



# PULSE T T O

GO WITH THE WAVE

## FEEL THE POWER OF *PULSE T T O*

There is no prior mindfulness or meditation experience required. Benefits to your well-being are cumulative with regular sessions and are effective from the first time you use your *Pulsetto*.

## OUR STORY

The purpose of *Pulsetto* is to provide stress resilience and well-being to people from all walks of life by utilizing effective methodologies and cutting-edge technology.

Based on decades of expertise working with stress and trauma-related conditions, we are bringing to the mainstream market a vagus nerve stimulation technology that will enable customers to treat conditions such as stress, poor sleep, and anxiety.

We are a small team working hard to bring *Pulsetto* to as many people as possible – your support and assistance are really appreciated, so please stay in touch or even leave a 5-star rating in the App Store or Google Play if you're enjoying your sessions.

### *Before that – make the most of your sessions*

- Set aside some uninterrupted time – even 10 to 15 minutes is sufficient.
- To avoid notifications, set your phone to sleep or do-not-disturb mode.
- Put Pulsetto on your neck and adjust the size to keep it in place.
- Make sure Bluetooth is turned on, begin your session using the app, then relax...




### *What should you expect after a session?*

Even if *Pulsetto* works from the first session, the long-term effects are cumulative and can vary. When you're finished, move gently and carefully as you become a better version of yourself! *Pulsetto* affects everyone differently; however, the most frequent long-term outcomes people describe are:

- improved sleep length and quality
- improved mood and anxiety lowered
- increased resilience to stress

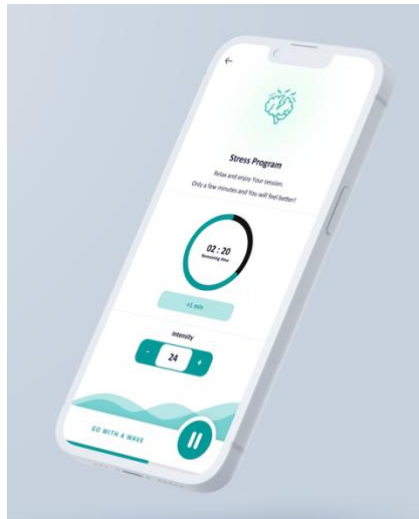
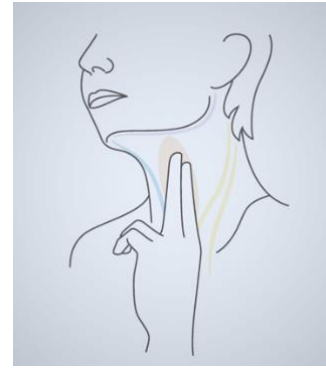
We advocate keeping an open mind – and please let us know what changes you see along the way; we'd love to hear from you.

## GETTING STARTED

and  Using your smartphone, search for '*Pulsetto*' in the App Store (iPhone) or Google Play (Android) and install the app. After downloading, open the app and follow the instructions to complete your setup.

1. Make sure that Bluetooth and location services are enabled on your phone, and the phone is near the '*Pulsetto*' device.
2. Please view the tutorial and follow the instructions in the Application.
3. Sign up to the application. If it is your first time, you will have to sign up to the *Pulsetto* application to become a Pulser.
4. When you first log in, you will see the tutorial messages. Later, you can find them on the "Settings" page under "Tutorial."
5. Remove any jewelry that may touch the session location.

6. Find a comfortable sitting position. (A place where you can see your neck in the mirror may be helpful.)
7. Make sure the session location is clean and dry.
8. Apply gel to the neck region. Apply on both sides.
9. Put the *Pulsetto* device on your neck and check if electrodes are on the site where you applied the gel. Not applying the gel as described may cause the stimulation to be uncomfortable or less effective.
10. Turn *Pulsetto* on by pressing the power button on the device. You will see a green LED indication around the button.
11. You will see the available programs on our applications on the home screen. You can read more on the settings page.



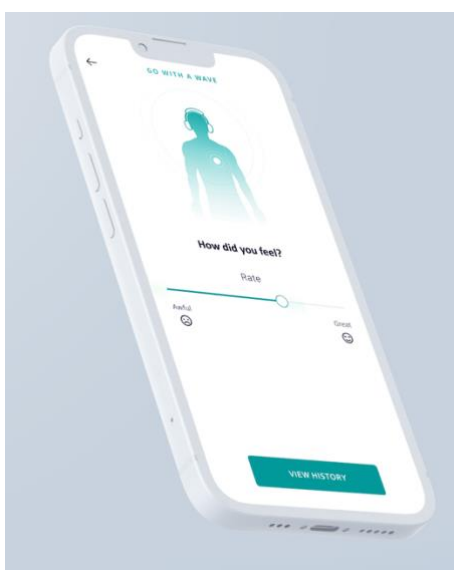
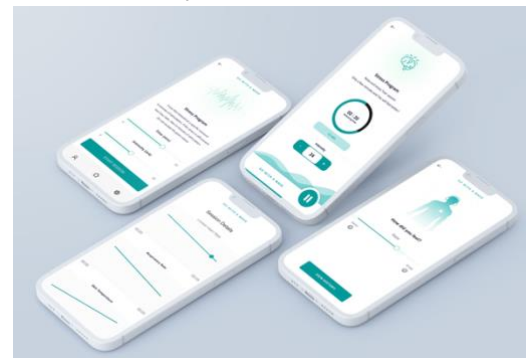
12. Position the device in the correct place on the neck over the session location. Adjust the collar dimension to feel mild to moderate pressure, so the device makes good contact with the skin; however, do not apply excessive pressure to the neck.

13. Select the program. You will see more instructions on the program screen.

14. Increase the intensity level in the application to the comfortable level you can tolerate. Once you have found your preferred intensity level, just enjoy your remaining session! You will likely feel muscle

contractions at the session location. These muscle contractions are normal and

should stop after the stimulation is complete. The appropriate intensity level differs for every person and may vary from stimulation to stimulation.



15. Following the session, you will have the ability to rate your session and view session details. Your profile has all of this information. This will also help us create a better user experience!

**NOTE:** You can always check your previous sessions and preferences in your profile to check the programs. And Pulsate even more!

**NOTE:** Neck muscle contractions that are not painful during the stimulation are normal and not a reason to stop the stimulation. If muscle contractions are too strong or uncomfortable, try:

- Removing *Pulsetto* from the neck.
- Lowering the intensity level by pressing the bottom area

of the control button.

- Repositioning the *Pulsetto* on the neck over the pulse and slowly increasing the intensity level again by pressing the top area of the control button.
- If the stimulation is still intolerable, turn the device off by pressing and holding the power button and discontinue the stimulation.

Clean *Pulsetto* by wiping the leftover gel off the stimulation surfaces with a soft, dry cloth. Clean the excess gel off your neck with a cloth or tissue. The gel is not intended to be left on the skin and may cause skin irritation for some people.

## INDICATIONS AND PRODUCT DESCRIPTION

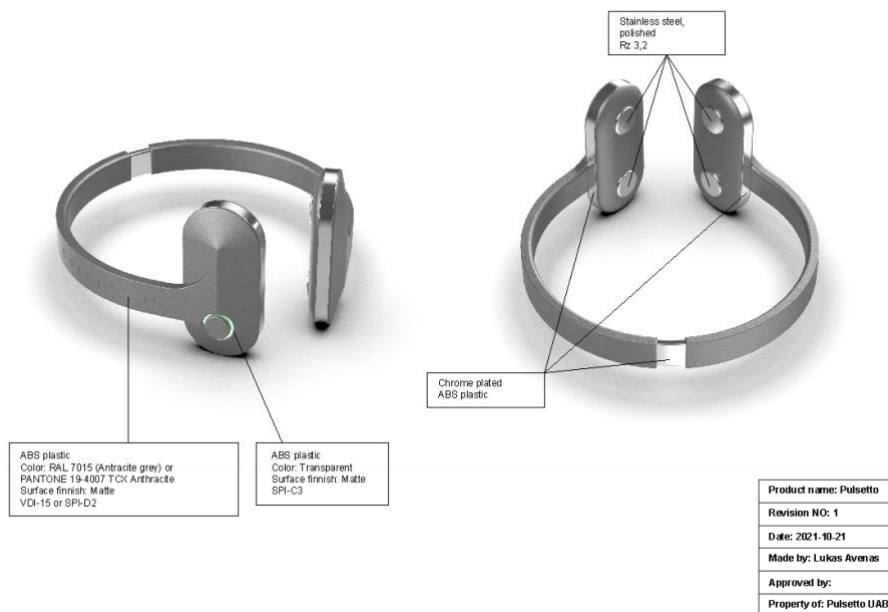
*Pulsetto* (non-invasive vagus nerve stimulator) is indicated for:

- Stress reduction
- Coping with anxiety
- Improving sleep

*Pulsetto* provides a mild electrical stimulation to the vagus nerve, which runs through the neck and carries information to the central nervous system. According to your selected program, each stimulation with *Pulsetto* lasts from 1 to 15 minutes. You can always add a couple of additional minutes.


The user controls the intensity level and duration.

*Pulsetto* is supplied non-sterile.







Device Feature	Description / Use
Stimulation Surfaces	Points of contact with the patient's skin
Power Button	Turns power ON/OFF
Adjustable sliding mechanism	Allows User to adjust the size
Charging cable	Charges the device

Functions:

Power Button	
	
<b>Press the power button to turn the device ON</b>	
<b>Hold the power button to turn the device OFF</b>	

### LED display symbols:

Icon Description	LED indicator	Description
Glowing blue light		Device is booting
Glowing green light		The device is ready for pairing
Blinking purple colors		The session started.
Glowing red light		Charging.

### Charging Instructions:

1. Plug the USB-C cable into the device charging point. Connect the other end of the USB-C cable to the power outlet minimum requirement of 0.5A.
2. The device LED will glow RED color while charging.

### Cleaning:

- Clean the device after each use by gently wiping the case and the stimulation surfaces with a soft, dry cloth to remove the leftover gel.
- Put the cap back on the device after use to protect the stimulation surfaces from dirt, debris, and damage.



## COMMON SIDE EFFECTS ASSOCIATED WITH *PULSETTO*

The most common side effects include:

- Application site discomfort
- Application site irritation/redness
- Local pain, face/head/neck area (including toothache)
- Muscle twitching and/or contractions, face/head/neck area (including facial droop and/or lip pull)
- Headache/migraine
- Dizziness
- Tingling, pricking, or a feeling of “pins and needles” on the skin where the device is applied (paresthesia/dysesthesia)
- These side effects typically resolve immediately after the stimulation is complete.

## CONTRAINDICATIONS



Contraindications include but are not limited to:

- Users with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
- Users with a metallic device such as a stent, bone plate, or bone screw implanted at or near their neck
- Users who are using another device at the same time (e.g., TENS Unit, muscle stimulator) or any portable electronic device (e.g., mobile phone)

Users should not use *Pulsetto*:

- While driving, operating machinery, or during any activity that may put the patient at risk of injury
- Near microwave machines, magnetic resonance imaging, radiofrequency surgical, or computer-aided tomography machines
- In an explosive atmosphere or in the presence of flammable gas mixtures
- If the user has an open wound, rash, infection, swelling, cut, sore, drug patch, or surgical scar(s) on the neck at the session location
- If the user has wet skin, is in the water, or just stepped out of the water (e.g., shower, bath, pool)

## WARNINGS, PRECAUTIONS, POTENTIAL ADVERSE EFFECTS

	Warnings indicate instructions, which, if not followed, may result in serious injury or death to the device user or to the patient.
	Precautions indicate instructions, which, if not followed, may result in damage to the equipment or degradation in the quality of the session.



### Warnings:

- The safety and efficacy of *Pulsetto* have not been evaluated in the following users or situations:
- Users with uncontrolled hypertension, hypotension, bradycardia, or tachycardia
- Users with a history of baseline cardiac disease or atherosclerotic cardiovascular disease, including congestive heart failure, known severe coronary artery disease, or recent myocardial infarction (within 5 years)
- Users with a history of abnormal baseline ECG, prolonged QT interval, or arrhythmia
- Users who have had surgery to cut the vagus nerve in the neck (cervical vagotomy)
- Pediatric Users

- Pregnant women
- Users with active cancer or cancer in remission
- Users with an abnormal cervical anatomy
- Users with a history of brain tumor, aneurysm, bleed or head trauma
- Users with a history of syncope or seizures

## ● PRECAUTIONS

### Before Use:

- You must carefully read the *Pulsetto* Instructions for Use.
- Only use *Pulsetto* as described in the Instructions for Use.
- Do not share *Pulsetto* with another person.
- *Pulsetto* should not be applied across or through the head, directly on the eyes, covering the mouth, chest, upper back, or heart.
- Remove jewelry that may touch the session location (necklaces, earrings, etc.).
- Carefully examine the device for any signs of damage or defects.

### Do not use *Pulsetto* if:

- The stimulation surfaces are broken or cracked.
- The casing is cracked, dented, or appears to be damaged.

### ***DURING SESSION:***

#### ***DISCONTINUE SESSION IF YOU EXPERIENCE:***

- Light-headedness, dizziness, or chest pain
- Excessive skin irritation

If the device seems to malfunction, discontinue use immediately. When possible, contact Customer Service for assistance with your device; Customer Service cannot provide medical assistance.

### ***CARING FOR YOUR DEVICE:***

- Turn off *Pulsetto* when it is not being used. If the device is not turned off, the battery may become depleted, and the device may not deliver sessions when needed. If the battery becomes depleted, place it in the charging cable to recharge.
- Keep *Pulsetto* away from water or other liquids, including cleaning liquids.
- Moisture may damage the device. Keep *Pulsetto* away from items such as nebulizers and steam kettles.
- Store *Pulsetto* in a safe location out of reach of children.
- Avoid exposure to extreme hot or cold temperatures outside the range of 0°C to 38°C (32°F to 100°F). Exposure to such conditions may cause the device to malfunction.
- Do not attempt to replace the device battery. If the device is not working, contact Customer Service.
- Do not open or take apart the case or attempt to repair or modify the device. There are no user-serviceable parts. If the device is not working, contact Customer Service.
- Do not intentionally damage, burn, or puncture the device.
- Wireless communications equipment, such as wireless home network devices, mobile phones, cordless telephones, and their base stations, and walkie-talkies, can affect this equipment. Keep *Pulsetto* at least 3.3 m (10.8 ft) away from these items while in use.

## Potential Adverse Effects

Potential adverse effects associated with the use of this device include but are not limited to the following:

- Application site discomfort
- Application site irritation/redness
- Local pain, face/head/neck area (including toothache)
- Muscle twitching and/or contractions, face/head/neck area (including facial droop and/or lip pull)
- Headache/migraine
- Dizziness
- Tingling, pricking, or a feeling of “pins and needles” on the skin where the device is applied (paresthesia/dysesthesia)

These side effects typically resolve immediately after the stimulation is complete.

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## POTENTIAL RISKS AND COMPLICATIONS ASSOCIATED WITH OTHER VAGUS NERVE STIMULATION DEVICES

The following risks and complications have been associated with other VNS devices and may potentially occur with *Pulsetto*:

- Coughing
- Gastrointestinal discomfort
- Headache
- Hoarseness or change in voice
- Irregular heartbeat (arrhythmia)
- Light-headedness/dizziness
- Metallic taste
- Muscle twitching and/or contractions of head/neck/face
- Nausea
- Pain
- Shortness of breath (dyspnea)
- Skin irritation
- Tingling, pricking, or a feeling of “pins and needles” (paresthesia/dysesthesia)

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## Precautions:

- Do not submerge the device in water; it is not water-resistant.
- Do not use soap, hand sanitizer, detergents, or other cleansers when cleaning the device.

## PRODUCT HANDLING

### **Operating Conditions – Pulsetto**

- Range: 10°C to 45°C (50°F to 113°F)
- Humidity: 10% to 90%
- Barometric Pressure: 80 to 101 kPa
- Altitude: Use below 2000 m
- Maximum Output: 30V (peak), 40mA (peak)

### **Storage/Transport Conditions**

- *Pulsetto* should be stored at room temperature away from moisture
- Range: 0°C to 50°C (32°F to 122°F)
- Humidity: 10% to 90%
- Barometric Pressure: 80 to 101 kPa

## TROUBLESHOOTING

### **Pulsetto does not turn on**

Charge Pulsetto. If the device is charging, the button will glow RED.

Restart Pulsetto. Turn Pulsetto off and on again.

Pulsetto does not charge.

Ensure the USB-C power cord is plugged correctly.

You can find more information in the FAQ section of the application or on the website.

## PRODUCT DISPOSAL



Regulations require that the disposal of electrical and electronic equipment, including used and unused medical devices, is handled in a controlled manner. A product that may be contaminated after use or contain chemicals or elements that may present hazards to people or the environment must be disposed of according to the applicable government regulations. Contact Customer Service (refer to Section 27) if you have questions about the appropriate disposal of this device.

**NOTE: *Pulsetto* contains a lithium battery that cannot be removed by the user.**

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## PRODUCT DESCRIPTION

Pulsetto is a Bluetooth Low Energy communication based device, powered from an internal rechargeable battery, LiPo 350mAh, 3.7V. The device is powered over a USB-C connector. The device has a single button to turn-on and turn-off. The main control is done over a dedicated smartphone application. The device has an internal DC-DC voltage converter that creates 0.2ms period, 12-46Vp-p, 50%duty cycle impulses 5 impulses that are repeated each 15ms.

Device has a single embedded ceramic antenna with gain of 0.5dBi and the transceiver that is set to 0dBm Tx. Device operates as a „System using digital modulation techniques“. Single channel bandwidth is 1MHz, operating frequency range is 2402-2480MHz.

## RETURNS POLICY & WARRANTY

If, for any reason, you are not happy with your purchase, you can return your order within 30 days from the date of delivery for a full refund. Please note that the item price and applicable taxes will be refunded. Shipping will not be refunded unless an error occurred on our part or the merchandise is deemed defective.

**Returns will not be accepted if any of the following conditions apply:**

1. The product is missing parts or has been damaged due to improper use.
2. The product has been damaged or modified from its original form in a manner not consistent with typical use.
3. The product is not returned with all hardware and accessories.
4. No refunds will be given after thirty (30) days from the date of delivery.
5. All returns must be in their original unaltered packaging.

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**NOTICE:**

*This device complies with Part 15 of the FCC Rules.*

*Operation is subject to the following two conditions:*

- (1) this device may not cause harmful interference, and*
- (2) this device must accept any interference received, including interference that may cause undesired operation.*

*Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio*

*exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:*

- (1) l'appareil ne doit pas produire de brouillage, et*
- (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.*

**NOTICE:**

*Changes or modifications made to this equipment not expressly approved by Pulsetto may void the FCC authorization to operate this equipment.*

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## ELECTRICAL CLASSIFICATION

- ❖ Electrical Classification (Pulsetto)
- UL 60601-1 Class III; EN 60601-1 Internally Powered Equipment
  - Type BF Applied part
  - IP22 Protected against ingress of solid foreign objects  $\geq 12.5$  mm diameter and protected against vertically falling water drops when enclosure tilted up to  $15^\circ$
  - Product contains Bluetooth RF transmitter: Frequency range of 2.379 to 2.496 GHz, GFSK Modulation, 1mW max power

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## ELECTROMAGNETIC COMPATIBILITY GUIDANCE

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**NOTE:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.