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 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 at 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 the refill unit (see item #2 below) and together are placed on the arm.
2. Refill unit. 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 treatment discretion.
4. Travel pouch
5. USB charging cable, type A to type C.
6. Nerivio mobile application (app) that can be downloaded from your app store

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 refill unit that deliver neurostimulation signals. The armband secures the device in its location.

The device is controlled by the Nerivio mobile 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

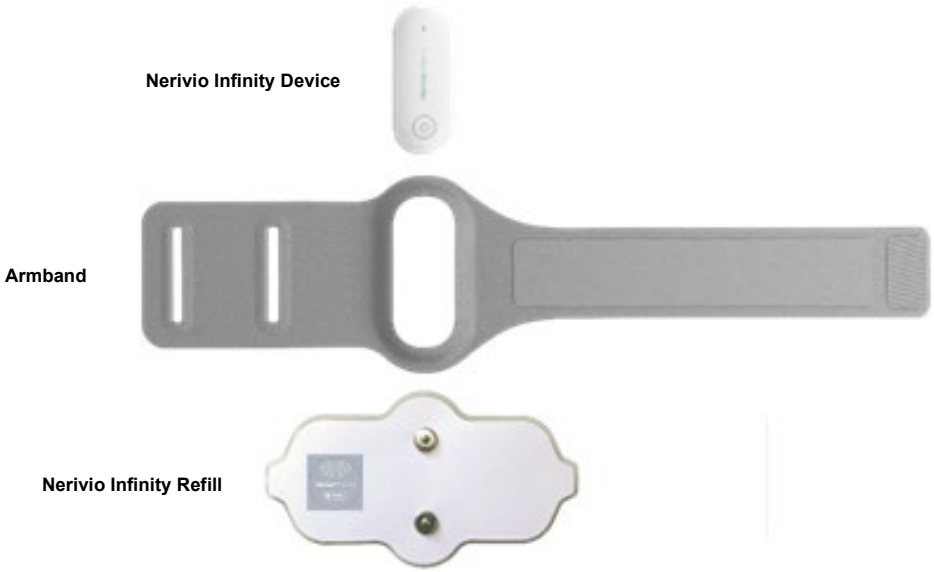
also provides notifications and indications on the connection status and on the remaining battery charge level. It also offers a migraine dairy feature which enables to track information about your migraine attacks.

1.3. PRODUCT FUNCTIONS

- The device is battery-powered; the battery is internal, integrated, and rechargeable.
- The device includes a replaceable refill unit, providing electrical stimulation to the skin, with an NFC-tag attached to it. The NFC-tag is used for the refill unit authentication by the Nerivio app.
- The device is activated by a power button.
- 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 discreet treatment. Two extensions are also provided for larger arm sizes.
- A mobile application (Nerivio app) is installed on a smartphone to control and monitor the treatment (as well as provide other features).

1.4. PACKAGE CONTENT

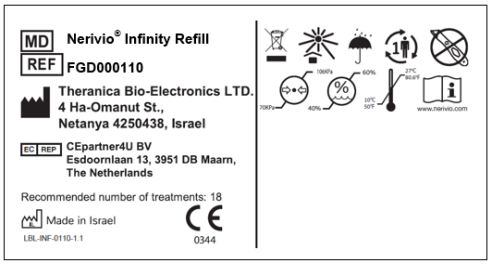
- 1 Nerivio® Infinity device
- 1 Refill unit with NFC-tag in a foil wrapper
- 1 Armband (XS)
- 2 Armband extensions
- 1 Travel pouch
- 1 QuickStart guide
- 1 USB type-A to USB type-C charging cable
- 1 Leaflet



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, this technology allows for wireless communication between devices when they are in proximity. For the Nerivio Infinity device, NFC is used to authenticate the refill unit, ensuring that only authorized refill units are used with the Nerivio Infinity device.
- BLE or BT: Bluetooth low energy

3. LABELS AND SYMBOLS

Device Labeling Template	Refill Unit Labeling Template
	

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**]

Symbol	Description
 YYYY-MM-DD	Manufacturer information and manufacturing date
 YYYY-MM-DD	Country code (**IL or TW**) and date of manufacture
	Type BF applied part (IEC60601-1)
	Catalog number
	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

Symbol	Description
	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.
	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 electrodes and do not touch the device contacts when it is operational.
- Do not charge the device when placed on the body or during treatment

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
- The long-term effects of chronic use of the device are unknown
- The device has not been evaluated for use in pregnant women and people less than 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 electrodes 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 electrodes, 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 electrodes and securing the device on your arm
- In case of device malfunction, remove the device from your arm and contact customer support
- It is recommended that your smartphone will be protected by a password (or other security mechanism) to refrain from unwanted people to activate the device
- Interference to 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 electrodes should be covered with the provided protective film and stored in its original package
- Do not expose the device to moisture and/or high humidity. If exposed, dry the device as soon as possible
- Before or after a treatment, rub the electrodes with your finger using a drop of water to improve their adhesiveness

- Do not clean the device with soap, alcohol, submerge in water, or scrub with abrasive material
- Do not disassemble or modify the device by yourself
- Do not attempt to detach the battery
- Keep the device out of the reach of infants, toddlers, children and pets
- The device uses Bluetooth technology; it may therefore be interfered by other equipment utilizing RF technology, even if the other equipment complies with CISPR emission requirements
- The device should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the 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 Infinity's 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.***

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

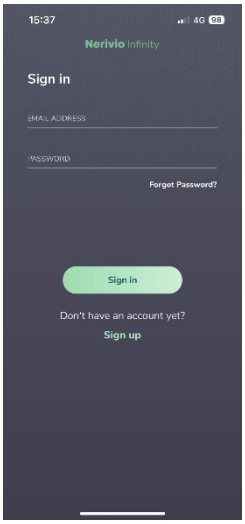
Do not attempt to perform any procedure before carefully reading all the instructions

6.1.1. DOWNLOADING AND INSTALLING THE APPLICATION

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

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

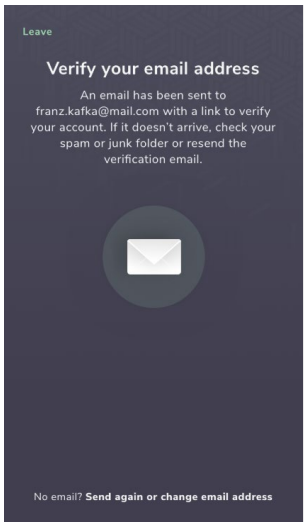
Step 3: You will be asked to create an account. Follow the app instructions. During the sign-up process, you will need to confirm the end-user license agreement and privacy policy (the EULA). The EULA confirmation is only required when the app is opened for the first time or when the EULA was changed. For safety reasons, you are advised to lock your smartphone with a password or any other means (biometric, etc.).

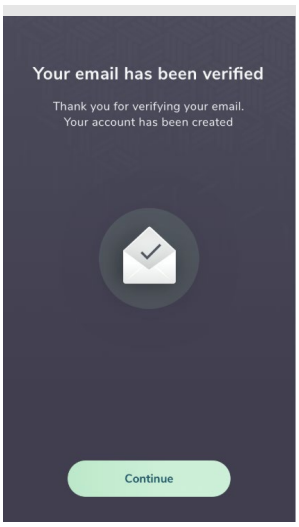


If this is the first time you are using the app, you will need to create an account in the "Sign up" screen. If you already have an account, use the "Sign in" to sign into your account.

When creating an account, you will need to choose a 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.

During the sign-up process, the app will send you a verification email to the email address which you have registered with. You will need to confirm this email to continue with the registration process. In case the verification email has not arrived within 10 minutes it is recommended checking junk emails or address the issue with internet provider to ensure it was not filtered out by spam filter.





In addition, Nerivio app interfaces to your phone's activity or FIT center in order to collect sleep activity to allow sophisticated analysis of your migraines. This is performed with your consent only.

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

1. Create your Adult account by using the process above.
2. After logging in, go to Account Settings (under More menu) to add create an Adolescent account.

Start the process by clicking on "Add child" and follow the instructions there onwards.

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 battery capacity can be read via the app when the charger is disconnected. The charging process may take several hours but, in any event, the process might be stopped 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 discharged battery for a long time or overcharging the device. For extending the battery life avoid exposing your device or charging it outside the recommended operational and storage conditions described in the section 9.2.

Make sure that the device is charged before your treatment to at least 15% of the battery charge. 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 (or other equipment) USB port as it may not always meet the required specification or provide required safety protections.

If you do not have a suitable adapter, please contact 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:

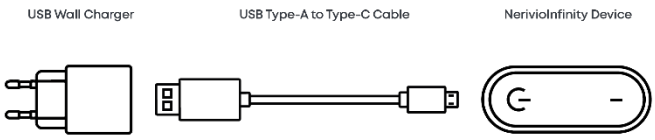


Figure 1 - Sequence of Connecting Device to Charger

When connected, LED indications are as follows –

Red light: Charging in progress

Green light: Charge is complete, battery is full

A full charge cycle will typically take 3.5-4 hours. However, a 30-minute charge will bring the battery level to a sufficient level for at least one treatment. The Nerivio mobile application can be used to check the remaining battery charge. Remember to unplug the device from the charger and connect it to the mobile application for monitoring 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

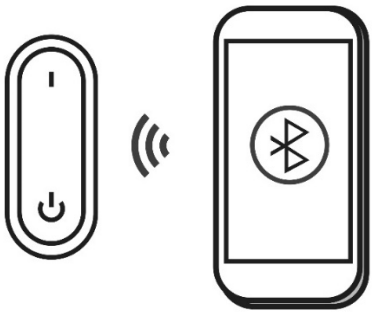
6.1.3. CONNECTING THE DEVICE TO THE APP FOR THE FIRST TIME

Step 1: Turn on the device using the power button located at the external part of the device. A slow flashing (mostly on) 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

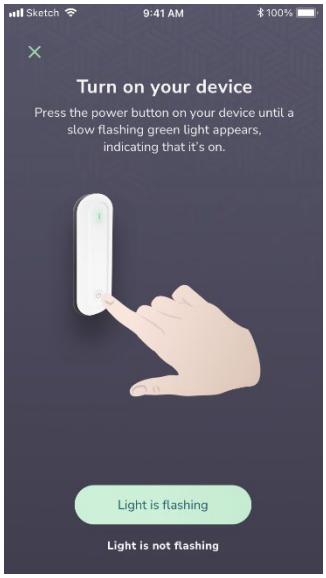
Step 2: Enable Bluetooth on your smartphone. ***Before you begin, make sure the device is charged.*** Then, open the mobile app, turn on the device, and connect the Nerivio Infinity device to the app using the app instructions. The device and the smartphone should be in proximity of 1 inch (~2.5 cm) 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 has been established. A fast-flashing green light indicates the device is connected to the app.

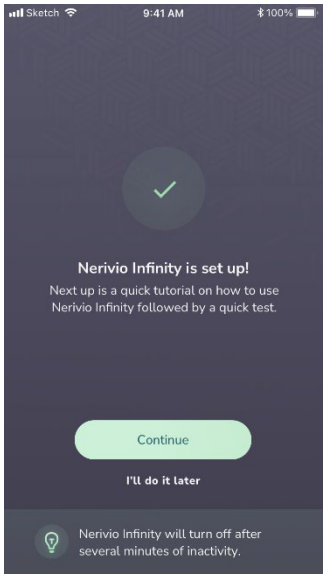
Note that each device can only be associated with one user.



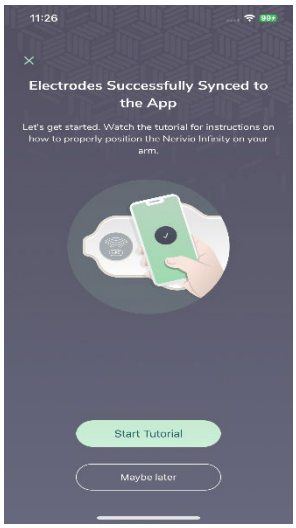
Do not share the device. The device is intended for a single user.

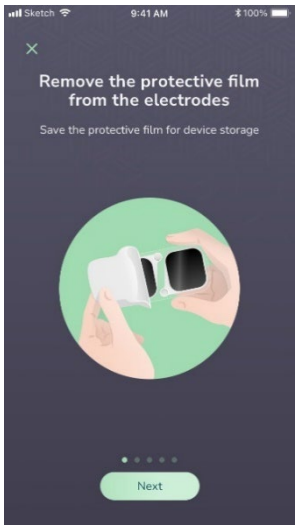
The following screens will appear, they describe a successful connection between the Nerivio Infinity device and your smartphone:

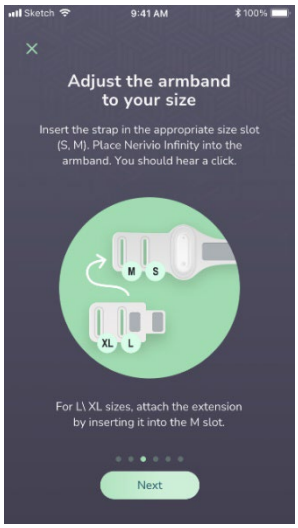


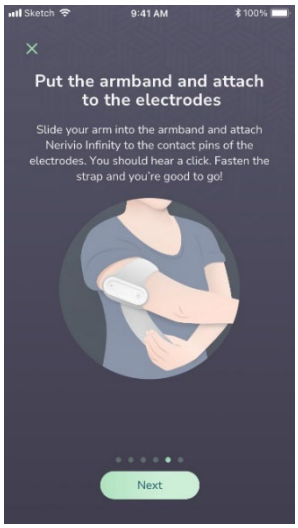


Step 3: The instructions of how to treat a migraine headache with Nerivio Infinity will be presented. You can skip it by pressing “Skip” or “Next”.









Note: There are two armband extensions included in the package, allowing you to adjust the armband length to fit all arm sizes comfortably.

Step 4: Place the device and the refill unit in its original package or in the Travel pouch to store it for next use or start a treatment following the instructions below. If the device was on for over 5 minutes when no treatment was initiated, it automatically shuts down. Turn it back on to start a treatment.

6.1.4. THE APP SCREENS

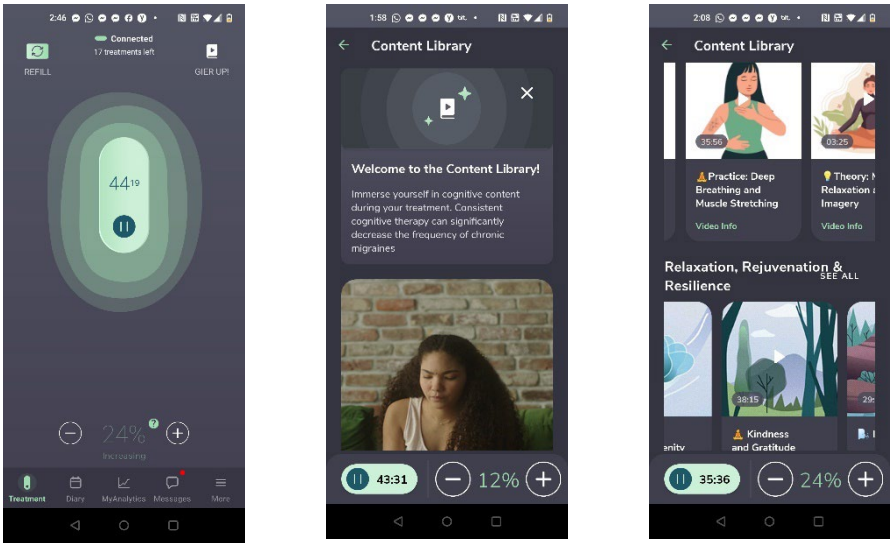
The app includes a *treatment screen (home screen)*, a *diary screen, MyAnalytics screen*, *messages screen* and a *More screen*.

Treatment screen – This screen enables to initiate, control, monitor, pause and stop a treatment session. A battery charge status is available when the device is connected.

GIER Up! 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 Infinity 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 migraine 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.



From left to right:

A) The GIER UP! button is located at the top-right corner of the treatment screen and is enabled a few seconds after the treatment starts.

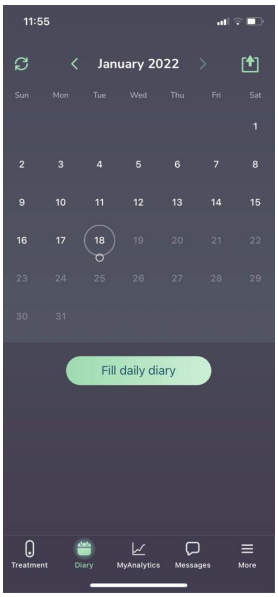
B) GIER welcome screen (shown 3 times only) provides the entry point to the GIER library.

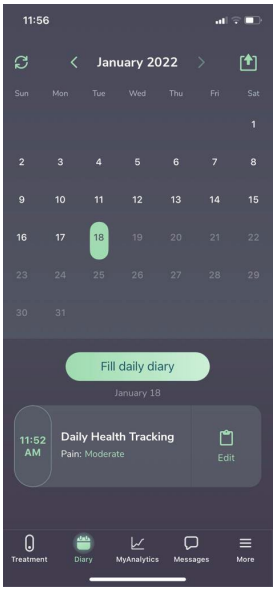
C) Inside the GIER library you'll find a plethora of content curated to themes.

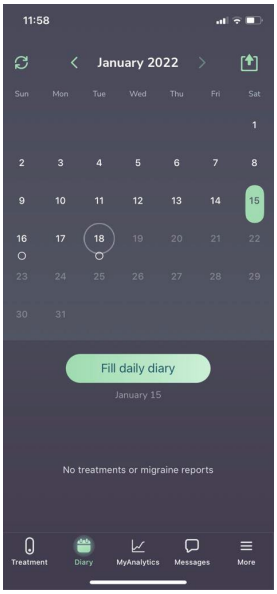
Important to note that the GIER library is scrollable both vertically and horizontally – be sure to explore the library for its exciting content.

Diary screen – This screen enables you to track and edit your treatment sessions and migraine headaches. Clicking on Diary in the app will open a calendar in which all your treatment sessions and reported migraines are stored. Treatment sessions are marked as green dots on the treatments days and daily diary records 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 diary entry by pressing the edit button of the record. The diary 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 button, which enables you to download the file and save it locally or send it by email or any messaging app installed on your phone.



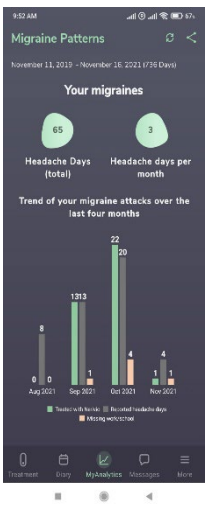


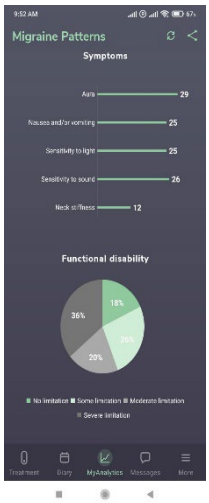


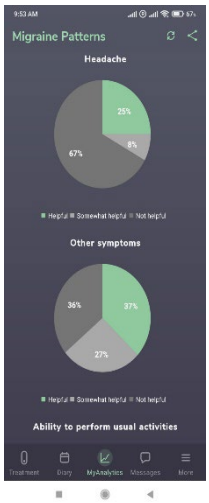
MyAnalytics screen

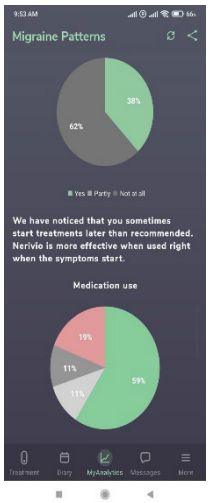
Your migraine records are summarized in the MyAnalytics screen. MyAnalytics presents the number of migraines you have had, your headache pain levels, and presence of other symptoms. It provides information on how well you adhere to the recommended instructions of Nerivio Infinity such as treating early. MyAnalytics presents whether your treatments with Nerivio Infinity were helpful for your headaches and other symptoms and provides information on the types of medications you use. It displays the distribution of your migraines across the weekdays and time in the day (e.g., mornings). This information only exists if you record your symptoms when you treat your migraines and after the treatment is over when you receive notifications.

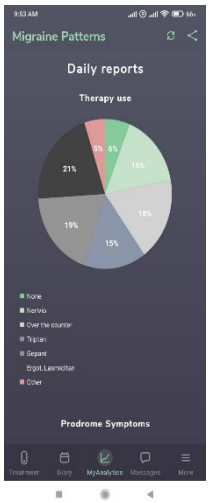
The information on MyAnalytics can be exported to a PDF and shared with your healthcare provider, a family member, or a friend. This is done by clicking the SHARE button, which enables you to download the file and save it locally or send it by email or any messaging app installed on your phone.







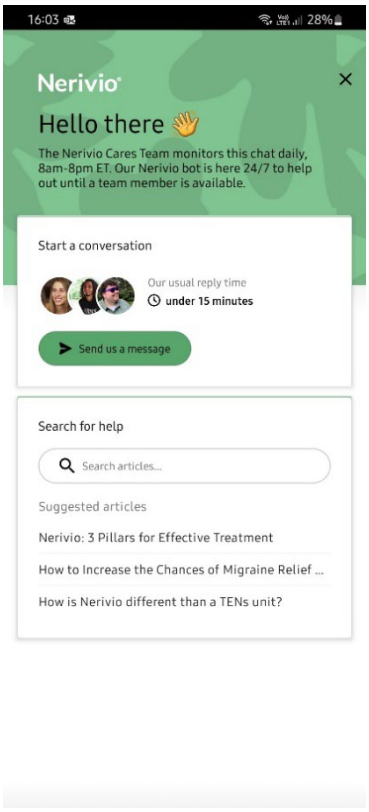


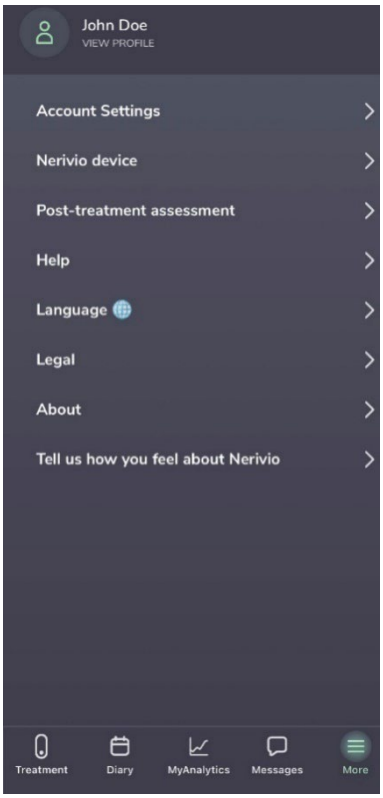


Messages screen – This screen provides access to app notifications that have been received.

More screen – This screen provides access to some of the technical aspects of the app:

- View profile – select this to view or edit your account details.
- Account settings – select this to manage three functions:
    - Create and view an adolescent's or children's account. As Nerivio Infinity is indicated for patients 8+, you can have an adolescent or children use Nerivio Infinity and the app via creating an adolescent or children account from an existing adult account. The specific age enabling creation of adolescent or children account may vary from region to region, please make sure to follow the instructions on the screen to complete this process.
    - Sign out: You may either sign out of your account or change the automatic sign-out settings.
- Nerivio Infinity device– select this to order a Nerivio Infinity device or its refill unit, or to connect to a different new Nerivio Infinity device or to enter a special code, if applicable.
- Post-treatment assessment – select this to report your migraine symptoms at 2 hours post-treatment. When a post-treatment assessment is available, a green badge will be presented on the More menu.
- Help – this screen provides access to the instructional videos that explain how to treat a migraine headache with the Nerivio Infinity device, to the Nerivio Infinity user manual, to tutorials for using the Nerivio Infinity device, to frequently asked questions, to troubleshooting and enables to contact customer support via email or phone.
- Language – select this to choose you preferred language.
- Legal– select this to view the EULA terms and conditions and data privacy information, if applicable.
- About- select this to view the app version and the connected device info.
- Tell us how you feel about Nerivio Infinity - select this to rate and share with us your feedback on the Nerivio Infinity device.
- Have a question? Chat with us – select this to chat directly with our experienced support professionals about any question you may have:





6.2. TREATING A MIGRAINE HEADACHE

The acute treatment should be performed at the onset of a migraine headache. For effective results, you should start the treatment as soon as you feel the first symptoms of the migraine and within the first hour (60 minutes) of the migraine symptoms onset (headache and/or aura).

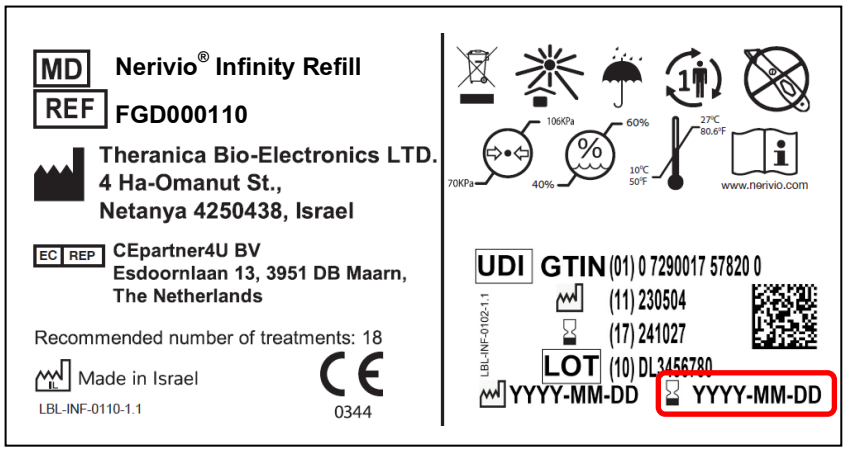
For migraine prevention therapy, the treatment shall be self-administered every other day regardless of the migraine symptoms. It is possible to administer acute treatment as described above, even if the device is used for preventive therapy. In case the acute treatment was already performed, you may skip your preventive treatment during the same day.

The treatment duration is 45 minutes.

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.

Step 1: Check the refill unit expiration date and recommended number of treatments, you can find this information on the label located on the refill unit's protective film and on the refill unit package.



Do not use the electrodes pad kit 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 slow flashing (mostly on) 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.

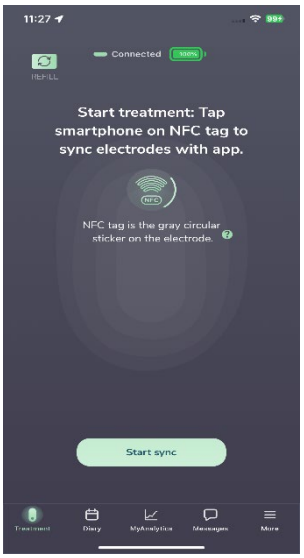
Step 4: Pairing the device to the app via Bluetooth – open the app and confirm the device is connected successfully. If the device does not connect automatically, tap the 'Connect' button to manually pair it with your phone. The connection status can be viewed in the app on the top of the treatment screen. The battery remaining charge is shown in %. For a full treatment the device shall be charged to at least 15%[1].

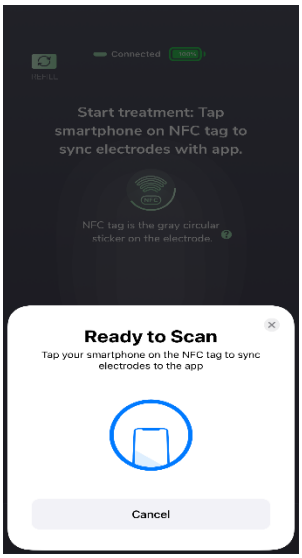
[1] It might be required to have larger available charge capacity for a full treatment after the battery capacity is decreased during device usage.

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 them on a flat surface. Make sure you keep the aluminum bag for refill unit storage. Locate the NFC tag on the refill unit and tap your smartphone on the NFC tag. Make sure you receive on-screen confirmation that the app has detected the NFC.

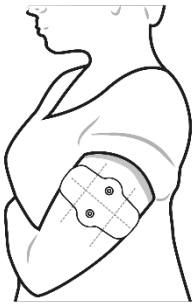




[This Screen for iPhone Only]

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

Step 7: Place the refill unit on your upper arm so that the electrodes 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.



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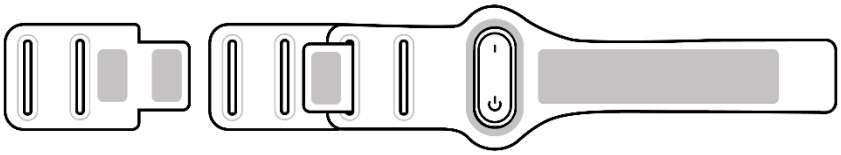
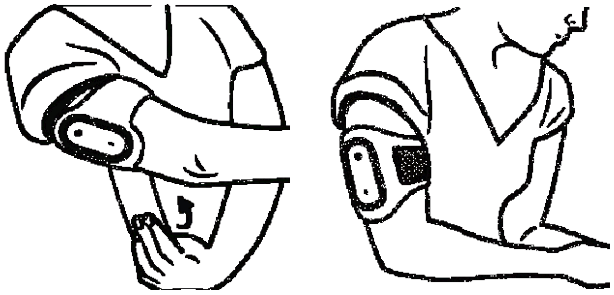
Step 8: Place the device into the armband by snapping it into the inner circle and adjust the armband to your size. The Extensions allow you to adjust the armband to your perfect arm size. When the strap and device are secured to the arm (see step 8), the feeling should be tight and yet comfortable.



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 electrodes 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, click 'Start' on 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.

Note: If an extended period has passed since step 5, simply tap your phone on the NFC tag again.

Do not start a treatment before connecting electrodes 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 electrodes, 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

The long-term effects of chronic use of the device are unknown

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 refill unit 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

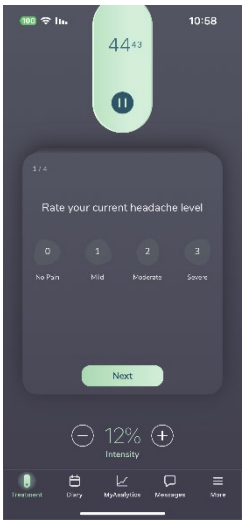
Once you find the strongest and most convenient stimulation intensity level, relax and continue with the treatment. If during the treatment the sensation is not strong, if it feels uncomfortable or painful, adjust the intensity level using the "+" and "-" buttons.

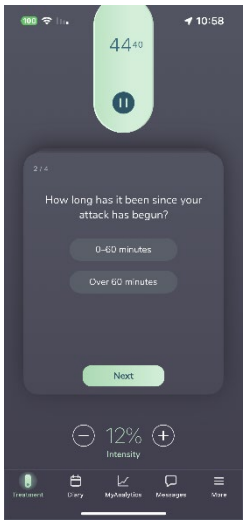
- The default starting intensity level is 12%.
- Note that long/continuous presses should be avoided.
- If you have significantly increased the intensity and still do not feel the stimulation, please refer to troubleshooting or contact customer support.

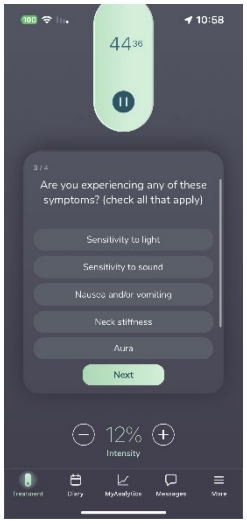
For your safety, the intensity will increase slowly. This gradual increase will be presented in the app by a flashing “increasing” indication that will stop once the desired intensity is reached.

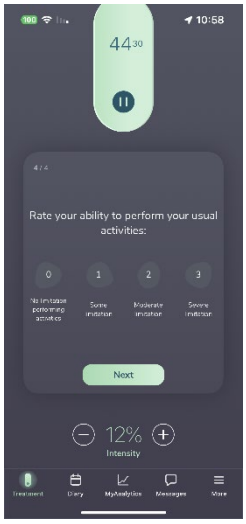
Step 12: After the treatment has begun, questions regarding your migraine symptoms will be automatically displayed. You can record your migraine symptoms or skip this by touching “Next”.

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









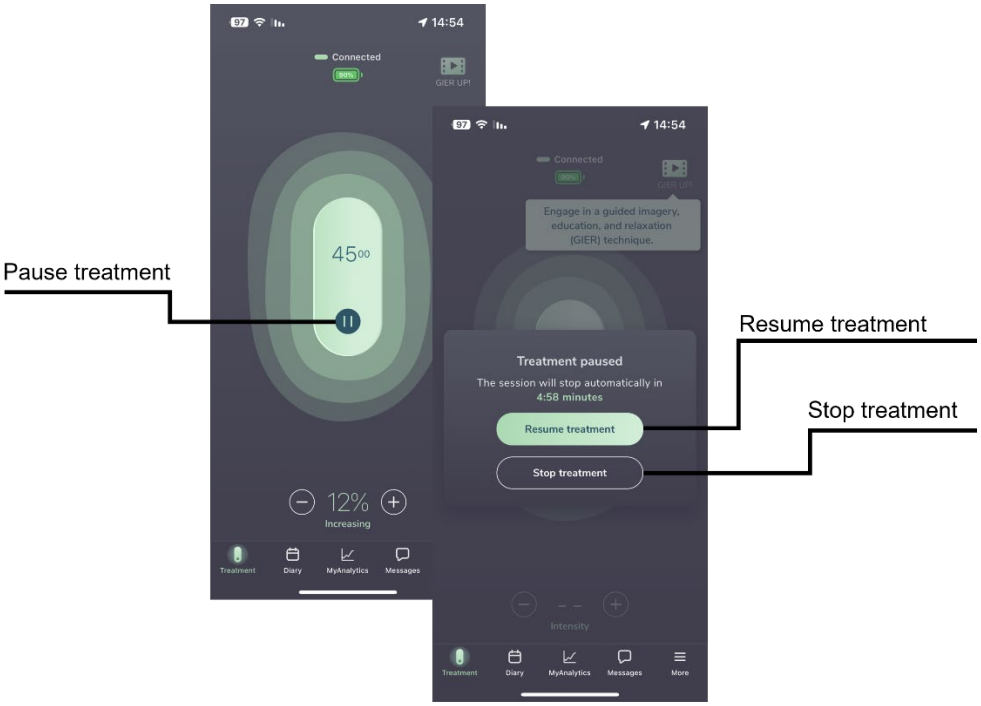
You can also record your post-treatment outcomes via notifications that will be sent to you or in the post-treatment assessment section in the More menu.

6.2.1. TREATMENT IN PROGRESS

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

You can pause the treatment session for up to 5 minutes by pressing 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

6.2.2. TREATMENT COMPLETED

Step 1: When the treatment is completed, remove the armband, device and the 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 electrodes (the protective film is reusable).

Step 3: Place the device in its original package or in the travel pouch to store it for the next use. Place the refill unit in it's original pack.

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.

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 inside the 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 travel pouch in an indoor environment according to the storage enviroment conditions specified in this user manual.

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

Do not expose the device to moisture and/or high humidity. If exposed, dry the device as soon as possible

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 DIARY

Keeping detailed records of migraine episodes can help in migraine management. The symptoms recorded during a treatment will be saved in a migraine diary that can be reviewed at any time via the app. Press "Diary" to review your migraine symptoms.

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

You can view and edit these reports at any time from the 'Diary' tab in Nerivio app.

To help you track your migraine headaches, the app will provide notification to record your symptoms 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 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 refill unit).
- If the refill unit 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 film. The refresh process can be repeated multiple times. Replace the refill unit 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 refill unit 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 refill unit varies depending on skin conditions, skin preparation, storage and climate. Replace the refill unit 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

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
	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 5 minutes. • For all subsequent treatments, the device will give you 3 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

Problem	What it may mean	What to do
	The device's battery is empty	Charge the device
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, 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 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:

Problem	What it may mean	What to do
		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 Nerivio 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. 3. The NFC chip on the refill unit is 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
	The refill unit 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 30 minutes for better effect. You can repeate this process several times to improve dry refill unit electrodes adhesion.
	The adhesive surface of the refill unit 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 and that the electrodes are in contact with your skin	The device is not properly placed on the arm and/or the electrodes are not in contact with your skin	Make sure the protective film was removed from the refill unit. The device 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

8.3. LED STATUS

LED indication	Status
Flashing green very rapidly (5 times per second)	The device is shutting down or an error 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
Solid green	[During charge only] Battery is full

LED indication	Status
	[No charger connected] Device is booting or replacing firmware during firmware recovery
Solid purple	[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 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 refill unit is 18 treatments or until the product use-by date indicated on its label.

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9. OPERATION SPECIFICATION

9.1. ENVIRONMENT OPERATING CONDITIONS

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

Relative humidity range: 35%-65%

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%-60%, with no condensing

Atmospheric pressure: 70-106 kPa

9.3. ENVIRONMENTAL TRASNPORTATION AND STORAGE CONDITIONS

Temperature range:	+10º to +27º C (50'F-80.6'F)
Relative humidity range:	40%-60%, 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	100-120Hz
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 a 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, modulated
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	 40mA

2KΩ 10KΩ	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	100-120Hz, average 110Hz	
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 -Output mode -Time to cut-off	Yes Yes No No Yes No	Yes Yes Yes (remaining charge in %) Yes (stimulation intensity) Yes (stimulation time indicator) Yes (stimulation time indicator)

Power source	Integrated, rechargeable secondary cell Li-Ion battery. Up to 4.2V, 430mah max.
Processor control	Yes
Wireless control	Yes
Wireless communication	Frequency range: 2.400-2.4835 GHz Modulation: Gaussian frequency shift Output power: ≤0 dBm
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. 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 electrodes, stop the operation of the other devices or move away from the interfering source.

- 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 to 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. 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

11. SMARTPHONE REQUIREMENTS

Refer to 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.
- 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.

In order 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. 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 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

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

Note: the following tables is formatted based on IEC60601-1-2.

Test	Standard	Class/ Severity level	Test result
Emission (IEC 60601-1-2 section 7.1 & 7.2 & IEC 60601-2-10 section 202) and (ETSI EN 301 489-1/ ETSI EN 301 489-17 sec.7.1)			
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
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 Flicker test	EN61000-3-3	230 VAC mains	Complies

15.3. ELECTROMAGNETIC 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
Immunity (IEC 60601-1-2 section 8.9 - 8.11 & IEC 60601-2-10 section 202) and (ETSI EN 301 489-1/ ETSI EN 301 489-17 sec.7.2)			
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
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	± 2.0 kV on AC mains, Tr/Th – 5/50 ns, 5 kHz	Complies
Immunity from Surge	EN 61000-4-5	Test is not applicable (refer to Section 2.6)	Exempted
Immunity from conducted disturbances induced by radio-frequency fields	EN 61000-4-6	3.0 V_{RMS} on 230 VAC mains 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

15.4. 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.

15.5. 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 / IEC 60601-2-10 edition 2.2 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 V3.2.4 (2020) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility

Nerivio® Infinity

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