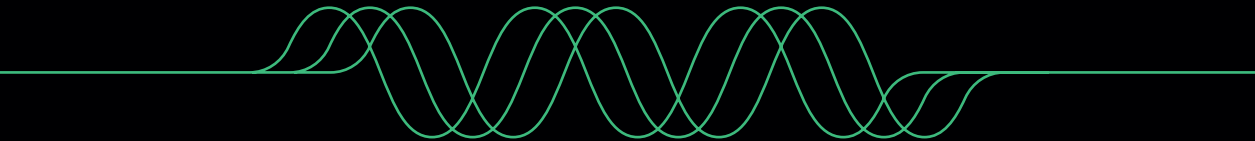


ABOUT
PULSETTO



GO WITH THE WAVE

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FEEL THE POWER OF PULSETTO

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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*.

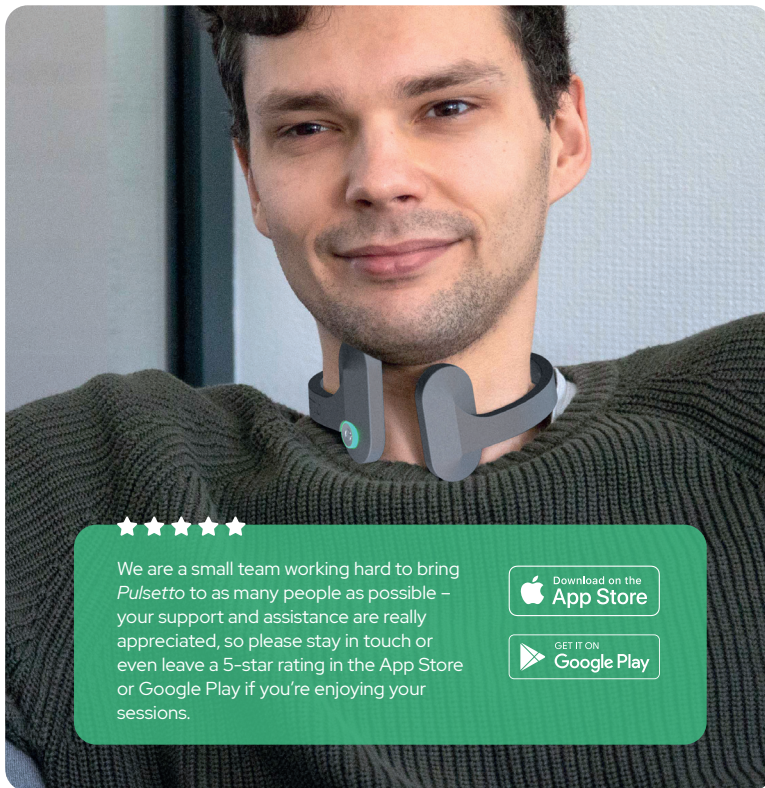


OUR STORY

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.

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Based on decades of expertise working with stress and trauma-related conditions, we are bringing to the mainstream market a **vagus nerve activation** 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.





How to get ready? Make the most of your sessions

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1

Set aside some uninterrupted time – even 10 to 15 minutes is sufficient.

2

To avoid notifications, set your phone to sleep or do-not-disturb mode.

3

Put *Pulsetto* on your neck and adjust the size to keep it in place.

4

Make sure Bluetooth is turned on, begin your session using the app, and 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:

1

improved sleep length and quality

2

improved mood and lowered anxiety

3

increased resilience to stress

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

Leave your insights here:



GETTING STARTED

Using your smartphone, search for “Pulsetto” in the App Store (iOS) or Google Play (Android) and install the app.

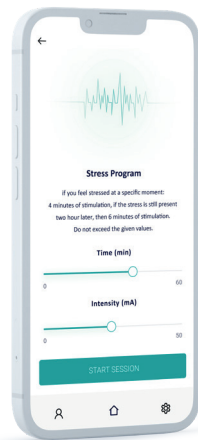
Scan code to download the app.

After downloading, open the app and follow the instructions to complete your setup.



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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 contacts are on the site where you applied the gel. Not applying the gel as described may cause the pulsation 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 the home screen. You can read more on the “Settings” page.



- 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.
- Select the program. You will see more instructions on the program screen.
- 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 pulsation is complete. The appropriate intensity level differs for every person and may vary from pulsation to pulsation.

- 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!

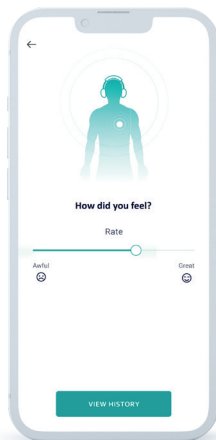
NOTE: You can always check your previous sessions and preferences in your profile to check the programs. And Pulsate even more!

NOTE: Neck muscle contractions that are not painful during the pulsation are normal and not a reason to stop the pulsating. 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 *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 pulsation is still intolerable, turn the device off by pressing and holding the power button and discontinue the pulsation.

Clean *Pulsetto* by wiping the leftover gel off the contact 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 pulsation) is indicated for:



Stress reduction



Coping with anxiety

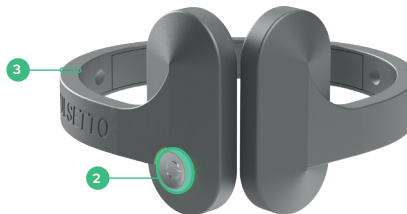
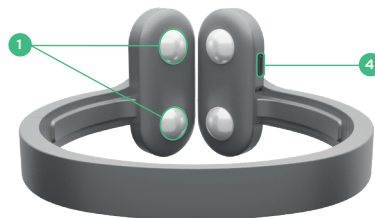


Improving sleep

Pulsetto provides a mild pulsation to the vagus nerve, which runs through the neck and carries information to the central nervous system. According to your selected program, each pulsation with *Pulsetto* lasts from 6 to 10 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

- 1 Contact surfaces
- 2 Power button
- 3 Adjustable sliding mechanism
- 4 Charging port

Description / Use

- 1 Points of contact with the patient's skin
- 2 Turns the power ON/OFF
- 3 Allows User to adjust the size
- 4 Charges the device



Functions:

Power button

Press the power button to turn the **device ON**

Hold the power button to turn the **device OFF**

LED display symbols:

LED indicator

- | | |
|--|--|
|  Device is booting
(Glowing blue light) |  Device is ready for pairing
(Glowing green light) |
|  The session has started
(Blinking purple light) |  Charging
(Glowing red light) |

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:

1. Clean the device after each use by gently wiping the case and the pulsation surfaces with a soft, dry cloth to remove the leftover gel.
2. Put the cap back on the device after use to protect the pulsation 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 pulsation is complete.

CONTRAINDICATIONS

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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 contact 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 3.3m (10.8ft) 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 pulsation is complete.

POTENTIAL RISKS AND COMPLICATIONS ASSOCIATED WITH OTHER VAGUS NERVE PULSATION DEVICES

The following risks and complications have been associated with other VNS devices:

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- 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)



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

Range: 10°C to 45°C (50°F to 113°F) | Humidity: 10% to 90% | Barometric Pressure: 80 to 101 kPa | Altitude: Use below 2000m
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 in 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.

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

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 it on and 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 a 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 occurs 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.

NOTICE:

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

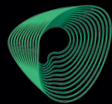
- (1) this device may not cause harmful interference, and*
- (2) this device must accept any interference received, including interference that may cause undesired operation.*

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.



PULSETTO

GO WITH THE WAVE