Nurosym™

Instructions for Use

hello

Welcome to your new Nurosym device

These instructions show you how to set up your Nurosym device, and get you on a schedule specific for you, that you can use every day.

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 of the suitability of the Nurosym device, consult your doctor before use.

The Nurosym Neuromodulation device is intended to provide non-invasive Auricular VNS delivered through the tragus. The Nurosym device is indicated for the treatment of symptoms associated with Depression, Anxiety, Pain and Insomnia.

Contents

Item Name	Quantity	Model / SKU / Version
Nurosym Device	1	II
Charging Cable	1	RC01
Earpiece	1	RE01R
Carry Case	1	RFC01
Instruction for use	1	3.2

Do not use accessories and detachable parts not specified or authorized by the manufacturer as it may cause damage to the unit or danger to the user or patients.

WARNINGS AND PRECAUTIONS

Warnings

- Read these instructions carefully to ensure proper use of the Nurosym 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 Nurosym 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.
- 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 earpiece 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.
- Contact your healthcare provider if your symptoms worsen.
- Electronic monitoring equipment, such as ECG alarms, may not operate properly when the Nurosym device is in close proximity while being used.

Contraindications:

- Patients who have undergone surgery to cut the vagus nerve (cervical vagotomy);
- Patients diagnosed with severe bradycardia;
- Patients with a permanent (that cannot be removed before using Nurosym) implanted metallic or electronic device or jewelry at or/ within 1 cm from the ear tragus ;

  Below are listed situations that are contraindications unless the patient receives a different medical opinion on the device use by their medical doctor and/or is under the opportune supervision from a medical doctor while using the device. If you fall under one of these categories, your doctor might advise whether, in your specific case, the device is safe to use, potentially following certain precautions or under specific supervision:

  - Patients with any implanted device (including electronic and/or medical devices) at the ear, heart (e.g. pacemakers*) or stimulating the nervous system (e.g. invasive vagus nerve stimulators);
  - Patients with known severe coronary disease or recent myocardial infarction (within 5 years);
  - Pediatric patients*;
  - Pregnant women**.

  * Both pediatric patients and patients with pacemakers have been enrolled in clinical studies with the Parasym device, and no side effects or interferences of any kind have been observed so far in the clinical setting.
  ** Pregnant women have not been studied in clinical studies.

Precautions

Before Use:

- You must read the Nurosym Instructions for Use before using Nurosym. 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 Nurosym support if you have any questions about how to use the device or require any further clarification of these Instructions.
- Only use Nurosym as described in these Instructions for Use or as otherwise directed by your HCP.
- Remove jewellry that may interfere with the electrode location (earrings etc.) before using Nurosym.
- 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 Nurosym with another person.

Do not use Nurosym 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 Nurosym away from water or other liquids.
- Keep Nurosym away from steam as moisture may damage the device.
- Store Nurosym 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 Nurosym support.
- 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 LED screen.

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

Side Effects Associated with Nurosym

Nurosym has the highest safety profile of VNS technology, with 0 serious adverse events reported in clinical study. Side effects are rare and typically resolve immediately after the stimulation is complete.The most common side effects include:

Application site discomfort
Application site irritation/redness
Tingling on the skin where the device is applied (paresthesia/dysesthesia)

Potential Risks and Complications associated with interact with the vagus nerve

In clinical studies, reported adverse effects for Nurosym are usually rare, mild and resolve shortly after treatment is completed. The following risks and complications have been associated with other devices that interact with the vagus nerve including surgically implanted devices, and may potentially occur with Nurosym:

- 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, authorised Nurosym distributor, or Parasym Ltd.

IF IN DOUBT CONSULT YOUR DOCTOR OR HEALTH CARE PRACTITIONER.

Environmental Conditions:

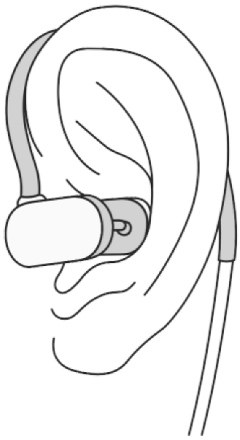
Temperature :	Operating: 5 ~ 40 ℃ Storage : -25 ~ 70 ℃
R.H.ambient :	Operating: 15% ~ 93% RH Storage : 0% ~ 93% RH
Altitude :	Operating: 700hPa to 1060hPA Storage : 500hPa to 1060hPA

At least 30 min is required for the device to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min is required for the device to cool from the maximum storage temperature between uses until it is ready for intended use.

Device Diagrams

Stimulator Unit

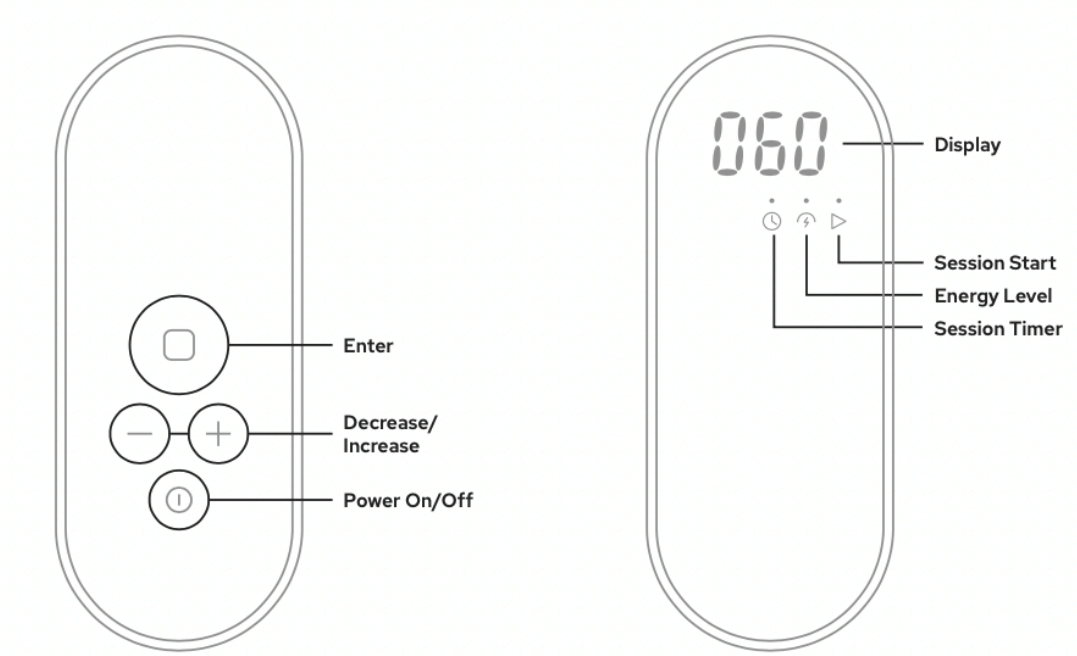
Earpiece electrode



Earpiece placement

Charging cable

Display and controls



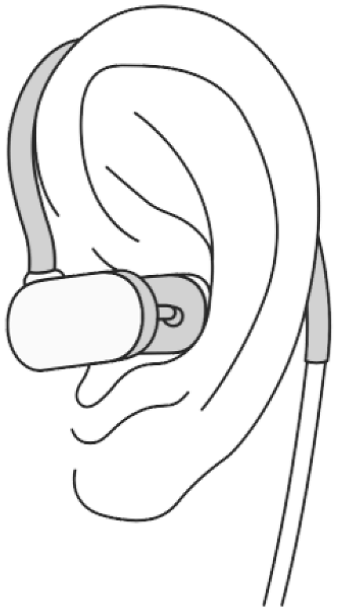
1. Plug charging cable into Nurosym Device

Make sure the device is fully charged before first use.

2. Insert earpiece lead into Nurosym Device

3. Clip the earpiece to the tragus of the left ear

Wrap the malleable wire behind the ear.



4. Choose your session time

Press and hold the power button for 3 seconds. The display will show the number of minutes for your session.

Notes: The treatment time is displayed. Adjust by pressing +/- and press ENTER to confirm session duration, you will then progress to choosing intensity level (Step 5)

5. Choose your intensity level

The display will show the intensity level.

A. Ensure the earpiece has a firm connection to the left tragus.

B. 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.

C. 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.

D. Each user's preferred Intensity level will vary and more Intensity is not necessarily better.

E. Once you find a comfortable level, press ENTER to begin your session. You may want to adjust the level again during your session, this is normal and can be done at any time (see 6.1).

6. Nurosym is on

The blue LED light indicates that the device is on and delivering current.

6.1 Changing Intensity during a session.

To change Intensity during a session:

Press any button to wake the device

1. Double-press the Enter Button to unlock the device.
2. Amend Intensity by +/- buttons.
3. Confirm by pressing Enter. This will resume the session.

Nurosym Mode

Nurosym is preset to the optimal mode for your treatment.

Reset Nurosym

1. Press any button to wake the device
2. Press and hold [power button] + [minus “-” button] for 5 seconds
3. The screen will flash twice. This indicates the device has been reset.

Session Time

Pressing any button will wake the device to show the display.

During a session, the display will show how long is left in minutes.

Here the display shows ‘30’ minutes remaining.

Pausing a session

1. Press any button to wake the device
2. Press the power button once. The rightmost LED will flash.

※*The remaining time shows the light turning off to the left as the treatment time decreases*

Here the display shows ‘30’, indicating there is 30 minutes left of a recommended 60 minutes session. All LEDs will be displayed at the beginning of the session, and will gradually decrease throughout the session proportional to the time remaining. When the device is paused, the rightmost LED will flash and the blue light will turn off to indicate no current being delivered.

The session will resume and the blue light will turn back on.

Battery Indicator

A fully charged battery should run for at least 7 hours.

The display will indicate a low battery with the below example.

When the device is powered on, ‘Lo’ will be shown on the display, with a single flashing LED to indicate low battery.

When the battery symbol on the LCD screen flashes, it is time to charge the battery.

Built-in rechargeable lithium battery specification:

Manufacturer: Shenzhen WeAction Electronics Co., Ltd

Model:WEL 703048

Rating: DC 3.7 V,900mAH

Battery precautions

Replacement of lithium or fuel cells can cause unacceptable risk.
If there is a problem with the battery, it must be returned to your supplier for repair.
This product is equipped with a Lithium-ion battery. Failure to follow these instructions could cause the lithium-ion battery to leak acid, become hot, explode or ignite and cause injury and /or damage:
Do NOT expose to temperatures over 60°C (140F)
Do NOT put, store or leave it near sources of heat, in direct strong sunlight, in a high temperature location, in a pressurized container or in a microwave oven.

Warning: Do not use accessories and detachable parts not specified or authorized by the manufacturer, doing so may cause damage to the unit or danger to the user or patients.

Common Intensity Questions

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

It is common for sensory thresholds to change throughout sessions 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 variables including but not limited to; time of day, skin conductivity and stress levels.

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 or for too long a period of time.

Warning: It is recommended not to use the device for more than 60 minutes at a 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 the unit 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.

The unit does not function at all
Check the device is fully charged.

Unit switches off unexpectedly
This is likely to be the power-save function. If the session has ended the device will power-off automatically. If the device is paused, it will power off automatically after 5 minutes.

There is no stimulus (simulation).

Check the intensity is set above zero.
Check the lead wire is inserted into the port correctly, firmly in the socket.
Check the position of the earpiece with the skin, ensuring both metal plates are firmly pressed against the skin.

Speak to one of our support team

If you have any questions, please contact support, we'll get right back to you.

Cleaning and Maintenance

Charge device as soon as the flashing symbol appears. Care should be taken to not get moisture in the internal circuitry or the device ports. No other user maintenance of the main unit is required.

1. Insure that the earpiece electrode is clean and free from scratches before use

NOTES: The earpiece provided can be reused, but only for a single patient.

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 earpiece is not connected to the unit.

3. Do not immerse the device in water.

4. Do not use any other cleaning solution than soap and water.

Expected Service life

Nurosym has been designed to last for more than 5 years, but is guaranteed for 2 years. Damage to the leads or earpiece is not covered by the warranty.

Lead life depends greatly on use. Always handle the lead with care.

The shelf life of electrodes is 3 years.

Testing the Device

The device can be tested by making sure the device is charged and pressing the power button where the screen should turn on and remain on.

Testing the Earpiece

The earpiece can be tested before each treatment session by slowly increasing the intensity until a tingling sensation is felt. There should be a constant tingling or sensation of stimulation. If this is intermittent, there may be a fault in the lead. If there is a fault or if the earpiece is found to no longer work, please contact Support.

Warnings:
No servicing/maintenance while the ME equipment is in use.
The patient can maintain the device and its accessories according to the user manual
Note: the safety and efficacy of the Nurosym device has not been established in individuals with: Implantable medical devices, 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.

Nurosym Specification

Battery: Power supply:	DC 3.7 V (built-in rechargeable lithium battery) DC 5 V;1 A (for charge only)
Waveform:	Nurosym proprietary waveform
Mode:	Preset 1
Treatment Timer:	Continuous, 1min - 60min
Applied Part:	Earpiece electrode
Expected service life	5 years
IP classification	IP22
Mode of operation	Continuous operation

Power supply
- Rated input voltage shall not exceed 250 V
- Classification of protection against electric shock: Class II
- The adapter needs to comply with IEC 60601-1, IEC 60950-1 or IEC 62368-1

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

Warnings:
Don’t use near active HF surgical equipment and 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 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Symbols Explanation

	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.
	Type BF Applied Part
	Refer to Instructions for Use
	Manufacturer
	On/off (push-push) Note: Each position: on/off is stable position
	CE Mark with Notified Body Reference 0197
IP22	Protected against access to hazardous parts with a finger, and the jointed test finger of 12 mm Φ, 80 mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5 mm Φ and greater. Protected against vertically falling water drops when the enclosure is tilted up to 15º. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15'' on either side of the vertical.
	Serial Number: indicates the manufacturer's serial number so that a specific medical device can be identified.
	Batch code: indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the authorized representative in the European Community

Service and Maintenance

- The patient is an intended operator.
- Do not service and maintain the device while in use with a patient.
- Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
- The user must not attempt any repairs to the device or accessories. Please contact the retailer for repair.
- Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

  WARNING: Do not modify this device without authorization of the manufacturer.
- Only our authorized service agents should carry out repairs to the device.

European Representative
Parasym OÜ,
Majaka 26
11412 Tallinn, Estonia
legal@parasym.co

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