

Parasym

Parasym™ tVNS Device Instructions For Use





hello

Welcome to your new Parasym device.

These instructions show you how to set up your Parasym device, and get you on a schedule specific to you, that you can use every day. Two AA alkaline batteries are included so you can start straight away.

Before using your device, please make sure you have read all the precautions, warnings and safety information, followed by the guidance for proper setup. If in doubt as to the suitability of the Parasym device, consult your doctor before use.

The Parasym non-invasive Vagus Nerve Stimulator (VNS) is intended to provide non-invasive Auricular VNS delivered through the tragus. The Parasym device is indicated for the management of symptoms associated with depression, pain, anxiety and insomnia.

WARNINGS AND PRECAUTIONS

Warnings

- Read these instructions carefully to ensure proper use of the Parasym device.
- Do not inhale or swallow small parts.
- Do not wrap the lead wire around the neck.
- Do not apply stimulation in the bath or shower or while sleeping.
- Do not get the Parasym device wet.
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.
- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- Do not apply stimulation over the patient's neck or mouth because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across the patient's chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.
- Do not apply electrodes near the thorax because the introduction of electrical current may increase the risk of cardiac fibrillation.
- Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.
- Use this device only with the electrodes, and accessories recommended by the manufacturer as using others may be unsafe.
- Potential hazard from simultaneous connection of a patient to a high frequency surgical ME equipment and the device that may result in burns and possible damage to the device.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME equipment may produce instability in the stimulator output.
- The long-term effects of the chronic use of the device have not been evaluated.
- Contact your healthcare provider (HCP) if your symptoms worsen.
- Electronic monitoring equipment such as EKG alarms may not operate properly when the Parasym device is in close proximity while being used.

Contraindications:

- Patients with an active implantable medical device, such as a cardiac pacemaker, hearing aid implant, or any implanted metallic or electronic device
- Patients with a history of baseline cardiac disease or atherosclerotic cardiovascular disease, including congestive heart failure (CHF), known severe coronary artery disease or recent myocardial infarction (within 5 years).
- Patients with diagnosed bradycardia.
- Patients who have had surgery to cut the vagus nerve in the neck (cervical vagotomy).
- Patients diagnosed with narrowing of the arteries (carotid atherosclerosis).
- Patients whose pain syndromes are undiagnosed.
- Pediatric patients.
- Pregnant women.

Precautions

Before Use:

- You must read the Parasym Instructions for Use before using Parasym. However, reading the Instructions for Use may not be enough to fully explain the safe and effective use of the device. Ask your HCP or contact Parasym support if you have any questions about how to use the device or require any further clarification of these Instructions.
- Only use Parasym as described in these Instructions for Use or as otherwise directed by your HCP.
- Remove jewelry that may interfere with the electrode location (earrings etc.) before using Parasym.
- Always carefully examine the device for any signs of damage or defects before use.
- Do not strip the batteries' outer seal when inserting (for risk of short-circuiting), this can be avoided by taking care when inserting.
- Do not share your Parasym with another person.

Do not use Parasym if:

- The skin on the tragus is broken or cracked.
- The device casing is cracked, dented, or appears to be damaged.

Discontinue use if you experience:

- Lightheadedness, dizziness, or chest pain.
- Excessive skin irritation.

Caring for Your Device:

- Do not pull leadwires to remove the electrode.
- Keep Parasym away from water or other liquids.
- Keep Parasym away from steam as moisture may damage the device.
- Store Parasym in a safe location out of reach of children.
- Do not place the unit close to excessive heat.
- 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 Parasym support.
- Use only the specified batteries: 2x 1.5 volt AA Alkaline. Use of any other battery could damage the unit.
- Remove the batteries from the unit, when it is not used for a long time.
- Keep the unit away from sources of high magnetic fields such as TV'S, microwave ovens and hi-fi speakers, as these may affect the LCD screen.

If the device seems to malfunction, when possible, contact Parasym support for assistance. Parasym support cannot provide medical assistance.

POTENTIAL RISKS AND COMPLICATIONS

Adverse effects are usually rare, mild and resolve shortly after treatment is completed.

Tingling/pain/redness/itching at the site of electrode placement during long term application

Burn at the stimulation site if used continuously at a high intensity

Light-headedness/dizziness

Fatigue

Shortness of breath

headaches

Abnormal heart rhythm

Sweating

Fatigue

Tinnitus

Diarrhea

If you do not experience a response to treatment within one month, consult your health care practitioner, authorized Parasym distributor, or Parasym Ltd.

IF IN DOUBT CONSULT YOUR DOCTOR OR HCP.

Environmental Conditions:

Temperature :	Operating: 5 ~ 40 °C Storage : -25 ~ 70 °C
R.H.ambient :	Operating: 15% ~ 93% RH Storage : 0% ~ 93% RH
Altitude :	Operating: 700hPa to 1060hPA Storage : 500hPa to 1060hPA

Instructions For Use

Ear Clip Electrode



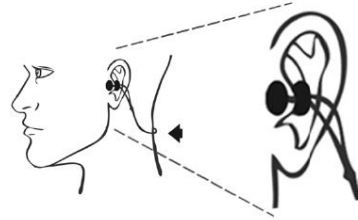
Parasytm™ Device

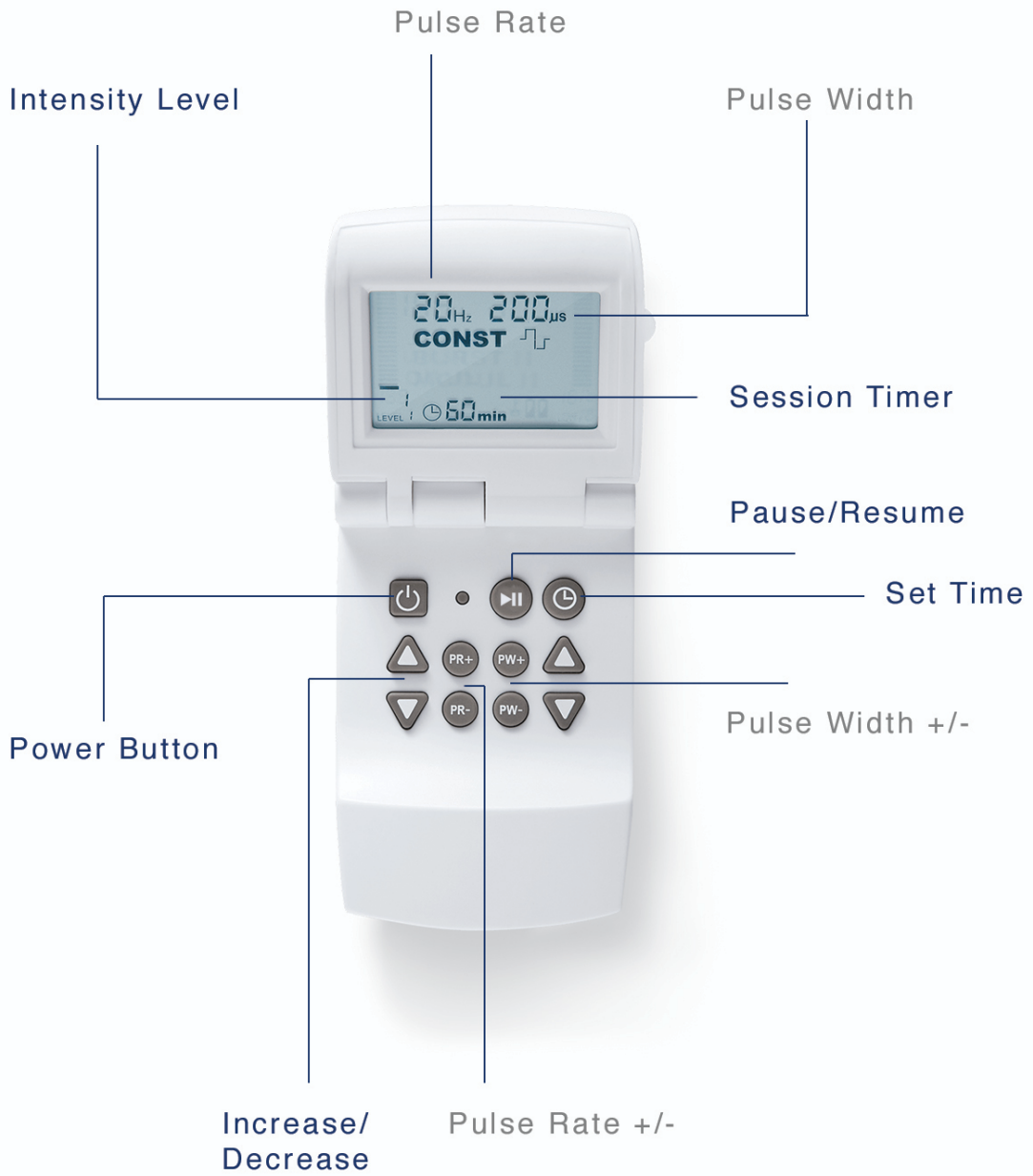
Insert lead plug into port



Electrode Placement

Connect the electrode to the tragus of the left ear, running the cable behind the neck over the right shoulder.







Quick Start Guide

1. Insert the two AA alkaline batteries

Take care doing this, be careful not to strip the material covering the batteries.

2. Plug the lead included into the CH1 port.

3. Electrode Placement

3.1. Clip the electrode to your left tragus

(See diagram on Page 8) - Make sure this is a good connection with both gold plates in firm contact with the skin

4. Push the Power Button

5. You can now input the settings for your treatment (see next page)

Note: It is recommended to incorporate Parasym into your daily routine, keeping the time of day for each session consistent.

Parasym Settings

- (a) Pulse Rate = **20 Hz**
- (b) Pulse Width = **200 μ s**
- (c) Intensity = **See section below**
- (d) Recommended Time = **60m/day**

1. Adjust the settings with the corresponding +/- buttons to match the display shown above. (Reference diagram on page 9)
2. The Parasym device can be used for 60 minutes per day. This can be achieved by pressing the timer button to '60 min'. The device will automatically shut down after 60 minutes. Please find a convenient time each day, using the treatment at the same time each day, for consistency.
Daily treatment sessions with the Parasym device may be used as often as necessary but for most people it is best to treat between once a day and twice a week. Results usually improve and last longer with additional treatments.
3. Parasym will automatically power off after the session ends. If you end your session early, press the Power button to switch off the device.

Note: When the batteries are low, the battery symbol will flash indicating that the batteries should be replaced. Batteries typically last well over 1 year.

Finding your Intensity level

After setup, repeat for each treatment session

01. Ensure electrode has a firm connection to the left tragus
(See p.8 image).
02. Slowly increase Intensity by one level per second. Take care not to rush this process. Stop as soon as you feel a light tingling sensation.
03. Adjust from here aiming to feel a comfortable pulsing. If you experience any pain, lower the Intensity right away. If the sensation is sharp, you may need to adjust the placement of your earpiece.
04. Each user's preferred Intensity level will vary and more Intensity is not necessarily better.
05. Once you find a comfortable level you can begin your session. You may want to adjust the level again during your session, this is normal and can be done at any time.

Common Intensity Questions

My stimulation intensity changes frequently throughout my treatment session, is this ok?

It is common for sensory thresholds to change throughout a session as well as between sessions. This is because the variables that affect conductivity, which causes perception of the stimulation and establishes a sensory level, can vary depending on time of day, skin conductivity and stress levels etc.

Should I be able to feel the stimulation during my session?

You should be able to feel a mild tingling or pulsing sensation at your tragus although it is common to become used to this sensation.

Note: The tragus is a sensitive area and it is important not to over-stimulate with too high an Intensity level or for too long a period of time.

Will I still need to take medications?

You and your healthcare provider (HCP) should discuss your ongoing treatment routine, including the use of any additional therapies and/or medications. It is important to always follow your HCP's recommendations about your medications.



Troubleshooting

If Parasym does not appear to be operating correctly, refer below to determine the cause. Should none of these measures correct the problem, please contact your supplier.

Parasym does not function at all

Check the batteries are inserted correctly.
Replace batteries.

Parasym switches off unexpectedly

This is likely to be the power-save function. If no buttons are pressed and the intensity level is zero, the unit will power-off automatically after a few minutes.

There is no stimulus (simulation) from one channel

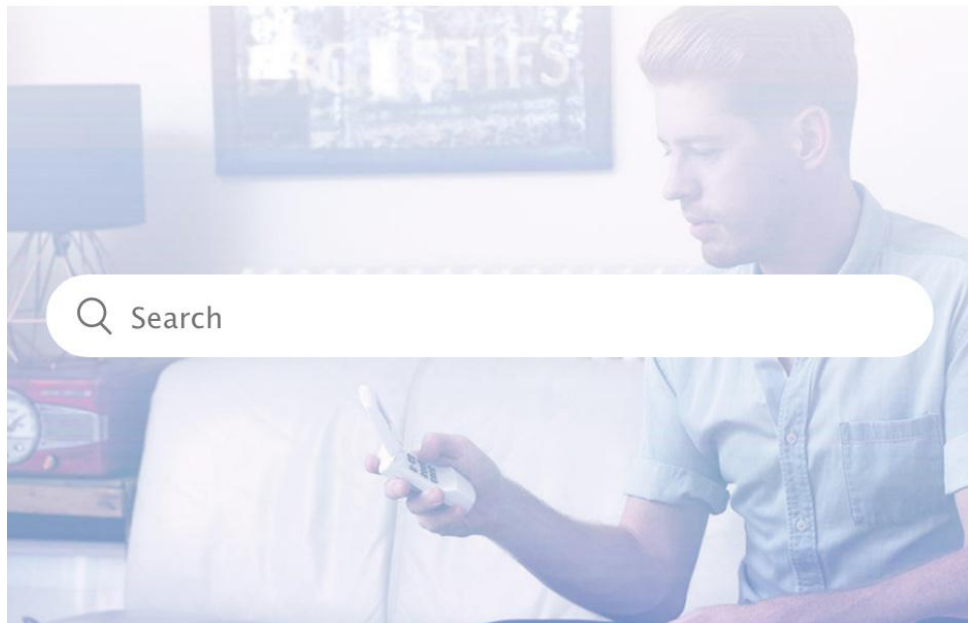
Check the Intensity is set above zero.
Check the lead is inserted into the unit correctly, firmly in the socket.
Check the lead is in CH1 (when controlling channel 1).
Check the position of the earclip with the skin, both metal plates should be firmly pressed against the skin.

Visit our Help Center

Our Help Centre has answers to most common questions. You can access this at: www.parasym.co/hc

Parasym

≡ Sign in



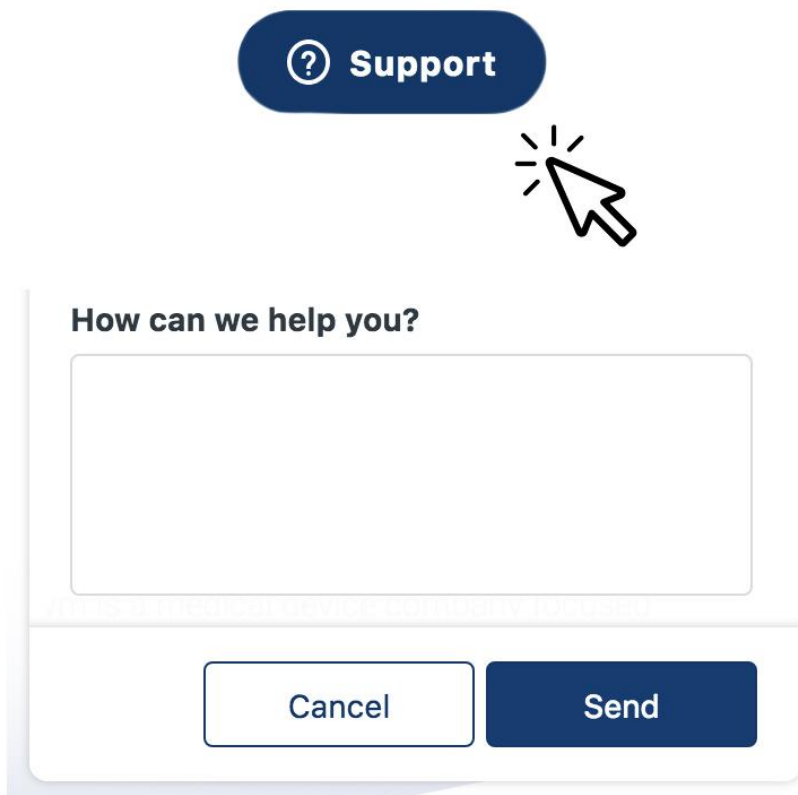
Getting to know the Parasym Device

Setting up the Parasym Device

Speak to one of our support team

Reach out to us via our support messaging widget on our website www.parasym.co and we'll get right back to you.

You can also email us directly at hello@parasym.co and your message will go through to our support team.



The image shows a support widget interface. At the top is a dark blue rounded rectangle containing a white question mark icon and the word "Support". A mouse cursor icon is pointing at the bottom right of this button. Below the button is a white rounded rectangle with a light blue border. Inside this box, the text "How can we help you?" is positioned above a large, empty white text input field. At the bottom of the white box are two buttons: a white button with a dark blue border labeled "Cancel" and a solid dark blue button labeled "Send".

Cleaning and Maintenance

Replace batteries as soon as the flashing symbol appears. Care should be taken to not get moisture in the internal circuitry or inside the battery compartment.

1. Clean your device before use.
2. The case and lead wires can be cleaned by wiping with a damp cloth and a solution of mild soap and water. Wipe dry. This must be done when the device is switched off and the earclip electrode is not connected to the unit.
3. **Do not** immerse the device in water.
4. **Do not** use any cleaning solution other than soap and water.

Testing Parasym

Parasym can be tested by making sure the batteries are in the device correctly, pressing the power button where the LCD screen should turn on and remain on.

Testing the Electrode

The electrode can be tested before each treatment session with the standard sensory and therapeutic threshold protocol found in the Quick Start Section. Stimulation should be a constant tingling or pulsing sensation. If this is intermittent, there may be a fault in the lead. If there is a fault or if the electrode is found to no longer work, please contact Parasym Support.

Key points to note

- Do not raise the stimulation Intensity level to a level where there is pain or discomfort on the tragus.
- For safety reasons, only use alkaline batteries in the device.
- Turn Parasym off before applying or removing the electrode.
- Make sure the earclip is plugged firmly into Channel 1 (the left channel). Make sure that Intensity is set on Channel 1 (the left side of the display).
- To help take the weight off the connection and increase mobility, you can arrange the lead behind your neck and over the right shoulder (as shown in the image on page 8).

Note: the safety and efficacy of the Parasym device has not been established in individuals with: Implantable medical devices, a history of cardiac disease, diagnosed narrowing of the arteries (carotid atherosclerosis), bradycardia (an abnormally low resting heart rate), pregnant women and pediatric patients.

Discontinue use if you experience:

- Lightheadedness, dizziness, chest pain, or excessive skin irritation

Reactions such as irritation at the stimulation site are rare. If this does occur, and becomes unpleasant, stop the stimulation. The irritation or discomfort should cease shortly after stopping stimulation. If skin irritation persists, discontinue use and consult your doctor.

Original Accessory

The unit must be used only with the original type of accessories.
Replacement earclip electrodes are available from your supplier.

List of Accessories:

- 2 X 1.5 volt AA Alkaline
- 1 X earclip electrode (Model: PREW)

Parasym Specification

Model:	Parasym PK01
Output:	Maximum 36 mA (average value/Pulse Width100 μ S) across 500 Ohm load, RMS Value 6.08mA
Pulse Width:	From 50 μ S to 250 μ S adjustable
Pulse rate:	From 1Hz to 30Hz Adjustable
Waveform:	Parasym Proprietary
Mode:	CONST—Constant Stimulation
Treatment Timer:	Continuous, 15min, 30min, 45min, 60min, 90min
Applied Part:	Earclip electrode: Gold plated metal
Electrode conductive area:	0.23 cm ²
Expected service life	5 years
IP classification	IP22

Caution:

If battery leakage occurs and comes in contact with the skin or eyes, wash thoroughly with lots of water and seek medical advice.

Warning:

Do not adjust or position the adaptor plug near the mains power outlet.

Don't use near active HF surgical equipment or the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

PRODUCT WARRANTY INFORMATION

This product is warranted to be free from manufacturing defects for 2 years from date of purchase.

This warranty is void if the product is modified or altered, is subject to misuse or abuse; damaged in transit; lack of responsible care; is dropped; if an incorrect battery has been fitted; if the unit has been immersed in water; if damage occurs by reason of failure to follow the written instruction booklet enclosed; or if product repairs are carried out without authority from Prasym Ltd.

Disposal of Waste Electrical and Electronic Products (WEEE)



One of the provisions of the European Directive 2002 / 96 / CE is that anything electrical or electronic should not be treated as domestic waste and simply thrown away. New products are now being marked with the symbol to remind you. Your local council or retailer will be able to tell you where your nearest facility is. The collection facilities will send items for treatment, recovery and recycling, so by using them you'll help to save resources and minimize the effects on the environment.

Symbols Explanation



Type BF Applied Part



Serial number



Refer to Instructions for Use



Compliance with WEEE regulations



Manufacturer / Supplier



IP22; Dust and rain protected.

Manufacturer / Supplier

Parasym Ltd, 4th Floor, 18 St. Cross Street, London, EC1N 8UN
care@parasym.co



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www.parasym.co