health clinic environment. The use environment will be a normal room condition (temperature +15 - +30°C, humidity 20-70% RH).

Device is not intended to be used in facilities providing emergency medical services or critical life-supporting treatment services, or in operating rooms or similar environments where patient is connected to other medical devices.

## Precautions

- Use only Salustim electrodes designed for the EVANES Ear Unit.
- Use only the SaluStim charger for recharging the EVANES Ear Unit.

- Use only a standard USB-C connector to connect the charger to the USB charger 5V with USB connector.
- Do not place the device near excessive heat or in water.
- Long-term taVNS stimulation at the electrode site may cause skin irritation. If therapy is experienced unpleasant, discontinue use until re-evaluated by a therapist or physician.
- Keep the device out of the reach of children.
- Do not use the device, if it is broken (plastic parts are broken, cracked, electrode contacts are detached).
- If you feel that treatment current is inconvenient, reduce the treatment by pressing B2 button (-) button or remove the device from the ear.
- If you feel pain during the treatment remove the device from the ear. After that set the device to the charger so it will be reset. Wait at least 5 minutes before starting the treatment again. Then, if you feel pain again, contact your therapist or us.

#### Adverse reactions

- Allergic reactions are rare. However, an allergic reaction to the electrode may occur in the form of skin irritation. An electrode burn on the electrode site may rarely occur. If skin irritation **persists**, discontinue the use and consult a therapist or physician.
- If you feel inconvenience or any health-related symptoms during the treatment, remove the device from the ear.

## 4. TECHNICAL CONSTRUCTION AND SPECIFICATION

### Technical Construction

The product consists of a wearable device with an electrode unit. The device is used on a user's ear. The product consists also a charging box unit for charging the wearable device when it is not in use. A charger input device is used for powering the charger unit during a charging operation.

The product elements are: the ear device unit, charger unit and electrode unit as shown in Fig. 1. The charger input device does not belong to the product. It is an external low power unit (5V-USB) which will be used for powering the charger when the ear unit is set into the charger for recharging.



Fig 1. The product elements; the ear device unit, charger unit and electrode unit.

The charger input device does not belong to the product package.

The electrode unit comprises two electrode areas for delivering the stimulation current to the user's ear skin. The electrode unit is smooth and intended to be used several times. The electrode unit is connectable / disconnectable by snap connectors to the ear device unit. Different sizes of electrodes will be offered to fit the ear unit optimally to user's ear.

The ear device unit is the main part of the system. It is a rechargeable battery operated. The recharging is only possible when the device is set on the charger box. The treatment is not possible during the device is in the charger box. The ear device unit comprises control buttons and a LED indicator. The control button A controls audio volume up and down and starts the device. The control button B (1 and 2) can control the intensity of the stimulation current. The button B can be also used for starting the device. The ear device unit has an electronic unit with a microcontroller which controls and monitors the device. The LED indicator indicates the status of the device and status of the charging during charging. The LED indicator is visible when the ear device unit is set in the charger box.

The charger box is used as a storage and carry-on box for the ear device unit when it is not in use. The ear device unit can be charged in the charger box when the charger device unit is connected to external low voltage (5V) USB power source.

The charger box comprises the charging pins for the ear device unit. The charger box has also a self-test circuitry for testing the ear device unit. The self-test circuitry is connected through the electrode pins to the ear device unit. The charger box is designed in the way that when it is open the powered charging pins are not reachable and touchable by a test finger. Thus, the charging is only possible when the charger box is closed. The charger box has a connector for the charger input device. The charger input is 5VDC.

The charger input device is used for powering charger box. Its output is 5VDC. The charger input device is preferred to have an output cable with a connector to the charger box. The charger input device may also have an USB or similar output and then a separate cable such USB-USB-C cable is used for connecting the charger input device and the charger box.

The charger input device nor USB-USB-C cable are not part the G2 product offering.

## Technical specification

- Device: taVNS EVANES device by SaluStim
- Output: max 7 mA (peak-to peak) across 10000 Ohm load
- Pulse width: 500µs (positive pulse 250µs followed by negative pulse 250µs)
- Waveform: Symmetric biphasic rectangular
- Pulse rate: 20 Hz
- Breathing guidance period: 12 seconds: 2.5s inhale, 1 s break, 7.5s exhale, 1 s break.
- Treatment timer: 10 min, 20 min, 30 min, 40 min, 50 min, 60 min per session. Max 120 min /24 hours.

## 5. TREATMENT PREPARATION

- If you have received the treatment procedure, program and guidance from your doctor or therapist, please follow that.

- If you have not any special program, please check a suitable program available in [www.salustim.com](http://www.salustim.com).
- The treatment can be for example two 30 minutes sessions per day (morning time and evening time) and continuing 1-3 weeks.
- Due to safety and convenience the device will limit the maximum use time to 60 minutes at time and 120 minutes during the 24 hours.

Preparation of the treatment:

- There is not special preparation for using the device. You will need to charge the device to enable to make treatment for the session.
- To prepare the treatment session to be effective and convenient, select a suitable non-disturbing time and place so that you can also relax during the treatment session planned 10-60 minutes.

## 6. SAFE AND EFFECTIVE USE

- Follow strictly the instruction of the User Manual.
- Use only Salustim electrodes designed for the EVANES Ear Unit.
- Use only the SaluStim charger for recharging the Ear Unit.
- Do not open or Ear Unit or Charger Unit devices. In case of any technical problem contact SaluStim.
- If you the device is broken or you suspect that it does not properly, contact SaluStim.
- taVNS EVANES device does not any particular maintenance except recharging the battery of the ear unit. Use always only the EVANES recharger for recharging the Ear Unit. The electrodes are recommended to be changed after 1-3 use sessions and always if there is any defect electrode areas or snap connectors are defected or dirty and light swiping is not enough for cleaning them.

## 7. Care and maintenance

The unit may be cleaned by wiping it with a damp cloth and a solution of mild soap and water. Wipe dry after cleaning. Do not immerse the unit in water.

No other user maintenance of the main unit is required.

## 8. TROUBLESHOOTING

The device has a self-test for checking the safety and functions. In the case of detected failure the Audio will inform “ Failure detected xx “. xx means the error code in numbers.

In the case of “Failure detected” by the self-test of if the device does not start treatment or in case of malfunctioning audio or treatment, please:

- set the Ear Unit to the charger and connect the charger into the charger input device
- close the lid of the charger ( the device will be reset)
- Wait about 10 seconds until the LED will start blinking once per five second (charging going) or LED is blinking once per every two seconds (recharging ready)



To reset the Ear Unit

- Push the button B1 for 8-10 seconds (+ button on the top of the Ear Unit).

If the problem occurs, contact us. Contact information presented on the last page.

## 9. Warranty

In addition to your statutory rights, the distributor agrees that if any defect in materials or workmanship appears in this product within two years of the original date of consumer purchase, it will repair (or at its option, replace) the unit free of charge for parts and labour. This applies only if the product has been used for intended purposes and not damaged through misuse, accident or neglect nor modified or repaired by anyone other than an authorized distributor or its authorized agents.

If a problem occurs, please check the unit is being used in accordance with instructions. If the fault persists after checking the troubleshooting section, return it with dated proof of purchase to your nearest stockist or original supplier. Please include your name, phone number, email and address and a description of the fault.

Note: only authorized service agents should carry out repairs to the unit. For technical documents, please contact the manufacturer.

As consumable items, battery and electrodes are not included within this warranty.

## 10. FAQ

## 11. CONTACT

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