theranica

Nerivio® Infinity

A wireless non-invasive rechargeable neuromodulation device for treatment of migraine

USER MANUAL

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1. INTRODUCTION

1.1. ABOUT THIS MANUAL

This manual provides the information necessary for the user to effectively use the Nerivio Infinity device.

- Do not attempt to perform any procedure before carefully reading all instructions.
- Always follow product labeling and the manufacturer's recommendations.
- For any inquiry, please contact customer support at support@nerivio.com.

1.2. PRODUCT OVERVIEW

Nerivio Infinity is a durable, wearable, battery-powered medical device for the acute and/or preventive treatment of migraine with or without aura in patients 8 years of age or older. The Nerivio Infinity device is controlled by a mobile application. The device is intended for self-administration in a home environment.

The device is worn on the upper arm and transmits transcutaneous remote electrical nerve stimulation (REN) by applying weak electrical pulses that invoke conditioned pain modulation (CPM) to inhibit migraine pain. Nerivio Infinity is intended for self-administration at the onset of a migraine episode for acute treatment or every other day for prevention.

The Nerivio Infinity system includes several main components:

1. The Nerivio Infinity device. The device shall be connected to a Refill unit (see item #2 below) and both components are then placed on the arm.
2. Nerivio Infinity Refill unit - electrodes pad kit. The refill unit shall be connected to the device to comprise a single functioning unit.
3. Armband and 2 extensions. The armband should be wrapped around the device on the arm to improve the contact between the device and the skin, to secure its location on the arm and to conceal the device for greater treatment discretion.
4. Travel pouch
5. USB charging cable, type A to type C.
6. Software mobile application (app).

The external side of the Nerivio Infinity device includes a power button and two-color LED indicator that signals various modes of operation. The internal side includes magnetic connectors to the electrodes that deliver neurostimulation signals. The armband secures the device in its location.

The device is controlled by an application which is installed on a smartphone. The application controls the device, retrieves operational records from the device and stores the data for further retrospective processing/reviewing.

The application enables the user to activate the stimulation, control the stimulation intensity, monitor the treatment duration and pause or stop the stimulation. The application

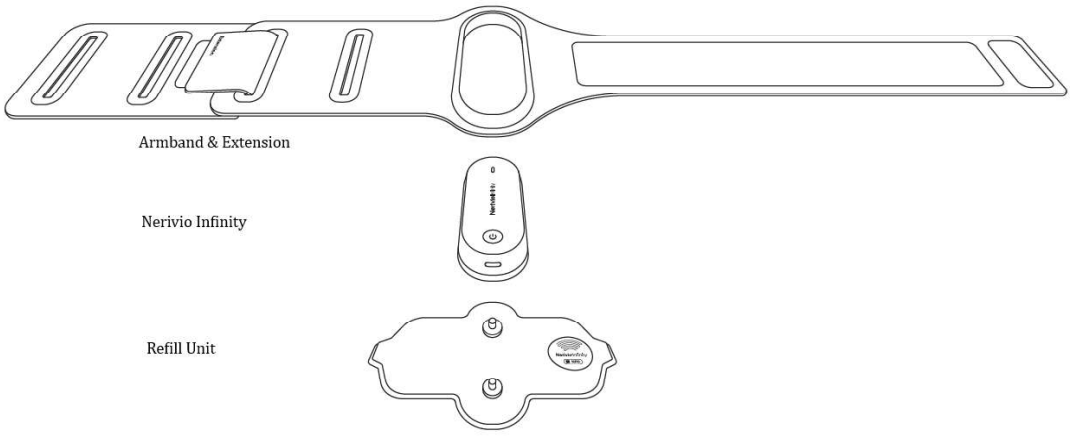
also provides notifications and indications on the connection status and on the remaining battery charge level. It also offers a migraine dairy feature which enables to track information about your migraine attacks.

1.3. PRODUCT FUNCTIONS

- The device is battery-powered; the battery is internal, integrated, and rechargeable.
- The device includes a Refill unit - replaceable electrodes pad accessory, providing electrical stimulation to the skin, with an NFC-tag attached to it. The NFC-tag is used for the electrode pad's authentication by the Nerivio app.
- The device is activated by a power button.
- An armband, which should be wrapped around the device on the arm to improve the contact between the device and the skin, to secure its location on the arm and to conceal the device to enable a discreet treatment. Two armband extensions are provided for larger arm sizes.
- An application (app) installed on a smartphone to control and monitor the treatment (as well as provide other features).

1.4. PACKAGE CONTENT

- 1 Nerivio® Infinity device
- 1 Nerivio Infinity Refill unit - electrodes pad in a reusable foil wrapper
- 1 Armband
- 2 Armband extensions
- 1 Travel pouch
- 1 QuickStart guide
- 1 USB type-A to USB type-C charging cable
- 1 Leaflet



2. GLOSSARY

App: Mobile application running on a smartphone

LED: Light-Emitting Diode

EMC: Electromagnetic compatibility

TENS: Transcutaneous electrical nerve stimulation

FDA: The Food and Drug Administration

FCC: The Federal Communications Commission

CPM: Conditional pain modulation

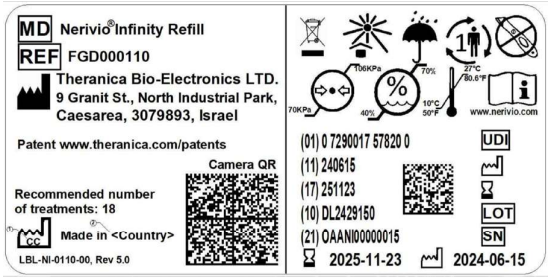
REN: Remote electrical neuromodulation

NFC: Near filed communication,

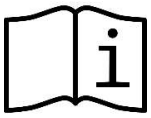
BLE or BT: Bluetooth low energy

3. LABELS AND SYMBOLS

Device labeling template	and	Refill unit (Electrodes pad) labeling template



*The label is for reference only

Symbol	Description
	Read and fully understand user manual before using this device.
 www.nerivio.com	Consult instructions for use or consult electronic instructions for use
	Compliance with FCC Federal Communications Commission Class B – certified for home use FCC identifier: [**2AOH8-NI**]
 YYYY-MM-DD	Manufacturer information and manufacturing date
 YYYY-MM-DD	Country code (**CC**) and date of manufacture
	Type BF applied part (IEC60601-1)

Symbol	Description
REF	Catalog number
SN	Serial number
IP22	Ingress protection rating
	Use by date - indicates the date after which the device is not to be used
	Keep dry
	Temperature limits
	Humidity limitation
	Atmospheric pressure limitation
	Caution
	Keep away from sunlight
	Special requirements for waste of electrical and electronic equipment (WEEE Directive). This product must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste per Directive 2012/19/EC in the European Union is required. Contact the manufacturer for details.
	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Symbol	Description
	Fragile, handle with care
	The device is in conformity with the applicable requirements set out in with European Union Medical Device Regulation (EU) 2017/745 and other applicable Union harmonization legislation
	Unique Device Identification. A series of numeric or alphanumeric characters that allows unambiguous identification of specific devices on the market
	Authorized Representative in the European Union
	Medical device
	The device may be used multiple times on a single patient
	Do not open with a sharp object
	NFC (Near Field Communication) technology

4. SAFETY

4.1. CONDITIONS FOR USE

4.1.1. INDICATION FOR USE

The Nerivio 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.

4.1.2. CONTRAINDICATIONS

I. The device should not be used by people with uncontrolled epilepsy.

II. 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.

4.2. WARNINGS, PRECAUTIONS AND ADVERSE EVENTS

The following icons are used throughout this user manual:

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

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.

Note: indicates important information regarding the use of the system

Warnings

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 class II, IEC 60601-1 certificated AC wall adapter/charger with two means of operator protection to charge the device. Avoid using computer's (or other equipment) 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 refill unit and do not touch the device contacts when it is operational.

Do not charge the device when placed on the body or during treatment

Precautions

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

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

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

Do not use the refill unit past expiration date and recommended number of uses

Check the device and accessories 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 refill unit, if the electrodes become significantly dirty, damaged or used for over 18 treatments
- Keep and use 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 refill unit 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 to activate the device
- Interference in the 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 refill unit 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 refill unit 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 Nerivio 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 Nerivio 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

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.

Refer to Nerivio family full information at the website http://www.nerivio.com/science/clinical-trials for a complete listing of clinical data and adverse events information

5. 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 seconds. You will then need to set the treatment intensity level by increasing it to the highest level that feels strong yet comfortable and not painful (see instructions below). If the sensation is uncomfortable or painful, you should decrease the intensity. If you experience hand numbness and/or muscle twitching, try changing the location of the refill unit on the arm.

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.

6. USING THE DEVICE

6.1. STARTING FOR THE FIRST TIME

Before using the device for the first time, the Nerivio app must be installed, and the device should be connected to the app. ***Make sure that Bluetooth connection on your smartphone is enabled.***

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

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

6.1.1. DOWNLOADING AND INSTALLING THE APPLICATION

Step 1: Verify that your smartphone/tablet is compatible with the Nerivio app (refer to frequently asked questions section (FAQ) at https://nerivio.com/faq for smartphone requirements).

Step 2: Download and install the Nerivio app via Google Play or App Store (depending on your operating system).

Figure 1 - Nerivio app Icon

Step 3:

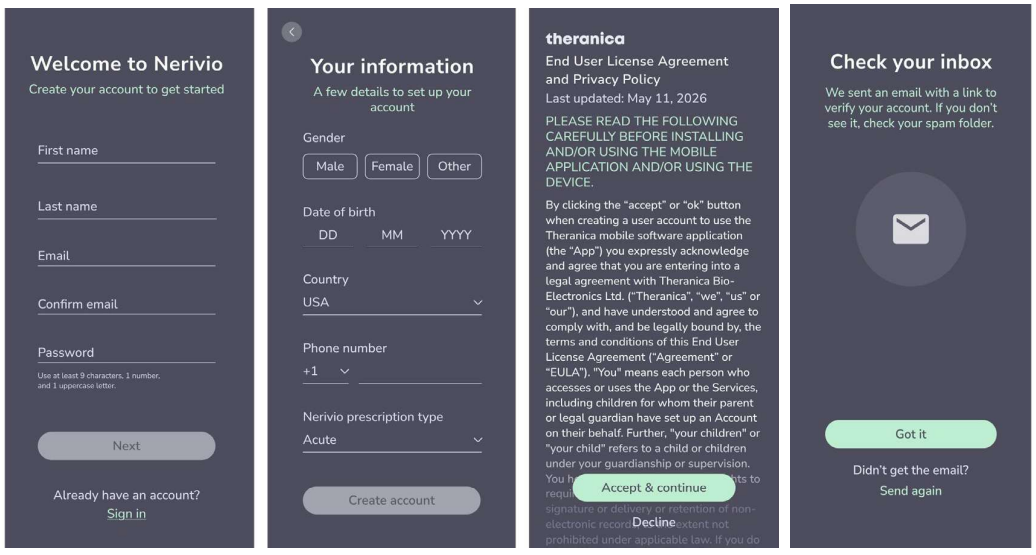
When you open the app for the first time, the **Welcome to Nerivio** screen is displayed. To create a new account, enter your first name, last name, email address, confirm your email address, and choose a password. Your password must contain at least 9 characters, including 1 number, 1 lowercase letter, and 1 uppercase letter. Tap **Next.**

If you already have an account, tap **Sign in** at the bottom of the screen and enter your email address and password. After you tap **Create account**, a verification email will be sent to the email address you entered. Open the email and tap the link to complete your account verification.

After verification is complete, a confirmation screen is displayed. Return to the Nerivio app to continue the account creation process. If you do not receive the email within a few minutes, check your junk or spam folder. Make sure your smartphone or tablet is connected to the internet. If needed, return to the app and tap **Send again**

On the following screen, enter the requested details including gender, date of birth, country, phone number and Nerivio prescription type. Tap **Create account** to proceed.

You will then be asked to review the End User License Agreement and Privacy Policy (the "EULA"). Tap **Accept & continue** to complete your registration. You must accept the EULA to use the app.



It is possible to open an account for a child under the age of 13, but the process needs to be initiated by an adult caregiver, in the following manner:

1. Adult (parent) creates their own account using the process above.
2. After logging in, go to “More” -> “Account Settings”. -> “Child accounts”
3. Start the process by clicking on “Add a child account” and follow the instructions there onwards.

Important note – connect the Nerivio Infinity device for the first time using the child’s App account and not the parent App account. The device is personal and intended for a single user. Once connected for the first time, the device can’t be transferred between different accounts.

6.1.2. CHARGING THE DEVICE

After receiving the device, the battery shall be charged to 100% for the first time. The full charge is indicated by a green color on the device LED when the charger is connected. Alternatively, the device’s battery capacity can be read via the App when the charger is disconnected. In addition to the remaining battery capacity percentage, the App will show battery status in red, orange or green colors. The red battery color indicates no sufficient capacity to run a treatment, orange is when the device can run a treatment, but close to depletion, and green indicates sufficient charge.

The charging process to 100% may take several hours. User may disconnect device from charger after 6 hours of charging. During a long storage period (over 3 months) the battery may discharge, and for preserving the battery life it is recommended to recharge the device to 50% capacity every 3-6 months. Avoid keeping the device with a discharged battery for a long time. Avoid overcharging the device. To extend the battery life, avoid exposing your device or charging it outside the recommended operational and storage conditions described in section 9.2.

Make sure that the device is charged before your treatment to the green battery capacity indication. The device shall not be charged when it is placed on the body or during treatment. The device cannot be charged when inserted into the armband.

Once the device is connected to a charger (automatic detection), the one and only possible operation at that time is charging. Any other function, including connectivity to the mobile application will be immediately terminated and the device will be powered off.

Use 5V, 500ma DC output, class II, IEC 60601-1 certificated AC wall adapter/USB charger with two means of operator protection. Avoid using computer’s USB port (or other equipment) as it may not always meet the required specification or provide required safety protections.

If you do not have a suitable adapter, please contact Nerivio Customer Support for assistance.

Use the provided USB type A to type C cable to charge the device, by connecting the cable on one end to the USB wall charger with type A output, and the other end to the type C charging port on the device, as shown here:

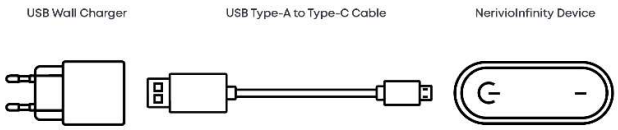


Figure 2 - Sequence of Connecting Device to Charger

When connected, the device LED indications are as follows:

Red light: Charging in progress

Green light: Charging is complete, and the battery is fully charged

A full charge cycle may take about 3 to 5 hours. However, a 30-minute charge typically brings the battery level to a sufficient level for at least one treatment. The Nerivio Infinity mobile application can be used to check the remaining battery charge. Unplug the device from the charger and connect it to the mobile application to monitor the remaining battery capacity.

Use only class II, IEC 60601-1 certificated AC wall adapter/charger with two means of operator protection to charge the device. Avoid using computer's (or other equipment) USB port to charge the device as it may not meet the required charger specification

Do not charge the device when placed on the body or during treatment

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

Keep and use the device under the recommended environmental conditions specified in user manual to avoid any damage to the device

During charging do not position the device so that it will be difficult to operate AC wall adapter or charger

If you do not have a suitable AC wall adaptor, please contact Customer Support for assistance

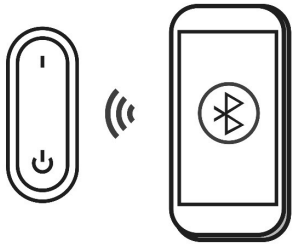
6.1.3. CONNECTING THE DEVICE TO THE APP FOR THE FIRST TIME

Step 1: Press the power button to turn on the device. A slowly flashing green light indicates the device is on.

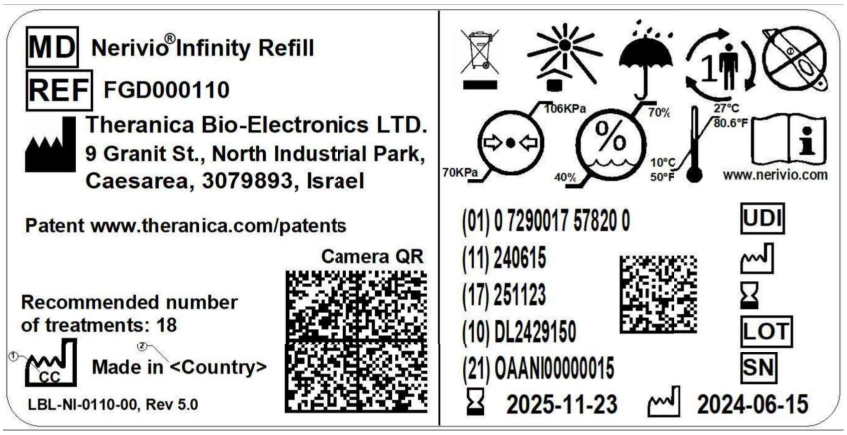
Check the device and its accessories for damage. If the device or accessory is damaged, return it to the manufacturer or contact customer support

Step 2: Enable Bluetooth on your smartphone. ***Before you begin, make sure the device is charged.*** Then, open the mobile app and connect the Nerivio Infinity device to the app using the app instructions. The device and the smartphone should be in proximity of 1 inch (~2.5 cm) or less. It is recommended not to place the device on the arm during the first connection to ensure close proximity to the phone. As you begin using the app, it may ask for additional permissions. Please allow these permissions so that the app works properly. You will be notified when a connection is established. A fast-flashing green light indicates the device is connected to the app.

Note that each device can only be associated with one user.

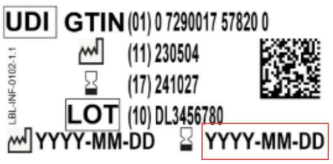


Step 3: Check the refill unit expiration date and recommended number of treatments on the label located on the protective film and on the package.



*The label is for reference only

Do not use the refill unit past expiration date or after recommended number of uses



Do not share the device. The device is intended for a single user.

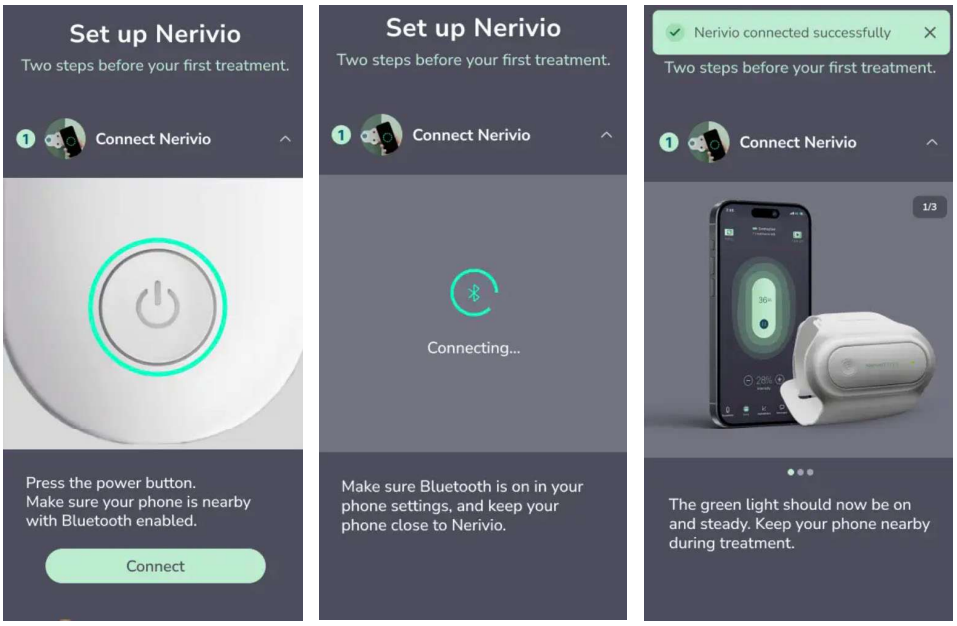
6.1.4. CONNECT NERIVIO

Note: The screens shown in this section are from the iOS version of the Nerivio app. The connection process is the same on Android, however the screens may appear slightly different.

When opening the app for the first time, or when the device is not detected, the app displays the **Set up Nerivio** screen. This screen includes two preparation steps: **Connect Nerivio** and **Wear Nerivio**.

Step 1: Connect your device

The **Set up Nerivio** screen displays the two steps required before your first treatment: **Connect Nerivio** and **Wear Nerivio**. Tap Connect Nerivio to expand the connection instructions on the start screen. Make sure Bluetooth is turned on in your phone settings and that your phone is close to the device.



Step 2: If the device is not found

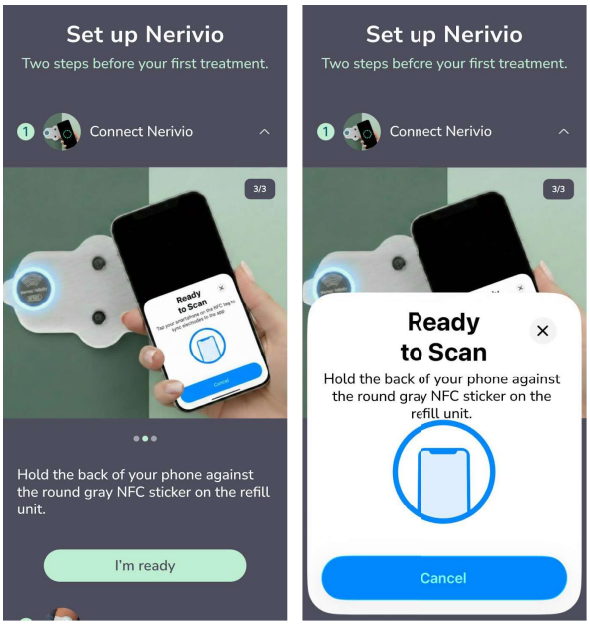
If the app displays **Nerivio not found,** confirm the following:

- The device is turned on
- Bluetooth is enabled on your phone
- Your phone is close to the device

Tap **Try again** to retry or call Nerivio Care for assistance.

Step 3: Scan the NFC sticker

Place the Refill unit on a flat surface with the round NFC sticker facing up. Tap **I'm ready**, then hold the back of your phone against the round gray NFC sticker on the Refill unit until the app confirms the scan. You may need to move your smartphone slightly over the refill unit to enhance the NFC connectivity.

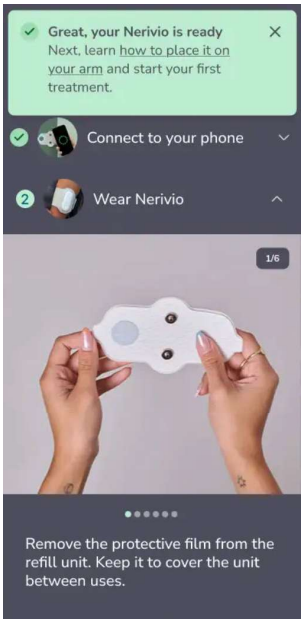


Step 4: If you are having trouble connecting

If the NFC scan fails, the app will offer an alternative. Tap Connect with QR code and use your phone camera to scan the QR code on the Refill unit sticker. If your Refill unit does not have a QR code, tap My refill unit doesn't have a QR code and follow the instructions.

Step 5: The device is connected and ready to wear

Once the connection is complete, a confirmation message is displayed and the **Wear Nerivio** guide opens. Follow the instructions to place device on your arm

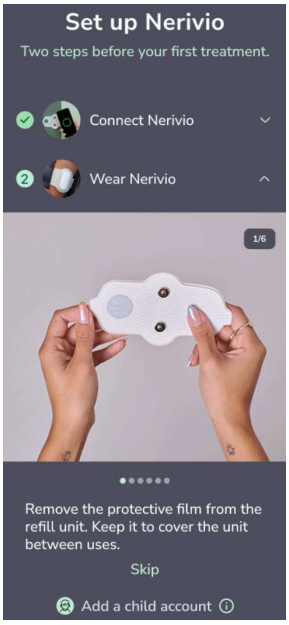


6.1.5. WEAR NERIVIO

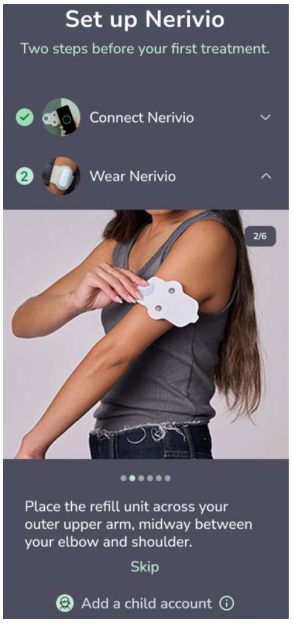
Note: The screens shown in this section are from the iOS version of the Nerivio app. The setup process is the same on Android, however the screens may appear slightly different.

Once your device is connected to the app, follow these steps to place it on your arm and start your first treatment.

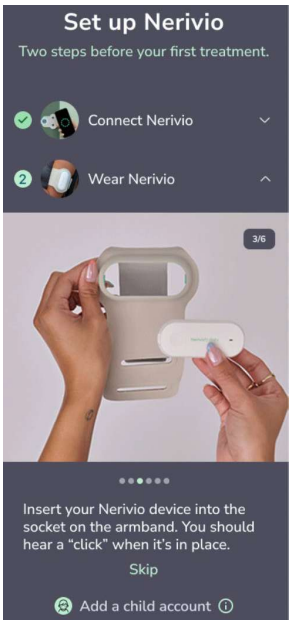
Step 1: Remove the protective film from the Refill unit. Save the film — you will need it to cover the adhesive side between uses.



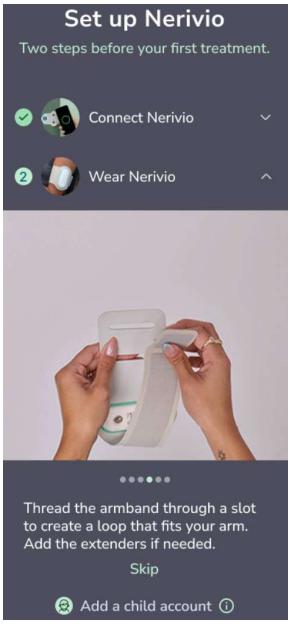
Step 2: Place the Refill unit across your outer upper arm, midway between your elbow and shoulder, with the adhesive side against your skin.



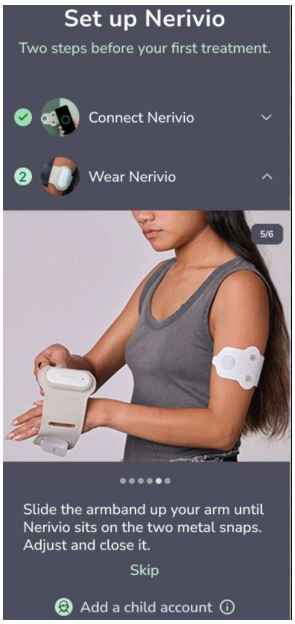
Step 3: Insert the Nerivio Infinity device into the socket on the armband. You should hear a "click" when it is in place.



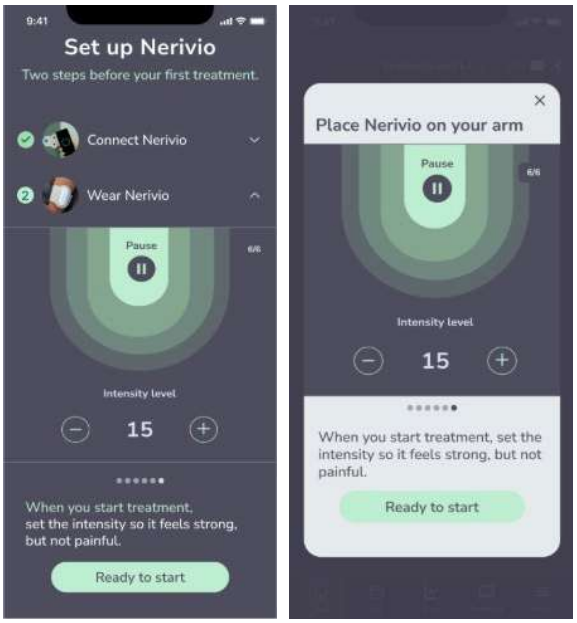
Step 4: Thread the end of the armband through the suitable slot to adjust the armband to your size and create a loop. Add the extenders if needed.



Step 5: Slide the armband up your arm until the Nerivio device is positioned over the two metal snap connectors on the refill unit. The armband should feel tight yet comfortable. Press the device into place, then adjust and fasten the armband so that it fits comfortably and holds the device securely on your arm.



Step 6: When you are ready, **tap Ready to start**. Treatment will begin at a default intensity of 12%. Once it starts, use the **"+"** and **"–"** buttons to increase or decrease the intensity until the stimulation feels strong but not painful, just below your pain threshold.



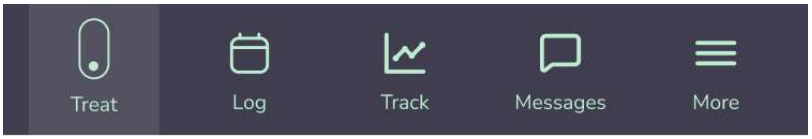
Step 7: When the 45-minute treatment is complete, the device will stop automatically. Remove the device and refill unit from your arm. Cover the adhesive side of the refill unit with the protective film and return it to the aluminum bag for storage between uses.

If no treatment is started within 10 minutes, it will shut down automatically. Turn it on again to start a treatment.

6.1.6. THE APP SCREENS

The app includes:

- Treat tab (home screen)
  - Refill button
  - GIER button
- Log tab
- Track tab
- Messages tab
- More tab



Refill button – displays the dispensing partner information for the provider that shipped your most recent Nerivio device. Use it when you want to refill a prescription or check an existing order.

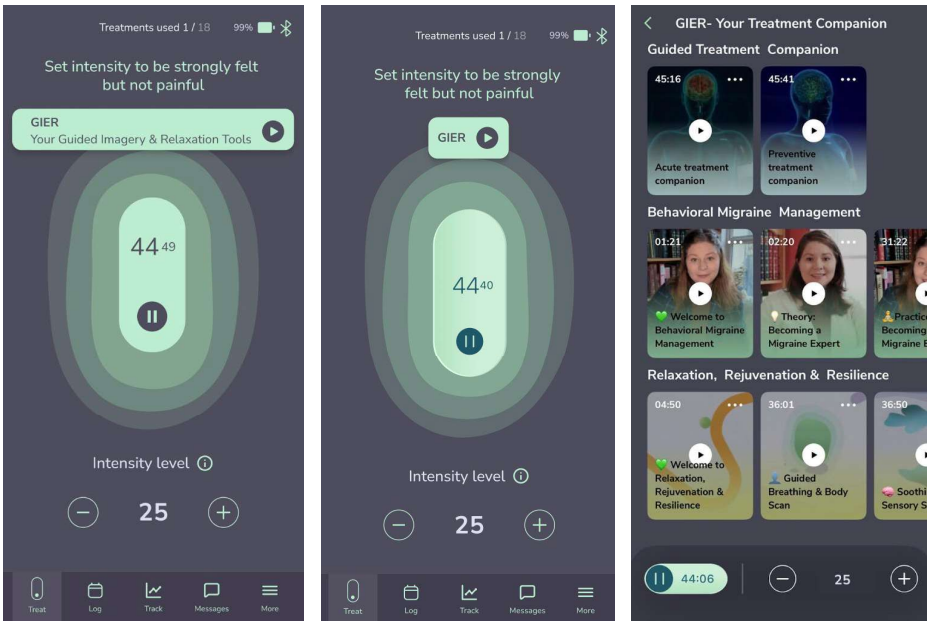
GIER button – the Guided Imagery, Education and Relaxation (GIER) feature is an audio-visual module of guided imagery, relaxation and education, designed for use in conjunction with the treatments. It includes a rich content library created by top headache psychologists. This content is available for free during your Nerivio treatments at home, on the go, and at your own pace.

- Educational Content:

Understanding your migraine can be powerful for migraine management. Discover what happens in your brain during migraine attacks and how Nerivio works to prevent and abort attacks. Learn why it's important to match your lifestyle to the needs of your brain.

- Guided Practices:

Harness the power of science-backed behavioral strategies to reclaim control of your migraine. Follow expert-led sessions designed to reduce pain, stress, and tension through guided imagery, breathing techniques, muscle relaxation, and more.



(A) **(B)** **(C)**

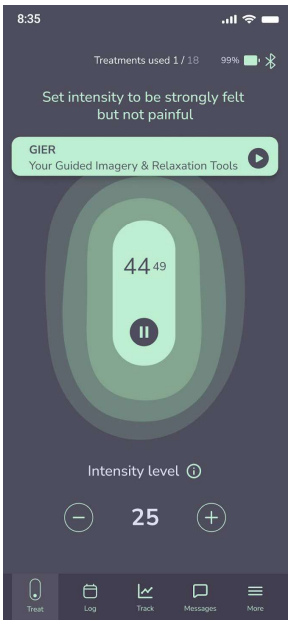
From left to right:

A) The GIER button is located at the top part of the treatment screen and is available a few seconds after the treatment starts.

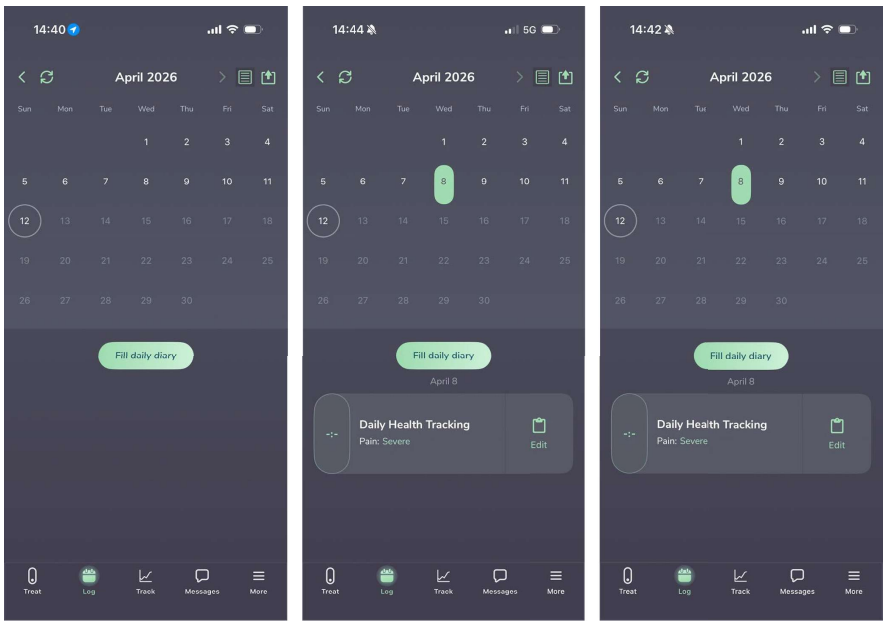
B) The GIER welcome banner (shown 3 times only) provides an additional entry point to the GIER library.

C) Inside the GIER library you'll find a plethora of video sessions curated to themes.

Treat tab – enables to initiate, control, monitor, pause and stop a treatment session. A battery charge status is available when the device is connected. The number of remaining treatment of the refill unit is presented on the treatment screen



Log tab – Enables you to track your treatment sessions and log your migraine headaches and symptoms. Clicking on Log will open a calendar in which all your treatment sessions and reported migraines are stored. The treatment sessions are marked as green dots on the treatment days and your daily diary logs are marked as white circle on the reported days.



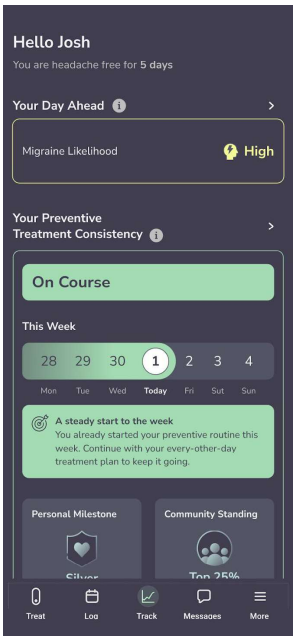
Clicking on the 'Fill daily diary' button will allow you to add a report of your migraine headache and other symptoms. This can be filled in daily, but not more than once a day. In the calendar view, clicking on a specific day will open the details of the daily health

tracking and treatments which occurred on this day. You may edit the Log entry by pressing the edit button of the record.

The Log information can be summarized in a table and exported and shared with your healthcare provider or any other caregiver. This is done by clicking the Share icon on the top right, which enables you to download the file and save it locally or send it by email or any messaging app installed on your phone

Track tab – presents information about your migraine attacks, Nerivio treatments, and preventive treatment consistency.

The information displayed in the Track tab is based on your app data, including Log entries and treatment reports.



Your Day Ahead feature (located in the Track tab)

Your Day Ahead provides an outlook on your likelihood of experiencing a migraine attack in the next 24 hours, based on a machine learning (ML) algorithm (not a clinical diagnosis). The ML algorithm analyzes patterns in your data entered in the app, including diary entries, treatment activity, and questionnaire responses, together with aggregated, de-identified historical data from Nerivio app users, analyzed in a compliant manner.

The algorithm uses up to 30 days of your recent data and updates the likelihood:

- Daily based on your most recent data
- Following new entries (e.g., diary or treatment reports)

To see your migraine outlook for the next 24 hours, complete at least one of the following:

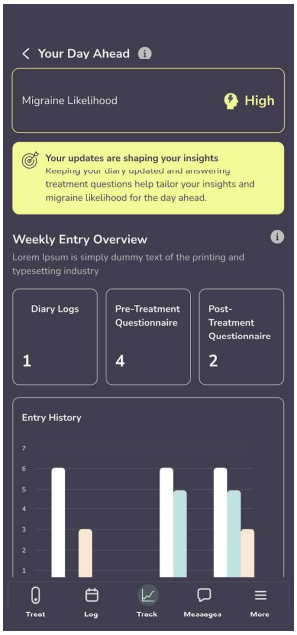
- A pre-treatment questionnaire
- A diary entry with a pain level other than “none”

If there is no pain, the user will get a pop up of “No Recent Data”

Migraine likelihood may be presented as:

- Low
- Moderate
- High

If there is no recent data, the app will display “No Recent Data”



Preventive Treatment Consistency feature (located in the Track tab)

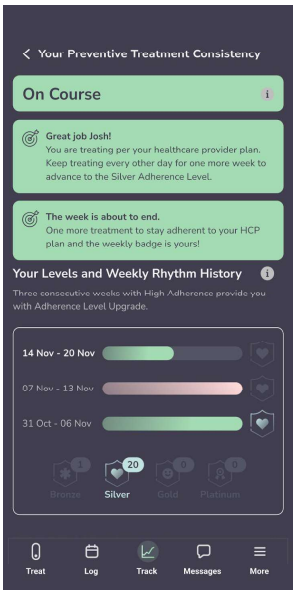
Preventive Treatment Consistency presents the level of your consistency with the every-other-day preventive treatment plan.

Consistency is calculated based on completion of treatments during the week and may be displayed as:

- Not Started
- Getting There
- On Course

The Track tab may also present:

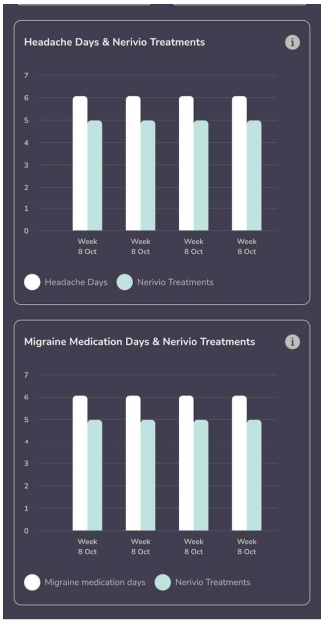
- Personal Milestone – based on consecutive “On Course” weeks
- Community Standing – presents your ranking relative to other users, based on your preventive treatment consistency accumulated over time.



This feature is available for users who indicate they were prescribed Nerivio for migraine prevention or for dual use (acute and prevention). This feature can be disabled in Settings.

Migraine Patterns
Migraine Patterns presents a summary of your migraine data, including:

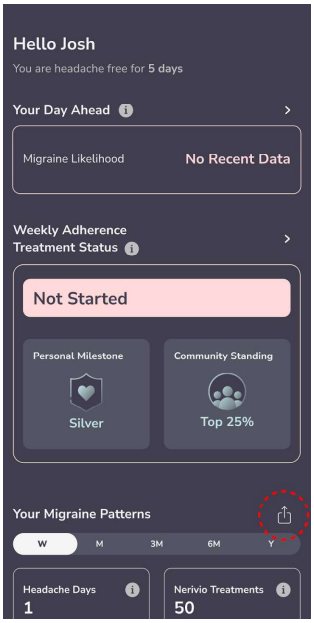
- Headache days and Nerivio treatments over time
- Data displayed across selectable timeframes
- Treatment outcome information based on log entries



Sharing Information
The information presented in the Track tab can be exported to a PDF file and shared with your healthcare provider.

To share your information:

- Tap the Share icon
- Download the file or send it using an email or messaging application installed on your phone



Your Migraine Patterns section (located in the Track tab)

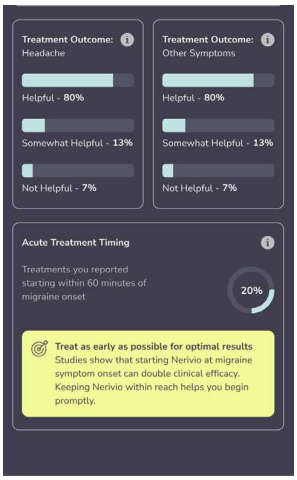
This section presents a summary of your reported treatment outcomes and treatment timing during the selected period (Week, Month, 3 Months, 6 Months, Year).

Based on your pre- and post-treatment questionnaires, the app presents:

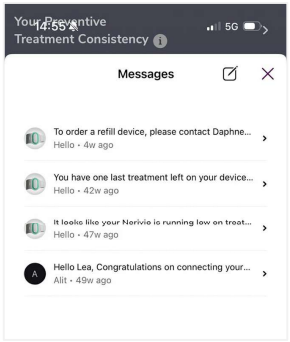
- Treatment Outcome: Headache – summarizes changes in your reported headache intensity
- Treatment Outcome: Other Symptoms – summarizes changes in your reported migraine-related symptoms

Outcomes are displayed as percentages (e.g., Helpful, somewhat helpful, Not helpful).

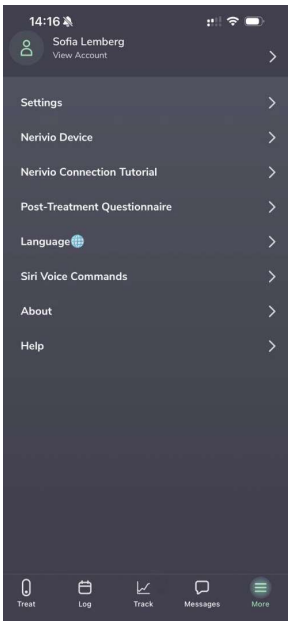
The section also presents Acute Treatment Timing, which shows the percentage of Nerivio treatments you started within 60 minutes of migraine onset during the selected period.



Messages tab – Provides access to in-app messages and important notifications about your treatments and Nerivio account.



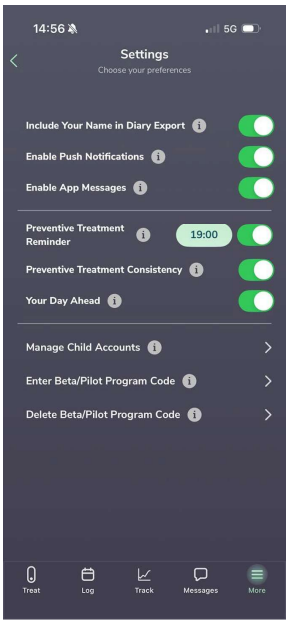
More tab - Provides access to your account information, app settings, and additional features.



View Account – select this to view your account details.

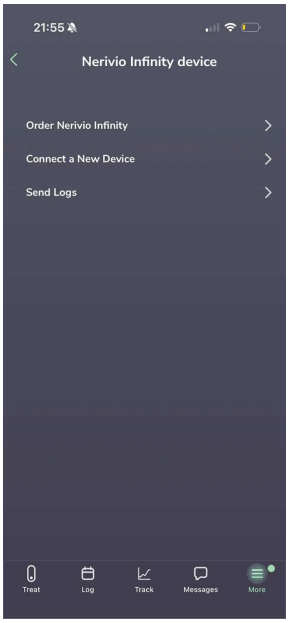
Settings – select this to manage your preferences, including:

- Include your name in diary export
- Enable push notifications
- Enable app messages
- Enable Preventive Treatment Reminders – select this to enable or disable reminders for preventive treatment and to set a preferred reminder time.
    - Reminders are adjusted automatically based on your treatment activity to align with your prescribed preventive treatment schedule (e.g., every-other-day).
- Enable Preventive Treatment Consistency feature
- Enable Your Day Ahead feature

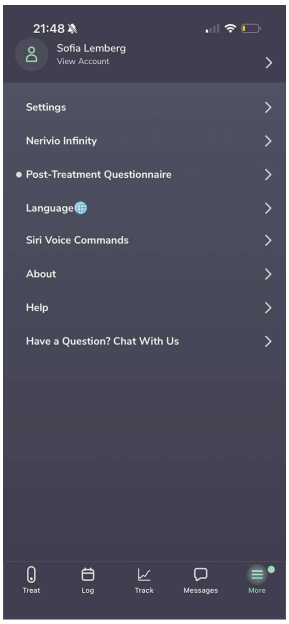


Nerivio Infinity – select this to manage your Nerivio Infinity device, including:

- Order Nerivio Infinity
- Connect a new device
- Send logs



Post-Treatment Questionnaire – Select this to report your migraine symptoms after treatment. When available, a green badge will be presented on the More menu.



Language – Select this to choose your preferred language.

Siri Voice Commands – Select this to enable and manage voice commands.

- The Siri Voice Commands guide below (iOS only) explains how to operate your Nerivio app and device using Siri voice commands. Commands can be issued in English or Spanish, and it is recommended to begin each command with the word “Nerivio” to ensure accurate recognition.

An example list of supported commands is provided in the following table:

Command	Functionality	Command in English	Command in Spanish
Connect to a device	connect to the Nerivio device	Nerivio connect	Nerivio conectar
Start a treatment	start a Nerivio treatment with the default intensity (12%)	Nerivio start	Nerivio comenzar
Update intensity <value>	Update the intensity to a given value between 0-100	Nerivio change intensity to <value>	Nerivio Establecer intensidad a <valor>

Increase Intensity	Increase the intensity by 1%	Nerivio increase	Nerivio aumentar
Decrease Intensity	decrease the intensity by 1%	Nerivio decrease	Nerivio Disminuir
Pause	Pause a treatment	Nerivio pause	Nerivio Pausar
Resume	Resume a treatment	Nerivio resume	Nerivio reutilizar
Stop	Stop the treatment	Nerivio stop	Nerivio detener

6.2. THREATING A MIGRAINE

ACUTE TREATMENT OF MIGRAINE ATTACKS

The treatment should be performed at the onset of a migraine headache. Treat as early as possible. For optimal results, start the treatment as soon as you experience the first symptoms of a migraine attack (such as headache or aura). The treatment duration is 45 minutes.

PREVENTIVE TREATMENT OF MIGRAINE

For migraine prevention therapy, the treatment should be performed every other day, regardless of your migraine status (e.g., whether you have a migraine or not on the day of the treatment).

Treatments can be performed at any time during the day; the most important thing is to pick a time that is convenient for you and stick to it. The Nerivio app offers treatment reminders, so you never miss a treatment.

COMBINING ACUTE AND PREVENTATIVE TREATMENTS

- Use Nerivio every other day to help prevent migraine
- Use Nerivio as needed to treat a migraine attack

Example (if you are starting on Monday)
Your schedule: Monday → Wednesday → Friday → Sunday

If a migraine attack happens on a scheduled day (e.g., Monday) and you did not perform your preventive treatment yet:

- If your migraine attack occurs before you start your preventive treatment, initiate the treatment as soon as you experience the first symptoms of a migraine attack (such as headache or aura).
- This treatment will count towards your preventive routine.
- Continue your schedule every other day as planned:
  - Wednesday → Friday → Sunday
  -

If a migraine attack happens on a scheduled day (e.g., Monday) and you already performed your preventive treatment:

- If your migraine attack occurs after you have completed your preventive treatment, you can initiate another treatment as soon as you experience the first symptoms of a migraine attack (such as headache or aura).
- Continue your preventive schedule every other day as planned:
  - Wednesday → Friday → Sunday
  -

If a migraine attack happens on a non-scheduled day (e.g., Tuesday):

- Start the treatment as soon as you experience the first symptoms of a migraine attack (such as headache or aura).
- Then continue using Nerivio every other day from your last treatment day
  - Thursday → Saturday → Monday

6.2.1 START A TREATMENT

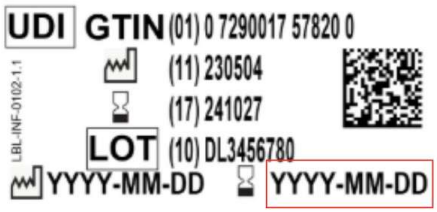
Before you begin, make sure the smartphone Bluetooth connection is enabled and the device is charged.

Do not share the device. The device is intended for a single user.

Note: The screens shown in this section are from the iOS version of the Nerivio app. The connection process is the same on Android, however the screens may appear slightly different.

Step 1: Check the refill unit expiration date and recommended number of treatments on the label located on the protective film and on the package.

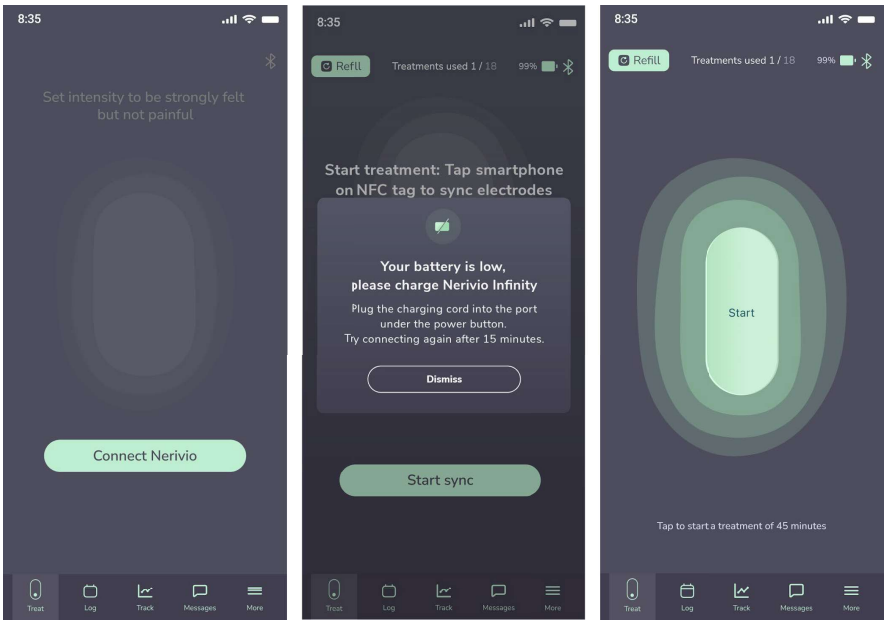
Do not use the refill unit past expiration date or after recommended number of uses



Step 2: Make sure that your arm skin is clean, dry and free from lotion.

Step 3: Turn on the device. A slowly flashing green light indicates the device is on. If the LED is still off, please charge the device. If this situation persists, please contact customer support.

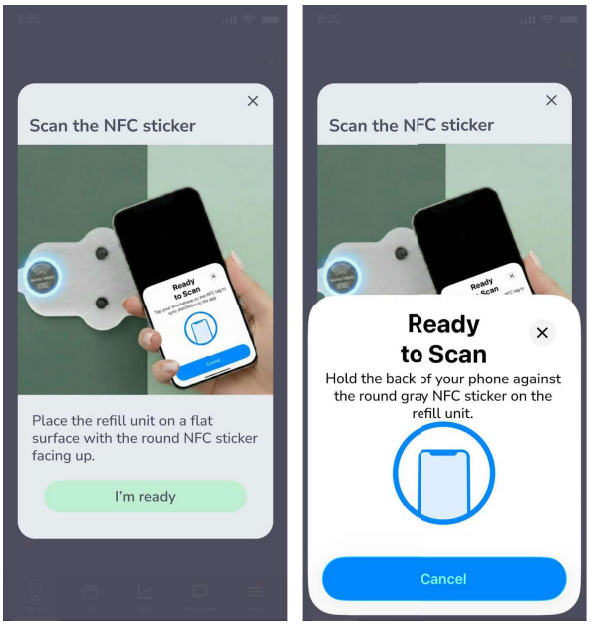
Step 4: Open the app and bring the smartphone and the device in proximity to each other. It will automatically search for your device and attempt to connect. If the app does not connect automatically, make sure the device is turned on, and your phone is nearby with Bluetooth enabled. Then tap **Connect Nerivio**



Step 5: Sync the refill unit to the app via NFC –

Make sure NFC is enabled on your device (to enable NFC on Android, open Settings, open Connections or Connected Devices [depending on your device], then open NFC or NFC and payment, and toggle NFC on. For iOS [iPhone 7 and later], NFC is enabled by default and does not require manual activation. Simply bring your iPhone near an NFC tag to interact with it).

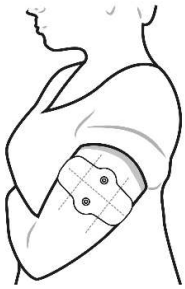
Take the refill unit out of the aluminum bag and place it on a flat surface. Keep the aluminum bag for storing the refill unit. Locate the round gray NFC sticker on the refill unit. In the app, tap I'm ready, then hold your smartphone against the sticker. Make sure you see an on-screen confirmation that the refill unit was detected.



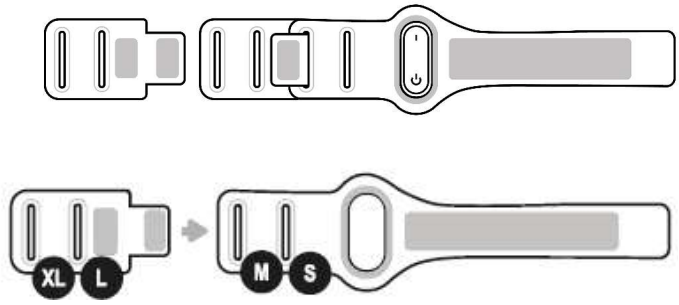
Note: If you are having difficulty syncing the refill unit via NFC, refer to the Connectivity Guide in section 6.1.4 for step-by-step troubleshooting including the QR-code alternative.

Step 6: Carefully remove the protective film from the refill unit pad and save it for storing and maintaining adhesiveness between uses.

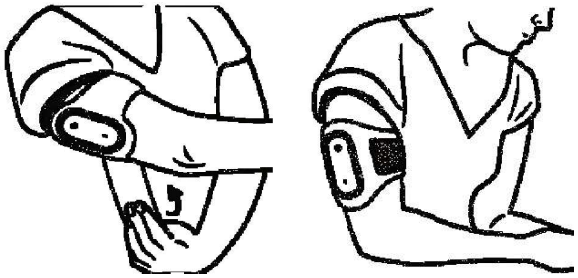
Step 7: Place the refill unit on your upper arm so that the refill unit are in contact with your skin and the snap-fastener's connectors are facing outwards. The refill unit should be located midway between the elbow and the shoulder and placed horizontally to the ground, so that fastening armband with a device around the arm will not displace the device.



Step 8: Place the device into the armband by snapping it into the inner circle and adjust the armband to your size. The Extensions allow you to adjust the armband to your perfect size. When the strap and device are secured to the arm (see step 8), the feeling should be tight and yet comfortable.



Step 9: Wrap the armband with the device around the refill unit on your arm and fasten the strap. Make sure that the device and refill unit are physically connected (you should hear/feel a snap/click sound). The armband will secure the device on its location and improve the contact between the device and your skin.



Do not place the device on a body without attaching refill unit and do not touch the device's contacts when the device is operational.

Do not use the device on the heart, chest, neck, head or any other body location other than the upper arm

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

It is important to use the device only when positioned correctly on the arm. The device should be located midway between the elbow and the shoulder, on the outer side of the arm and horizontally to the ground.

Step 10: To start the treatment, touch 'Start' in the treatment screen. The treatment has now begun and will stop automatically after 45 minutes. A slow flashing (mostly off) green light indicates the device is stimulating.

Do not start a treatment before connecting refill unit and securing the device on your arm

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 while driving, cycling, or operating any vehicle or machinery

Do not use the device before replacing the refill unit, if the electrodes become significantly dirty, damaged, or used for over 18 treatments

If the device was damaged, do not touch exposed electronics

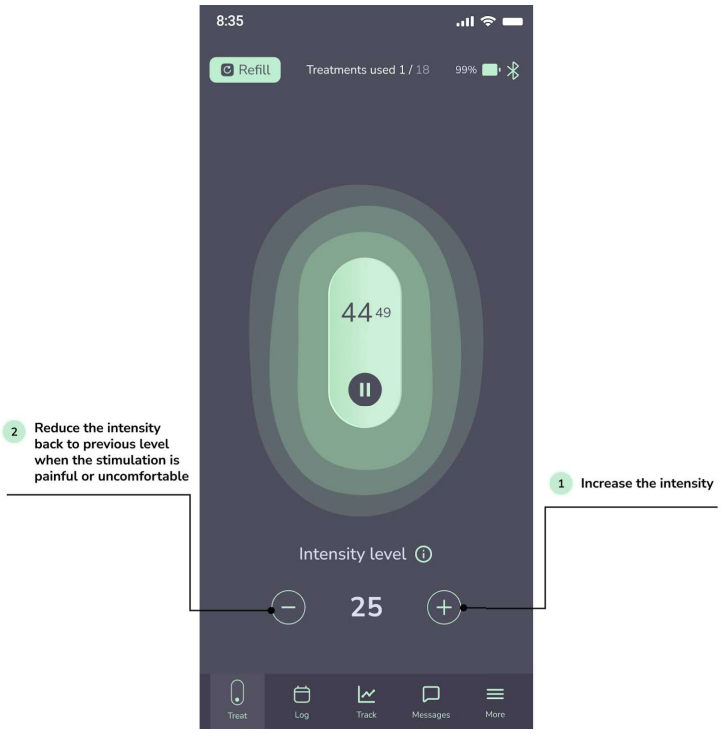
Do not use the device in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms)

Keep the device in a dry environment. Moisture may damage the device

Do not use the device in a magnetic resonance imaging (MRI) environment

In case of device malfunction, remove the device from your arm and contact customer support

In case the refill unit fail to properly adhere to the skin, rub the electrodes using a drop of water to improve their adhesiveness. If needed, contact customer support



Step 11: Set the treatment intensity level, so it feels strong yet comfortable and not painful. The treatment starts at a default intensity of 12%. Gradually increase the intensity as described below.

Setting intensity level:

a) Start increasing the stimulation intensity using the "+" button. Each press will increase the intensity by 1 unit.
b) When the stimulation is painful and/or uncomfortable, reduce the intensity to the previous level using the "-" button. Each press will decrease the intensity by 1 unit.
c) Increase and/or decrease the stimulation intensity until you find the highest intensity that feels strong but not painful.

For effective and convenient treatment, the intensity level is individually set so it feels strong yet comfortable and not painful

You should monitor the activity of the device throughout its operation

Once you find the strongest and most convenient stimulation intensity level, relax and continue with the treatment. If during the treatment the sensation is not strong, if it feels uncomfortable or painful, adjust the intensity level using the "+" and "-" buttons.

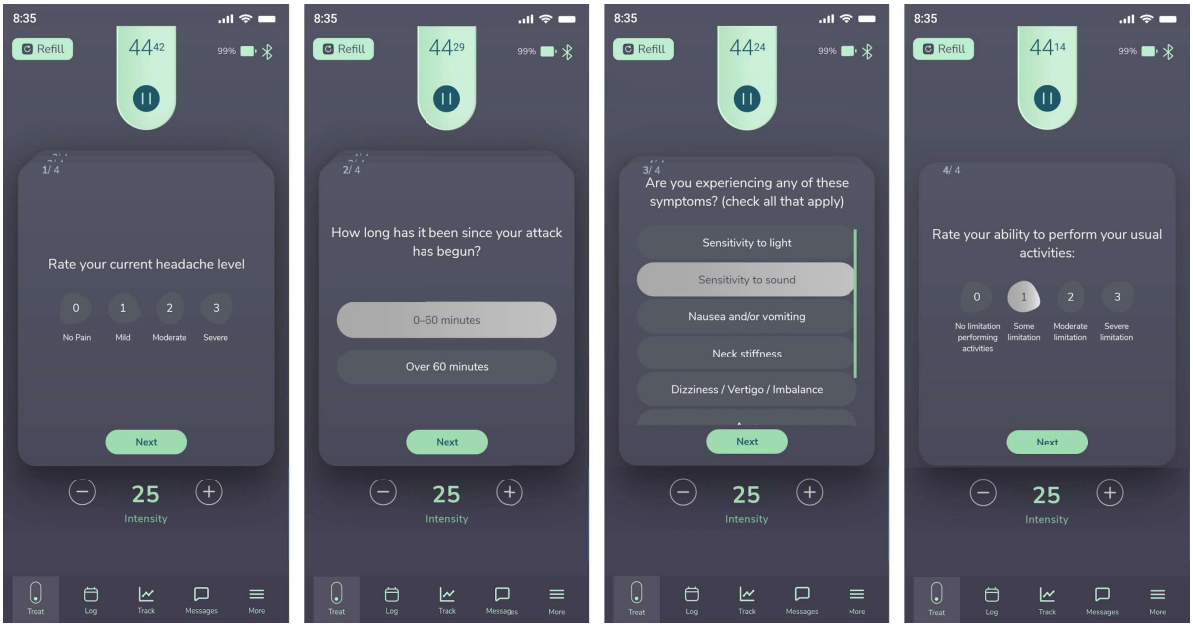
- The default starting intensity level is 12%.
- Note that long/continuous presses should be avoided.
- If you have significantly increased the intensity and still do not feel the stimulation, please refer to troubleshooting or contact customer support.

For your safety, the intensity will increase slowly. This gradual increase will be presented in the app by a flashing “increasing” indication that will stop once the desired intensity is reached.

Step 12: (*Available from 2nd treatment)

After the treatment has begun, questions on your migraine symptoms will be automatically displayed. You can record your migraine symptoms or skip this by touching “Next”.

Note that the treatment is still in progress, and it can still be controlled by the app



You can also record your post-treatment outcomes via notifications that will be sent to you or in the post-treatment assessment section in the More menu.

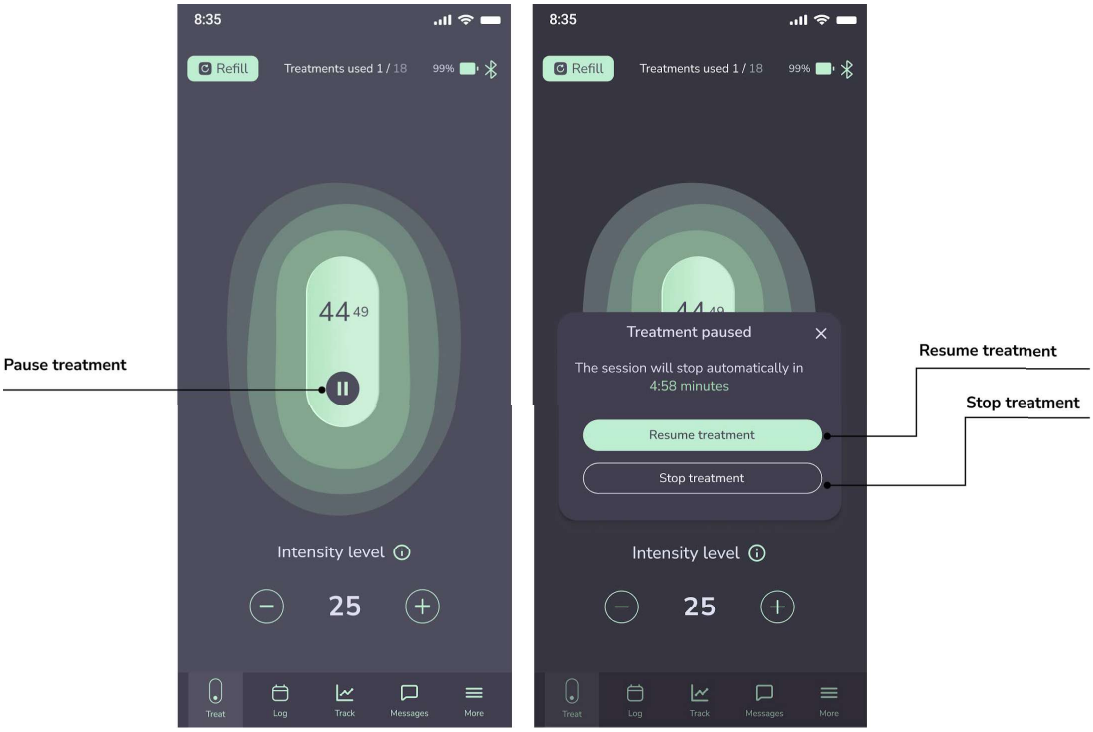
6.2.2 TREATMENT IN PROGRESS

The progress of the treatment can be monitored by the specified time remaining of the total treatment duration time (45 minutes).

You can pause the treatment session for up to 5 minutes by touching the pause button. Press ‘Resume treatment’ to resume the treatment. Each session can be paused up to 3

times. If a treatment is not resumed within 5 minutes, it will be stopped automatically. When the treatment is resumed, the stimulation intensity will gradually increase to the level used before pausing the treatment. This gradual increase will be presented in the app by a flashing “increasing” indication that will stop once the desired intensity is reached.

The treatment can be stopped early at any time by touching the pause button and then “Stop treatment”. Do not remove the device from your arm before the treatment has ended or has been stopped, unless the treatment cannot be stopped in the app.



During the treatment, you may press the GIER (Guided Intervention of Education and Relaxation) button at the top-right of the screen, to view and listen to a guided video explaining the treatment, which may assist you coping with the migraine attack.

During the treatment, you may experience slight muscle spasm, numbness of the hand and irritation of the skin. These sensations should resolve soon after the end of treatment.

If you experience an uncomfortable or painful sensation that does not resolve by decreasing the intensity, stop the treatment in the app and remove the device from the arm.

It is recommended that your smartphone will be protected by a password (or other security mechanism) to refrain from unwanted people activating the device

Interference to the Bluetooth connectivity may occur in the vicinity of equipment emitting RF (e.g. microwave, routers, WIFI devices)

- **For effective results, it is recommended to avoid using other electrical devices during treatment**
- **If the device was on for over 3 minutes when no treatment was in progress, it automatically shuts down. Turn the device back on to start a treatment.**
- **If the "Pause" or "Stop" buttons do not respond, you can carefully remove the device from your arm**

6.2.3 TREATMENT COMPLETED

Step 1: When the treatment is completed, remove the armband, device and refill unit from your arm. The device will turn off automatically one minute after the treatment session has ended (the green light will turn off).

Step 2: Apply the protective film on the refill unit (the protective film is reusable).

Step 3: Place the device in its original package or in the carrying bag to store it for next use. Place the refill unit in its foil wrapper and zip the bag in order to reduce dehydration of the electrodes.

Step 4: Close the app.

- **If after acute treatment your migraine headache is not aborted 30 minutes following the treatment, you may administer additional acute treatments.**
- **If you are experiencing migraine headache on the same day that you have administered preventive treatment, you may administer additional acute treatments.**
- **Administer preventive treatment every other day.**
- **Tips for Consecutive Treatments**

  At the end of an acute treatment, if you feel that 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.

6.3. STORING THE DEVICE FOR NEXT USE

Once the treatment has been completed, the device and refill unit need to be stored until the next treatment.

Step 1: Verify that the refill unit electrodes are covered with protective film. When not in use, place them it into the zipped foil wrapper in an indoor environment, away from direct sunlight and according to storage enviroment conditions specified in this user manual.

Step 2: Store the device in the original package or in the carrying bag in an indoor environment according to the storage enviroment conditions specified in this user manual.

To minimize moisture loss, when unused, the refill unit 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

The device and refill unit should be stored and cleaned according to the recommended conditions describe in the user manual

6.4. REVIEWING YOUR MIGRAINE LOG

Keeping detailed records of migraine episodes can help in migraine management. The symptoms recorded during a treatment will be saved in a migraine log that can be reviewed at any time via the app. Tap “Log” to review your migraine symptoms.

You can also report on a daily basis (but not more than once a day), a set of migraine symptoms including your current migraine headache, to record your symptoms in the log even if the device is not used.

You can view and edit these reports at any time from the ‘Log’ tab in Nerivio Infinity app.

To help you track your migraine headaches, the app will provide notification to fill your symptoms at 2 hours after a treatment session or a reported migraine headache. You can disable these notifications in the smartphone settings.

6.5. PERFORMING OVER-THE-AIR (OTA) SOFTWARE UPDATE

To ensure running the latest software in the device for best performance and experience, Nerivio Infinity app may occasionally pop-up a notification that a software upgrade to the device is available.

It is recommended to approve these updates. Such notifications will never pop-up during treatment, only during idle times.

Follow the instructions on the screen to perform the update. When the process is complete, the app will notify you. It is important to note that OTA updates the device software only, not the app. App updates are provided in the normal manner via the respective app stores.

During the OTA update, the green LED shall transition between blinking to being constant as per the progress of the process. Please follow the progress in the app.

The device shall be charged to at least 30% of the battery capacity to start OTA software update.

6.6. PERFORMING SOFTWARE RECOVERY

In the unlikely event that the device becomes unusable after a software update, there is a built-in Software Recovery process which allows the device to return to the previous device's software version provided that the device was upgraded to a new software version at least once. In case the device software was never upgraded, or the recovery process is performed twice, the device will be returned to the state in which it left the manufacturing facility. The process is conducted as follows:

a) Make sure that the battery is charged to at least 30%. Remove the charging cable.
b) Hold down the power button for 10 or more seconds, but less than 20 seconds (green LED is now constantly ON)
c) Release (leave unpressed for less than 5 seconds)
d) Press again the power button for 3 seconds or more
(seconds after this press, green LED will blink to indicate success)

This will initiate a recovery sequence that should bring the device to the default mode of operation.

7. CLEANING, MAINTENANCE AND DISPOSAL

7.1. CLEANING AND MAINTENANCE

- The device can be cleaned with dry cloth (except for the **electrodes on refill unit**).
- If the electrodes begin losing adhesion, gently rubbing one or two drops of water onto the gel surface may extend usage. Wait for about 30 minutes before placing the protective liner. Replace the electrodes if adhesion is not resorted.
- The armband can be washed with water and soap only. No bleach products should be used. Do not tumble dry. Do not iron.
- 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.
- Contact customer support if the package and/or device labeling are damaged.
- The lifetime of the electrodes varies depending on skin conditions, skin preparation, storage and climate. Replace the electrodes if damaged, dirty, or after 18 uses.
- The app can be updated using the standard update procedure of the mobile operating system.

Before or after a treatment, rub the electrodes using a drop of water to improve their adhesiveness

After rubbing electrodes with water, wait for 30 minutes for water to absorb before next use or applying protective liner.

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 use the device before replacing the electrodes, if the electrodes become significantly dirty, damaged or used for over 18 treatments

7.2. DISPOSAL

- This product should be disposed of in accordance with all applicable federal, state and local regulations related to the disposal of electronic equipment and batteries.
- If the battery has been fully discharged before use, and cannot be recharged, please contact customer support.
- Contact customer support for further information on the appropriate disposal of device components.

8. TROUBLESHOOTING

This section lists problems or observations that you may have, the possible cause(s) and recommended actions. Before addressing the troubleshooting table, please check and confirm the following:

1. Make sure that Bluetooth connection is enabled in your phone.
2. Make sure that device's battery is sufficiently charged (if not sure – charge for at least 30 minutes before use).
3. Make sure NFC is enabled on your device: to enable NFC on Android, open Settings, then open Connections or Connected Devices [depending on your device], then open NFC or NFC and payment, and toggle NFC on. For iOS [iPhone 7 and later], NFC is enabled by default and does not require manual activation. Simply bring your iPhone near an NFC tag to interact with it.

8.1. GENERAL

Problem	What it may mean	What to do
The device does not power on	The device is not working	Contact customer support at support@nerivio.com

Problem	What it may mean	What to do
	The power button was not held long enough	Press the power button continuously for 2-3 seconds
The device does not turn off	Nerivio Infinity has automatic shut off features • The first time the device is turned on to pair and set up, the device will shut off automatically after 10 minutes. • For all subsequent treatments, the device will give you 8 minutes to start the treatment. • If you pause the device during a treatment, the device will automatically shut off after 6 minutes if treatment is not restarted. • At the end of any treatment the device will automatically turn off after one minute. • When the charger is connected the device will automatically turn off within 5 seconds. These built-in timers will not impact the device's ability to provide 45-minute treatments.	If the charger is connected, disconnect the charger In case the device cannot turn off and the LED on is still on after 10 minutes of idle time, contact customer support at support@nerivio.com
The green LED is flashing very rapidly (5 times per second)	There is an error message on the screen	Connect the app to the device. View the error message in the app and follow the instructions. If the error does not appear on the screen, wait for the device to automatically turn off and then turn it back on
The LED is solid green	LED is solid green at the end of the charging If the charger is disconnected, it is device malfunction	Contact customer support at support@nerivio.com
The LED is solid purple	Battery or charging circuit malfunction.	Disconnect the charger, wait 30 seconds and reconnect. If the problem persists,

Problem	What it may mean	What to do
		contact customer support at support@nerivio.com
The device does not connect to the app	The device is turned off	If the LED is off, turn on the device
	Bluetooth connection is disabled on the phone	Enable the Bluetooth feature on your phone and try to reconnect
	The phone and the device are not close enough	Remove the device from your arm. Bring the phone closer to the device, to a range of 1 inch (2.5 cm)
	The device was automatically shut down since the treatment ended or has not been initiated for a prolonged duration of time.	If the LED is off, turn on the device
	The smartphone has been previously paired with a different device	Here are some steps you can try to resolve the connectivity issue. 1. Go to the Bluetooth settings on your phone and remove the device (on iPhone click info icon then forget device / on Android click gear icon then unpair). 2. Then turn on the device and the Bluetooth on your phone and pair (please be sure the phone and the device are side by side when you pair). 3. If the device does not connect go to the More menu at the bottom of the Nerivio Infinity App, select Nerivio Infinity device and then select Connect a new Nerivio Infinity device. 4. If you still cannot pair, do a total shutdown of your phone, restart your phone and try to pair.
	General issues related to the Bluetooth on your smartphone	Here are some steps you can try to resolve the connectivity issue. Please do not skip any steps: 1. Turn your phone off, turn your phone back on. 2. Turn Bluetooth off and back on again in the settings menu. Do not try to pair the device from the Bluetooth menu. 3. Turn on the device and pair (please be sure the phone and the device are side by side when you pair). 4. If the device does not connect go to the More menu at the bottom of the

Problem	What it may mean	What to do
		Nerivio Infinity App, select Nerivio Infinity device and then select Connect a new Nerivio Infinity device. If you still cannot pair, rest network settings on your smartphone
The device does not identify the refill unit via NFC	General issue related to the NFC reader	Here are some steps you can take to resolve the connectivity issue. Please do not skip any steps: 1. Enable “NFC” Icon on your phone. 2. Repeat the NFC sync procedure. Try these steps multiple times. If still not helpful, the NFC tag on the Refill Unit may be damaged and you need to replace the Refill Unit, contact your local customer support for further help
The stimulation is not felt	The treatment has not started yet or has been stopped or paused	Touch “Start” or “Resume treatment” in the “Treatment” screen
	The stimulation intentisty is too low	Increase the stimulation using the “+” button in the treatment screen, until you feel the stimulation
	The protective film was not removed	Remove the protective film from the refill unit electrodes
	The electrodes begin losing adhesion	When no treatment is active, gently rub with your finger one or two drops of water onto the gel surface of the electrodes. Wait for 10 minuts for better effect. You can repeate this process several times to improve dry electrodes adhesion.
	The adhesive surface of the electrodes is damaged	Replace the refill unit

8.2. MAIN ERRORS AND MESSAGES

Errors and messages displayed on the screen	What it may mean	What to do
Nerivio Infinity is not properly placed. Make sure that the protective film was removed	The device is not properly placed on the arm and/or the	Make sure the protective film was removed from the electrodes.

Errors and messages displayed on the screen	What it may mean	What to do
and that the refill unit electrodes are in contact with your skin	electrodes are not in contact with your skin	The refill unit should be placed directly on the skin of the arm
Nerivio Infinity is shutting down since no treatment is performed. Turn it back on to start a treatment	The device was on for a specific duration of time and no treatment was performed	Turn on the device
No Nerivio Infinity devices were found	Bluetooth is off	Enable Bluetooth on your smartphone
	The device is turned off	Turn on the device
	The device is too far from the smartphone	Bring the phone closer to the device, to a range of 1 inch (~2.5 cm)
Authentication failed	The device has already been associated with a different user	Connect to a different Nerivio Infinity
Device malfunction	The device isn't working properly	Remove the device or unplug it. Disconnect from the app. Do not charge. Contact support.

8.3. LED STATUS

LED indication	Status
Turned off	[During charge only] Verify charger fully plugged in, if Yes, Unplug the device, device malfunction
Flashing green very rapidly (5 times per second)	The device is shutting down, or an error/malfunction occurred
Flashing slowly (mostly on)	The device is ready to be connected to the app
Flashing rapidly	The device is connected to a smartphone
Flashing slowly (mostly off)	The device is in a treatment process
Solid red	[During charge only] Battery is charging

LED indication	Status
Solid green	[During charge only] Battery is full [No charger connected] Device is booting or replacing firmware during firmware recovery
Solid purple or flashing red	[During charge only] Battery or charging circuit malfunction.

8.4. CUSTOMER SUPPORT

Customer support is available to answer any questions you may have about your Nerivio Infinity device.

The Nerivio Infinity is a durable medical equipment with a replacable refill unit. The service lifetime expectancy of the Nerivio Infinity in typical use mode of about 18 treatments per month and under recommended operational use and storage conditions is 3 years.

The refill unit is a replaceable component that should be replaced after the recommended number of treatments (as indicated on the label).

The service lifetime of the replaceable refill unit is 18 treatments or until the product use-by date indicated on the refill unit's label.

Theranica Bio-Electronics LTD.

Address: 9 Granit St., North Industrial Park,
Caesarea, 3079893, Israel
Email: support@nerivio.com
Web: www.theranica.com and www.nerivio.com
Fax: +972-72-390-9762

9. OPERATION SPECIFICATION

9.1. ENVIRONMENT OPERATING CONDITIONS

Operating temperature range: +5º to +40º C (41'F-104'F)

Relative humidity range: 35%-70% RH, with no condensing

Atmospheric pressure: 70-106 kPa

9.2. ENVIRONMENTAL STORAGE AND TRANSPORTATION CONDITIONS BETWEEN USES

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

Relative humidity range: 40%-70% RH, with no condensing

Atmospheric pressure: 70-106 kPa

9.3. ENVIRONMENTAL TRANSPORTATION AND STORAGE CONDITIONS

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

Relative humidity range: 40%-70% RH, with no condensing

Atmospheric pressure: 70-106 kPa

9.4. ELECTRICAL PROPERTIES

Battery type: Rechargeable Li-Ion cell 3.7V 400mAh 1.48Wh

Maximum Battery Voltage: 4.2V

Maximum device output Current 40mA

Device output Frequency 10-120Hz

Charger output: 5V 500mA DC

Battery lifetime 300 recharge cycles at ambient temperature of 23±2℃.

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 fire, injury, burns, or other hazards.

Do not attempt to detach the battery

Recycle or dispose the device and accessories in accordance with disposal instructions in the user manual

10. TECHNICAL SPECIFICATIONS

Number of channels	1
Waveform	Biphasic rectangular, frequency alternating
Net charge (µC per pulse)	0 (charge is balanced by using a symmetrical, biphasic pulse)
Max output voltage 500Ω 2KΩ 10KΩ	 20V 60V 60V

Max output current 500Ω 2KΩ 10KΩ	 40mA 30mA 6mA	
Maximum phase charge 500Ω	8 µC	
Maximum average current 500Ω	1.76mA	
Maximum current density (peak) 500Ω	1.6 mA/cm²	
Maximum current density (r.m.s) 500Ω	0.34 mA/cm²	
Maximum average current density (abs value) 500Ω	0.07 mA/cm²	
Maximum average power density 500Ω	1.41mW/cm²	
Frequency	100 – 120 Hz	
Primary phase duration [µSec]	200	
Pulse duration [µSec]	400	
Burst mode	No	
Program duration [min]	45	
Electrode area	25cm^2	
Electrode compliance with 21 CFR 898	Yes	
Electrode cable	No	
Indication display	Device LED	Via the mobile application, if connected
-On/off status -Wireless connection -Low battery -Current level	Yes Yes No No	Yes Yes Yes (remaining charge in %) Yes (stimulation intensity)

-Output mode -Time to cut-off	Yes No	Yes (stimulation time indicator) Yes (stimulation time indicator)
Power source	Integrated, rechargeable secondary cell Li-Ion battery. Up to 4.2V, 400-430mah max.	
Processor control	Yes	
Wireless control	Yes	
Wireless communication: Bluetooth Low Energy (BLE)	Frequency range: 2.400-2.4835 GHz Modulation: Gaussian frequency shift Output power: ≤0 dBm	
Wireless communication: Near Field Communication (NFC)	Passive NFC (target, receiver), ISO 14443-3A compatible NTAG device. Frequency range: 13.553-13.567 MHz ISM band with a 847.5 kHz subcarrier. Modulation: modified Miller coding and Load modulation (tag to reader), 100% ASK (reader to tag) Output power: N/A, powered by initiator (active) device	
Automatic overload trip	Yes, limiter for max current and voltage	
Automatic no load trip	Yes, out-of-range load detection	
Automatic shutdown	Yes, timer	
Simulation intensity control	Yes, current amplitude is adjustable by the user	

Wireless Communication Interference

This device operates in the 2.400-2.4835 GHz ISM band using Bluetooth Low Energy. In case this device is used around other wireless devices such as microwave and wireless LAN, which operate at the same frequency band as this device, interference between this device and such other devices may occur. If an interference occurs before the treatment has begun, the treatment may not start. Once the treatment has started, the device maintains the treatment parameters (shape and frequency of pulses during stimulation, intensity and duration) autonomically and does not require any further control. However, the app may not enable you to stop the treatment or adjust the intensity, which may result in an uncomfortable feeling. If such sensation occurs, please remove the device from your arm without touching the refill unit electrodes, stop the operation of the other devices or move away from the interfering source.

The Refill unit (electrodes pad) has NFC-tag that is used for authentication via App that shall be installed on an NFC-equipped user's smartphone. In case the Refill unit is used

around other wireless devices, which operate at NFC frequency band, interference between the Refill unit and such other devices may occur. If an interference occurs before the treatment has begun at the time of authentication, the treatment may not start. The user shall repeat authentication attempt until it is successful. Once the treatment has started, the NFC-tag connection is no longer required to conduct the treatment.

- 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
- Interference in the Bluetooth connectivity may occur in the vicinity of equipment emitting RF (e.g. microwave, routers, Wi-Fi devices)
- 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 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 Nerivio Infinity device. This may result in incorrect operation of the device and create a potentially unsafe situation. 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.

11. SMARTPHONE REQUIREMENTS

Refer to frequently asked questions (FAQ) at www.nerivio.com/faq for smartphone requirements.

12. CYBERSECURITY

The Nerivio Infinity system software is comprised of the device embedded software ("Firmware"), an application back-up service ("Backend") hosted on Amazon Web Services and operated by the company, and an application frontend ("Client") hosted by the mobile application (the App) on the user's smartphone. The Nerivio Infinity is a closed system, which does not allow installation of additional external components to Firmware, Client software or Backend software. The Firmware can be subject to an over-the-air service patch, and you will be prompted via the App when the new Firmware update is available. The update is verified for authenticity and integrity before the installation. The App's Client software exposes only a user interface (UI).

The Backend is accessible only to authorized company personnel over a secure HTTPS communication channel. The company operates the Backend and assumes full responsibility for maintaining its cybersecurity, including patching, and securing the infrastructure and application code, as well as security incidents management.

The Client software runs on a mobile platform that is the responsibility of the user. The device Firmware and the Client software are not designed to detect or report on security events. The company recommends selecting a strong user password when creating account and protecting your mobile platform by a password (or other security mechanism) to refrain from unwanted people to activate the device or access your personal information. To verify user's account validity, the system includes authentication and verification through the user's email.

Instructions for Cybersecurity

The following cybersecurity controls are recommended to increase security of the Client software and user's mobile platform:

- The mobile platform should require authenticated access via user credentials. You are advised to lock your smartphone with a password or any other means (e.g. biometric, pin code or other).
- Restrict unauthorized physical access to the mobile platform and the device.
- Keep the mobile operating system on the mobile platform up to date with the latest security updates. Don't "Jailbreak", "Root" your mobile platform, or install unreleased (e.g. beta) or unofficial operating system versions.
- Download the App only from an official application store outlined in this user manual.
- Keep the App software and the device Firmware up to date. It is recommended to allow automatic upgrade of the App on your mobile platform.

- When creating the account choose a strong password. The password must be at least 9 alpha-numeric characters including at least 1 uppercase letter, at least 1 lowercase letter and at least 1 numeric digit.
- Notify customer service upon detection of a cybersecurity event related to the device or the App software.

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

For additional information on data protection and privacy refer to www.nerivio.com / privacy policy.

13. POTENTIAL ADVERSE REACTIONS

- People with sensitive skin may experience a rash or redness of the skin under the refill unit.

14. CLASSIFICATION

- Internally powered ME Equipment
- Type BF applied part
- Enclosure IP22
- Continuous operation

15. EMC STATEMENT

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, the Nerivio Infinity device may be susceptible to electromagnetic interference from other devices, even if they comply with CISPR emission requirements. Electromagnetic interference may result in incorrect operation of the Nerivio Infinity device and create a potentially unsafe situation.

The Nerivio Infinity device should not interfere with other devices.

To regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

The Nerivio Infinity medical device conforms with the IEC60601-1-2 standard for both immunity and emissions.

The Nerivio Infinity device requires special precautions regarding EMC and needs to be installed and used according to the EMC information provided in this manual:

- Do not use any unspecified accessories with the Nerivio Infinity device. This may result in increased emissions or decreased immunity of the device.
- The Nerivio Infinity device should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the Nerivio Infinity device

should be monitored to verify normal operation in the configuration in which it is used.

- Do not use devices which generate strong electrical or electromagnetic fields in proximity to the Nerivio Infinity device. This may result in incorrect operation of the device and create a potentially unsafe situation. 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 the correct operation of the device if the distance is shorter.
  The Nerivio Infinity device complies with immunity tests described below.

15.1. ELECTROMAGNETIC DOCUMENTATION COMPLIANCE

Test	Standard	Class/ Severity level	Test result
Documentation (IEC 60601-1-2 sections 4 and 5)			
General requirements	Section 4.1	--	Complies
Instruction for use	Section 5.2.1.	--	Complies
Technical Description	Section 5.2.2	--	Complies

15.2. ELECTROMAGNETIC EMISSIONS & IMMUNITY

The Nerivio Infinity is intended for use in the electromagnetic environment specified below. Please ensure that the device is used according to these specifications.

Test	Standard	Class/ Severity level	Test result
Documentation(IEC/EN 60601-1-2 sections 4 and 5& IEC/EN 60601-2-10 section 201.7.9)			
General requirements	Section 4.1	--	Complies
Instruction for use	Section 5.2.1.	--	Complies
Technical Description	Section 5.2.2	--	Complies
Emission (IEC/EN 60601-1-2 section 7.1 & 7.2& IEC/EN 60601-2-10 section 202)			
Conducted emission Freq. range:150 kHz - 30 MHz	CISPR 11	Group 1 Class B 230VAC, 120 VAC mains	Complies
Radiated emission Freq. range: 150kHz– 1GHz	CISPR 11	Group 1 Class B	Complies
Harmonic current emission test	IEC 61000-3-2	Test is not applicable (refer to Section 6.3)	Exempted
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3	230 VAC mains	Complies
Immunity(IEC/EN 60601-1-2 section 8.9 - 8.11& IEC/EN 60601-2-10 section 202)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	10.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8	30 A/m @ 50 / 60Hz	Complies
Immunity to proximity magnetic fields in range 9 kHz to 13,56 MHz	Section 8.11 IEC 61000-4-39	8 A/m @ 30kHz CW 65 A/m @134.2kHz PM 2.1kHz 50% 7.5 A/m @13.56MHz PM 50kHz 50%	Complies

Summary Cont'd:

Test	Standard	Class/ Severity level	Result
Emission (ETSI EN 301 489-1/ ETSI EN 301 489-17 sec.7.1)			
Conducted emission Freq. range:150 kHz - 30 MHz	EN55032	Class B 230 VAC mains	Complies
Radiated emission Freq. range: 30MHz–6GHz	EN55032	Class B	Complies
Harmonic current emission test	EN61000-3-2	Test is not applicable (refer to Section 6.3)	Exempted
Voltage changes, Voltage fluctuations and Flickertest	EN61000-3-3	230 VAC mains	Complies
Immunity (ETSI EN 301 489-1/ ETSI EN 301 489-17 sec.7.2)			
Immunity from Electrostatic discharge (ESD)	EN 61000-4-2	4 kV contact discharges & 8 kV air discharges	Complies
Immunity from radiated electromagnetic fields	EN 61000-4-3	3.0 V/m; 80 MHz ÷6 GHz, 80% AM, 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	EN 61000-4-4	± 1.0 kV on AC mains (PS), Tr/Th – 5/50 ns, 5 kHz	Complies
Immunity from Surge	EN 61000-4-5	*AC mains (PS):* ±1.0 kV DM Tr/Th – 1.2/50 (8/20) μs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	EN 61000-4-6	3.0 VRMS on AC mains (PS) 0.15÷ 80 MHz, 80% AM 1 kHz	Complies
Immunity from voltage dips, short interruptions and voltage variations	EN 61000-4-11	On 230VAC mains: 0% - 0.5 cy, 0% - 1cy 70% - 25cy, 0% - 250cy	Complies

15.3. PERFORMANCE CRITERIA PER IEC 60601-1-2, IEC 60601-2-10

Throughout the course of the immunity tests, the device has not become dangerous or unsafe. The following shall be DEGRADATION of performance that does not allowed:

- There are no component failures
- There are no FW error indications (indicated via LED)
- There is no reset to factory defaults
- There is no change in treatment status

Normal operation indication should be: The Nerivio Infinity continuously outputs its intended electrical stimulation, and the LED indication blinks at the correct rate

15.4. RECOMMENDED SEPARATION DISTANCES

Recommended separation distance between portable and mobile RF communications equipment and the NM
Nerivio Infinity is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the users of Nerivio Infinity can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Nerivio Infinity as recommended below, according to the maximum output power of the communications equipment.

Output Power of Transmitter in Watt	Separation distance according to frequency of transmitter in meter			
	150 kHz to 80 MHz		80 MHz to 800 MHz	800 MHz to 2.7 GHz
	$d = 1.16\sqrt{P}$	$d = 0.58\sqrt{P}$	$d = 0.35\sqrt{P}$	$d = 0.7\sqrt{P}$
0.01	0.12	0.06	0.04	0.07
0.1	0.37	0.18	0.11	0.22
1	1.16	0.58	0.35	0.7
10	3.67	1.8	1.1	2.2
100	11.6	5.8	3.5	7.0
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note**: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies **Note**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.				

16. FCC RADIO FREQUENCY INTERFERENCE STATEMENT

FCC Registration Number (FRN): 0027054477.

This equipment has been tested and found to comply with the limits of Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a installation. If this equipment causes interference with other devices, which may be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

• Reorient or relocate the device receiving the interference

• Increase the separation between the equipment

• Connect the equipment into an outlet on a circuit different from that to which the device is connected.

• Consult the manufacturer or field service technician for help

Theranica Bio-Electronics LTD. is not responsible for any radio or communication interference caused by using other than specified or recommended cables and battery or by unauthorized changes or modifications to this equipment. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and

2. This device must accept any interference received, including interference that may cause undesired operation.

17. APPLICABLE STANDARDS

- EN 60601-1:2006/A2:2021 / IEC 60601-1 edition 3.2 Medical electrical equipment, part 1: General requirements for basic safety and essential performance.
- EN 60601-1-2:2015/A1:2021 / IEC 60601-1-2 edition 4.1 Medical electrical equipment- Part 1-2: General requirements for safety – collateral standard: Electromagnetic compatibility –Requirements and tests.
- EN 60601-2-10:2015/A1:2016/A2:2023 / IEC 60601-2-10 edition 2.2 b:2023 Requirements for the safety of nerve and muscle stimulators
- ETSI EN 301 489-1 V2.2.3 (2019) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility.
- ETSI EN 301 489-17 V3.3.1 (2024) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility
- ETSI EN 301 489-3 V2.3.2 (2023) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU.

Nerivio® Infinity

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