

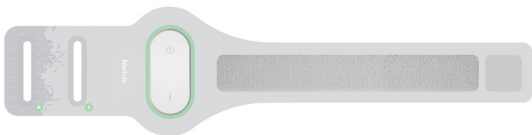
Nerivio®

QuickStart Guide



theranica

Getting Started



Thank you for using **Nerivio**® remote electrical neuromodulation device. Your new device will help with the relief of your migraine symptoms. Before using the device, review all the product instructions and the interactive tutorials in the **Nerivio**® app. The QuickStart guide and the interactive tutorials give you quick access to important aspects and limitations of the device. You should keep the QuickStart guide available for future reference. The user manual includes all safety information and instructions for use. The user manual is available in the help screen of the Nerivio app or at **www.nerivio.com**. A printable copy of the user manual can be requested by contacting Theranica at **support@nerivio.com**. Refer to **www.nerivio.com** for a complete listing of clinical data and adverse events information.

NOTE: **Nerivio**® is a prescription device. Use this device only if you have a valid prescription and after consulting with your health care professional. Use the device according to the indication for use described in this guide.

Conditions for Use

Indication for use

The **Nerivio**® is indicated for acute and/or preventive treatment of migraine with or without aura in patients 12 years of age or older. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura for acute treatment, or every other day for preventive treatment.

Contraindications (Who should not use the device?)

1. The device should not be used by people with uncontrolled epilepsy.
2. The device should not be used by people with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device. Such use could cause electric shock, electrical interference or serious injuries or medical conditions.

Important Safety Information



Warning: indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death.



Do not attempt to perform any procedure before carefully reading all the instructions



Do not use the device on the heart, chest, neck, head or any other body location other than the upper arm, because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure



Do not use the device over skin conditions, such as open wounds or rashes, or over swollen, red, infected or inflamed areas or skin eruptions or fragile skin on your upper arm at the treatment location



Do not share the device with other people. The device is intended to be used by a single person to avoid skin disease or any transmissible disease



Do not disassemble, crush, incinerate or short-circuit the battery. This could cause a fire, injury, burns, or other hazards



Precaution: indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.



The device has not been evaluated for use in people with congestive heart failure (CHF), severe cardiac or cerebrovascular disease



Federal Law restricts this device to sale by or on the order of a physician



The device should not be applied over areas of skin that lack normal sensation. If one upper arm is insensitive to physical sensation, use the other upper arm



Do not use the device over or in proximity to cancerous lesions



Do not use the device on an arm with a metallic implant. In such cases, consider using it on the other upper arm

- ! Do not use the device simultaneously with another electrical stimulation device
- ! Do not use the device while driving, cycling, or operating any vehicle or machinery
- ! Do not use the device on wet skin or when bathing, showering, during exercise, while sweating or in high humidity
- ! Do not use the device in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms)
- ! Do not use the device in a magnetic resonance imaging (MRI) environment
- ! The long-term effects of chronic use of the device are unknown
- ! The device has not been evaluated for use in pregnant women and people less than 12 years of age
- ! Do not use the device past expiration date
- ! Check the device for damages, debris and contamination. If the device is damaged, dirty or has any debris, please do not use it and contact the manufacturer's customer support
- ! If the device was damaged, do not touch exposed electronics
- ! Do not use the device if the electrodes become significantly dirty or damaged
- ! Keep the device under the recommended environmental conditions specified in user manual to avoid any damage to the device
- ! Do not start a treatment before placing the device on your arm
- ! In case of device malfunction, remove the device from your arm and contact customer support
- ! It is recommended that your smartphone will be protected by a password (or other security mechanism) to refrain from unwanted people to activate the device
- ! Interference to Bluetooth connectivity may occur in the vicinity of equipment emitting RF (e.g. microwave, routers, Wi-Fi devices)

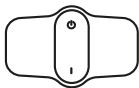
- ❗ To minimize moisture loss, when unused, the electrodes should be covered with the provided protective film and the device should be stored in its original package
- ❗ Do not expose the device to moisture and/or high humidity. If exposed, dry the device as soon as possible
- ❗ Before or after a treatment, rub the electrodes with your finger using a drop of water to improve their adhesiveness
- ❗ Do not clean the device with soap, alcohol, submerge in water, or scrub with abrasive material
- ❗ Do not disassemble or modify the device by yourself
- ❗ Do not attempt to recharge or detach the battery
- ❗ Keep the device out of the reach of infants, toddlers, children and pets
- ❗ The device uses Bluetooth technology; it may therefore be interfered by other equipment utilizing RF technology, even if the other equipment complies with CISPR emission requirements
- ❗ The device should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the Nerivio® should be observed to verify normal operation in the configuration in which it will be used
- ❗ Do not use devices which generate strong electrical or electromagnetic fields, near the Nerivio® device. This may result in incorrect operation of the device and create a potentially unsafe situation.
In order to reduce the risk of EM interference, it is recommended to keep a minimum distance of 30 cm (12 inches) between the device and other electromagnetically radiating devices. Verify correct operation of the device in case the distance is shorter. During the immunity tests the device operated normally

Adverse Reactions

During the treatment you might experience a temporary sensation of warmth, local tingling, numbness in the arm, pain in the arm, redness of the skin, or muscle spasm, which should disappear shortly after the end of the treatment.

Consult with your healthcare professional if these reactions persist, if the migraine headache worsens, if an allergic reaction occurs, or if there are any other concerns. If a serious incident that is related to the device has occurred, please report it to the manufacturer and the competent authority of the Member State in which you are established.

Package Contents

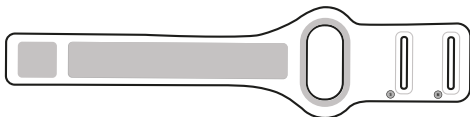


1 **Nerivio®** device.

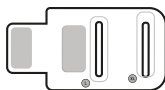
The device is good for 18 treatments



1 Carrying bag



1 Armband



1 Armband extension

What Does the Treatment Feel Like?

The device transmits electrical pulses. You may feel a strong sensation at first, but it will typically fade to a comfortable level after a couple of minutes.

Preparation

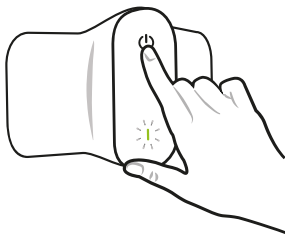
Step 1: Installing the Nerivio app

1. Download and install the **Nerivio®** app from the App Store or Google Play.
2. Open the app and create an account (or sign in). Follow the app instructions.



Step 2: Connecting the device to the app

1. Enable Bluetooth on your smartphone.
2. Turn on the device. A slow flashing (mostly on) green light indicates the device is on.
3. Connect the device to the app using the app instructions. The device and the smartphone should be in proximity of less than 1 inch (~2.5 cm). You will be notified when a connection has been established. A fast flashing green light indicates that the device is connected to the app.



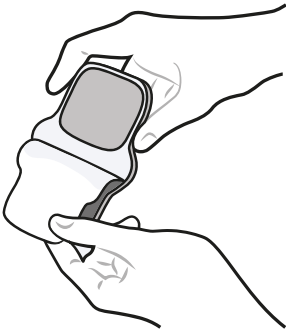
Using Your Device

Step 1: Place the device on your arm and wrap the armband around it

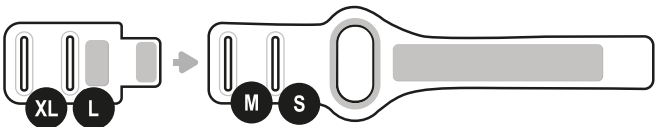


Remove tight-fitting clothing or tight rolled-up sleeve from one of your arms. Do not place the device on cloths. The device should be applied on normal, intact, clean, dry, healthy skin.

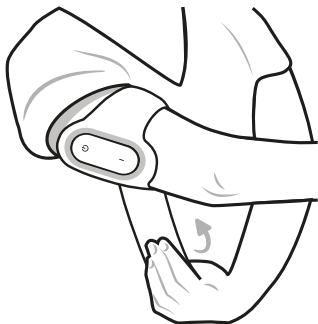
1. Turn on the device.
2. Remove the protective film and save it for device storage.
3. Place the device on the outer upper arm. The device should be located midway between the elbow and the shoulder.



4. Adjust the armband to your size. There are 4 sizes you can choose from (S, M, L, XL). Attach the extension to the armband for L and XL sizes.



5. Insert the strap to the buckle of your size.
6. Wrap the armband around the device on your arm and fasten the strap. The armband will improve the contact between the device and your skin.



Step 2: Start a treatment session

For effective results, the treatments should be initiated as early as possible and always within 60 minutes of migraine headache or aura onset, or every other day for preventive treatment.

1. Make sure the device is on, open the app and confirm the device is connected successfully.
2. Touch 'Start'. The treatment has now begun and will stop automatically after 45 minutes. A slow flashing (mostly off) green light indicates that the device is stimulating.
3. Set the treatment intensity level so it feels strong yet comfortable and not painful. This is important to maximize the clinical benefit of the treatment.
 - Start increasing the stimulation intensity using the '+' button.
 - When the stimulation is painful and/or uncomfortable, reduce the intensity to the previous level using the '-' button.



4. During the treatment, questions on your migraine symptoms will be automatically displayed. You can record your migraine symptoms in the diary or skip this by touching 'Skip'.
5. You can pause the treatment session for 5 minutes by touching the pause button. Touch 'Resume treatment' to continue or 'Stop treatment' to stop the current treatment session. Each session can only be paused 3 times.
6. To stop the treatment, touch the pause button and then touch 'Stop treatment'.
7. When the treatment is completed, remove the armband and the device from your arm. The device will turn off automatically one minute after the session has ended (the green light will turn off).
8. Apply the protective film on the electrodes and place the device in its box or in the travel bag to store it for next use.

Maintenance & Cleaning:

The device can be cleaned with a dry cloth (except for the electrodes).

If the electrodes begin losing adhesion, gently rubbing one or two drops of water onto the gel surface may extend usage.

To minimize moisture loss, when unused, the electrodes should be covered with the provided protective film and the device should be stored in its original package.

The armband can be washed with water and soap only. No bleach products should be used. Do not tumble dry. Do not iron.

Product Performance:

Pulse Width: 400 μ S (max)

Current: 40 mA (max)

Freq.: 100-120 Hz (max)

Bi-phasic symmetrical waveform

Need Help?

For troubleshooting or if you require further assistance, please refer to the user manual in the help screen of the app or contact customer support:

support@nerivio.com

1-937-637-4846 or 1-866-637-4846

www.nerivio.com
support@nerivio.com



Smartphone requirements:

- At least 4.7 inches multi-touchscreen with at least 720x1280 pixels resolution
- CPU of 1GHz or more, internal memory of 2GB or more, and internal storage of at least 16GB
- Connectivity capabilities of BT4.0 or above
- Supported operating systems – iOS versions 13 or newer and Android versions 7 or newer.











Please refer to **www.nerivio.com** for the most updated smartphone requirements

Storage conditions:

Temperature range: 50°F-80.6°F (+10° to +27° C)

Relative humidity range: 40%-50%, with no condensing

Atmospheric pressure: 70-106 kPa

 Nerivio® device Model FGD000075	  
 Theranica Bio-Electronics LTD. 4 Ha-Omanut St., Netanya 4250438, Israel	   
FCC ID: 2A0H8-NM	CEpartner4U BV Esdoornlaan 13, 3951 DB Maarn, The Netherlands
Battery: 1 x Li-MnO2 3.0V, 1.2Ah	
Battery Max. Voltage: 3.3V 	
Device Max. current: 40mA	
Frequency: 100-120Hz	
LBL-NM-0010-X.Y	



Made in Israel

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Theranica reserves the right to revise this guide and make changes in its content without notice. For complete, up-to-date terms, conditions and warnings please refer to the user manual or contact us at **support@nerivio.com**
Product warranty information can be found at **www.nerivio.com**