

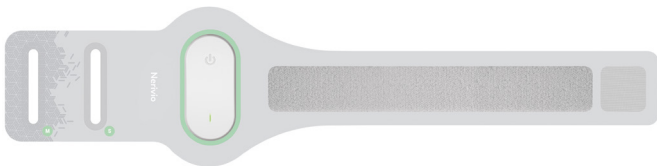
# Nerivio™

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.theranica.com](http://www.theranica.com)**. A printable copy of the user manual can be requested by contacting Theranica at **[support@theranica.com](mailto:support@theranica.com)**.

**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 treatment of migraine with or without aura in patients 18 years of age or older who do not have chronic migraine. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura.

### Contraindications (Who should not use the device?)

1. The device should not be used by people with congestive heart failure (CHF), severe cardiac or cerebrovascular disease.
2. The device should not be used by people with uncontrolled epilepsy.
3. 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

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

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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

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**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.

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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

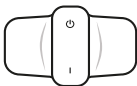
- ! Do not use the device simultaneously with another electrical stimulation device
- ! Do not use the device while driving, cycling, or operating any vehicle or machinery
- ! Do not use the device on wet skin or when bathing, showering, during exercise, while sweating or in high humidity
- ! Do not 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 18 years of age
- ! The safety and effectiveness of the device have not been evaluated in people with chronic migraine
- ! The safety and effectiveness of the device have not been evaluated for the preventive treatment of migraine headache
- ! Do not use the device past expiration date
- ! Check the device for damages. If the device is damaged, return it to the manufacturer or contact 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 in a dry environment. Moisture may damage 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

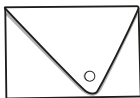
## Adverse Reactions

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

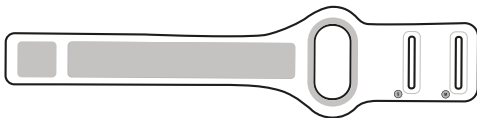
# Package Contents



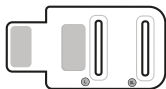
1 **Nerivio™** device. The device is good for 12 treatments



1 Travel 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

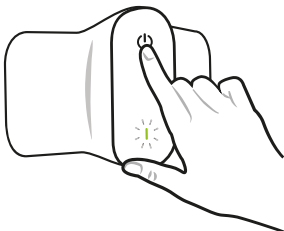
### Step 1: Installing the Nerivio app

1. Download and install the **Nerivio™** app from the App Store or Google Play.
2. Open the app and sign in or create an account. 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.



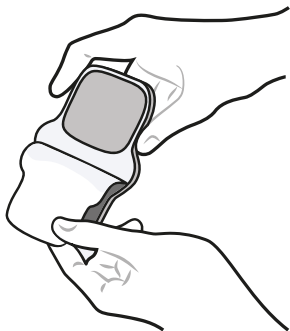
# Using Your Device

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

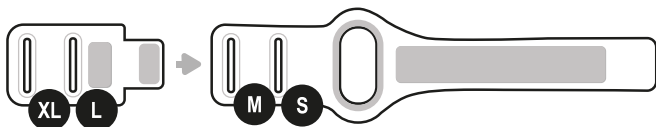


Remove tight-fitting clothing or tight rolled-up sleeve from one of your arms. Do not place the device on cloths. The device should be applied on normal, intact, clean, dry, healthy skin.

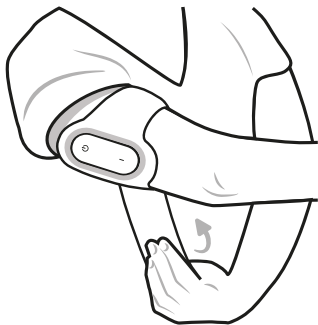
1. Turn on the device.
2. Remove the protective film and save it for device storage.
3. Place the device on the outer upper arm. The device should be located midway between the elbow and the shoulder.



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.

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.

## Additional App Features

### Diary:

The diary screen enables you to review your treatments history and report additional headaches.

### More:

The more screen provides access to some of the technical aspects of the app such as:

- **View profile** - Select this to view your account details
- **Help** - Select this to review the Nerivio user manual and to view instructional videos that explain how to treat a migraine attack with the device.

### 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 at

**support@theranica.com**

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

[www.theranica.com](http://www.theranica.com)  
[support@theranica.com](mailto:support@theranica.com)

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Designed, developed and manufactured by Theranica Bio-Electronics LTD.  
4 Ha-Omanut St., Netanya 4250438, Israel

Made in Israel

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