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Nervio Infinity

QuickStart Guide

Getting Started

Before using the device, please review all the product instructions and the interactive tutorials in the Nervio app. The QuickStart Guide and the interactive tutorials give you access to important aspects and limitations of the device. You should keep the QuickStart Guide available for future reference.

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



Conditions for Use

Indication for use

- ✓ The **Nervio Infinity** is indicated for acute and/or preventive treatment of migraine with or without aura in patients 8 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

Note - Children under the age of 12 should be guided by their parents the first time they use the device.

Contraindications (Who should not use the device?)

- ✗ The device should not be used by people with uncontrolled epilepsy.
- ✗ 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, immerse in water, crush, expose to a violent vibration, incinerate, over-charge, overheat or short-circuit the battery or the device. This could cause a fire, injury, burns, or other hazards
- ⚠ Use only SV, 500 ma DC, class II, IEC 60601-1 certified AC wall adapter/charger with two means of operator protection to charge the device. Avoid using computer's (or other equipment's) USB port to charge the device as it may not meet the required charger specification
- ⚠ Do not place the device on a body without attaching the electrodes and do not touch the device contacts when it is operational
- ⚠ Do not charge the device when placed on the body or during treatment

Precaution

Indication for use

- ⚠ **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
- ⚠ 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
- ⚠ Please consult your HCP if you are pregnant or intend to get pregnant prior to using the device
- ⚠ The device has not been evaluated for use in people less than 8 years of age
- ⚠ Do not use the electrodes past expiration date and recommended number of uses
- ⚠ Check the device and its accessory for damages, debris and contamination
- ⚠ If the device or accessory is damaged, or electrode is 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 before replacing the electrodes. If the electrodes become significantly dirty, damaged or used for over 18 treatments
- ⚠ 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 connecting electrodes and securing 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 activating the device

Adverse Reactions

Indication for use

- ⚠ 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 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 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 Nervio Infinity 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 Nervio Infinity 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

6 EASY STEPS TO MANAGE YOUR MIGRAINE WITH NERVIO INFINITY

STEP 1 Download the Nervio app

- Download the Nervio app on your smartphone by scanning the QR code or by visiting the App Store/Google Play. (Refer to FAQ at www.nervio.com for smartphone requirements.)
- Sign up and create your Nervio account.

STEP 2 Pair the device to the app via Bluetooth

- Enable Bluetooth on your smartphone.
- Turn on the Nervio Infinity device. You should see a green light flashing every 2 seconds on your device (a faster flash or no light at all indicates the battery is low or empty). The device and the smartphone should be in proximity of less than 1 inch (2.5 cm).
- Tap "Connect" when you see the prompt on your smartphone screen.

STEP 3 Sync the refill unit to the app via NFC

- Make sure NFC is enabled on your smartphone.
- Take the refill unit out of the Nervio Infinity Refill pack and place on a flat surface. Make sure you save the refill pack for storage.
- Locate the NFC tag on the refill unit and tap your smartphone on the NFC tag.
- Make sure you receive on-screen confirmation that the app has detected the NFC.

STEP 4 Place the refill unit on your arm

- Remove the protective liner from the refill unit. Make sure you save the protective liner for refill unit storage - each refill unit is good for up to 18 treatments.
- Stick the refill unit on the outer side of your upper arm. The refill unit should be located midway between the elbow and the shoulder.

STEP 5 Place Nervio Infinity and slide the armband over your arm

- Secure the Nervio Infinity device inside the armband.
- Adjust the armband to your size by inserting the strap in the appropriate size slot. To expand the armband, use the armband extensions.
- Slide the armband with the device on your arm and place on the refill unit. You should hear a click when the device is attached properly to the refill unit pins. Then, fasten the strap.

STEP 6 Start treatment and set your personal intensity

- Start treatment by pressing the 'Start' button in the Nervio app.
- To find your personal intensity, gradually increase the stimulation intensity using the 'Plus' button.
- Keep increasing until the stimulation is no longer comfortable.
- Now, decrease 15-20% down using the 'Minus' button.

TIP - the intensity level should feel strong, yet comfortable and not painful.

What Does the Treatment Feel Like?

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

During the Treatment

- Both acute and preventive treatments are 45 minutes.
- During the treatment, questions regarding your migraine symptoms will be automatically displayed. You can record your migraine symptoms in the diary or skip this by touching 'Skip'.
- You can pause the treatment session up to 5 minutes by touching the 'Pause' button in the middle of the treatment screen.
- Touch 'Resume treatment' to continue or 'Stop treatment' to stop the current treatment session. Each session can be paused only 3 times.
- To stop treatment, touch the 'Pause' button and then press 'Stop treatment'.

After the Treatment

6. When the treatment is complete, remove the armband, the device, and the refill unit from your arm.

TIP - the device will turn off automatically several minutes after the treatment has ended (the green light will turn off).

- Apply the protective liner on the reusable refill unit. Place the refill unit back in the Nervio Infinity Refill pack and place the device in its box or in the travel pouch to store it for next use. Be sure to zip the refill pack closed to help maintain the integrity and lifespan of the unit.

- Tips for Consecutive Treatments:** At the end of an **acute** treatment, if you feel that an additional treatment is required, wait at least 30 minutes before the next treatment. If you administer subsequent treatments, it is recommended to switch arms in between adjacent treatments, to reduce the likelihood of skin redness/rash or heat sensation on the skin. There is no need nor value in administering a total of more than 6 treatments on the same day.

Maintenance & Cleaning

The device can be cleaned with a dry cloth (except for the refill unit). The device can be stored in the travel pouch or the original package. The device software can be updated over the air (OTA) for cybersecurity and other patches. Refer to the user manual at www.nervio.com for further details.

Refill Unit: Every refill unit is good for up to 18 treatments. Replace the refill unit if it is damaged, dirty, or expired. The lifetime of the refill unit varies depending on skin conditions, skin preparation, storage, and climate.

To reduce the risk of the hydrogel running, keep the refill unit horizontal in the Nervio Infinity Refill pack between treatments. The refill unit should be re-sealed and stored between treatments in the Nervio Infinity Refill aluminum pack. If the electrodes lose adhesion, gently rub a drop or two of water on the gel. Wait 20-30 minutes for the water to absorb, then cover with the protective liner. Repeat as needed if the adhesion isn't restored.

Charging the Device

The device should be charged before your treatment to at least 15% of the battery charge. Please use the provided USB cable to charge the device.

TIP - the device battery capacity can be read via the app.

*Power adaptor is not provided

To charge, please follow these steps:

- Connect the cable on one end to a USB power adaptor with type A output.
- Connect the other end to the type C charging port on the device.
- Charge until a green light appears on the device, indicating the charge is complete and the battery is full.

TIP - a full charge cycle is recommended for the first time and may take 3.5-4 hours. However, a 30-minute charge is sufficient for at least one treatment.

For additional information regarding battery and charger, refer to the full user manual.

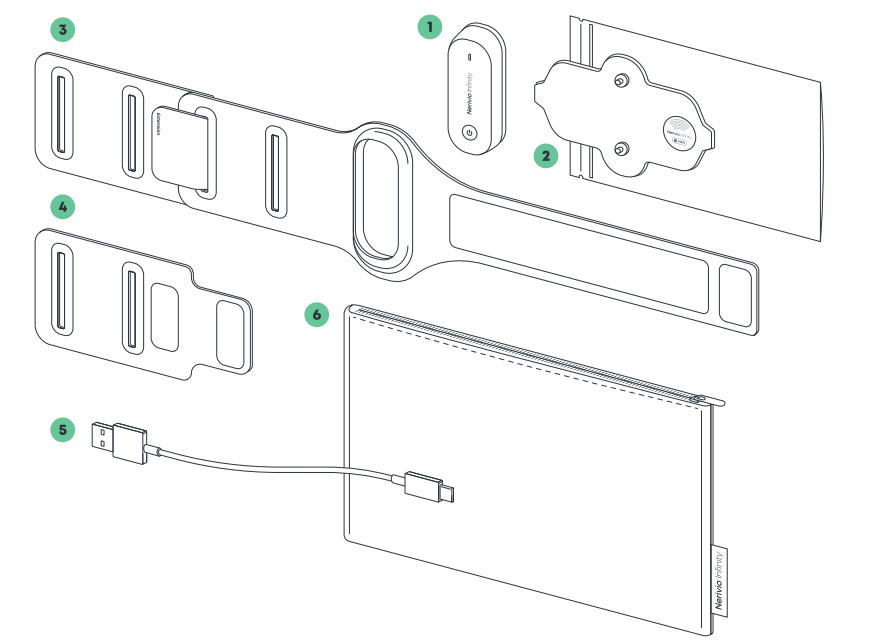
Product Performance

Pulse Width: 400 µS (max) Current: 40 mA (max)
Freq.: 100-120 Hz (max) Bi-phasic symmetrical waveform

The user manual is available in the help screen of the Nervio app or at www.nervio.com. A printable copy of the user manual can be requested by contacting Theranica at support@nervio.com. Refer to www.nervio.com for a complete listing of clinical data and adverse events information. The user manual includes all safety information and instructions for use.

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@nervio.com | 1-937-637-4846 or 1-866-637-4846



- 1 Nervio Infinity device
- 2 Nervio Infinity Refill pack
- 3 Armband
- 4 Armband extensions
- 5 USB charging cable
- 6 Travel pouch

Smartphone requirements:
Please refer to FAQ at www.nervio.com for the most updated smartphone requirements

Storage conditions:
Temperature range: 50°F-80°F (10° to 27° C). Relative humidity range: 40%-70%, with no condensing. Atmospheric pressure: 10-106 kPa

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