theranica

Nerivio™

A wireless non-invasive neuromodulation device for the acute treatment of migraine

USER MANUAL

Theranica reserves the right to change or improve its products and accompanying technical literature without specific notice.

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FC

℞ Only

2AOH8-NM

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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™ 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@theranica.com.

1.2. PRODUCT OVERVIEW

Nerivio™ is a wearable, battery-powered medical device for the acute treatment of migraine with or without aura in patients 18 years of age or older who do not have chronic migraine. Nerivio™ is controlled by a mobile application. The Nerivio™ is intended for self-administration at a home environment.

The device is worn on the upper arm and transmits transcutaneous electrical nerve stimulation by applying weak electrical pulses that invoke conditioned pain modulation (CPM) to inhibit migraine pain. Nerivio™ is intended for self-administration at the onset of a migraine episode.

The Nerivio™ system includes several main components:

1. The Nerivio™ device. The device is placed on the arm and produces electrical signals. The device is good for 12 treatments of 45 minutes.
2. Armband and an extension. 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 to enable a discreet treatment.
3. Software application (app)
4. Travel bag

The external side of the Nerivio™ device includes a power button and a LED indicator that signals various modes of operation. The internal side includes 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.

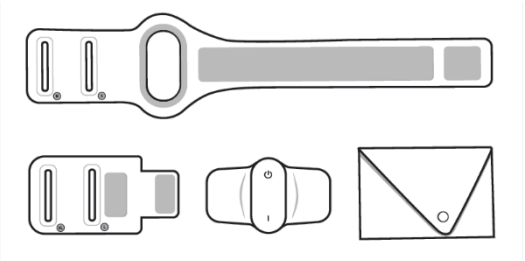
The application enables the user to activate the stimulation, control the stimulation intensity, monitor the treatment duration and pause or stop the stimulation. The application also provides notifications and indications on the connection status and on the remaining number of treatments. It also offers a migraine dairy feature which enables to track information about your migraine attacks. The migraine diary can also be accessed via the web.

1.3. PRODUCT FUNCTIONS

- The device is battery-powered; the battery is internal, integrated, and non-rechargeable.
- The device includes integrated electrodes, providing the electrical stimulation to the skin.
- 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 a discreet treatment. An extension is also 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™ device
- 1 Armband
- 1 Armband extension
- 1 Travel bag
- 1 QuickStart guide



2. GLOSSARY

App: Mobile application running on smartphone

LED: Light-Emitting Diode

EMC: Electromagnetic compatibility

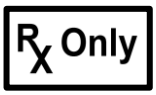
TENS: Transcutaneous electrical nerve stimulation

FDA: The Food and Drug Administration

FCC: The Federal Communications Commission

3. LABELS AND SYMBOLS

Symbol	Description
	Read and fully understand user manual before using this device
	Compliance with FCC Federal Communications Commission Class B – certified for home use FCC identifier: 2AOH8-NM
	Manufacturer
	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
	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

4. SAFETY

4.1. CONDITIONS FOR USE

4.1.1. INDICATION FOR USE

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

4.1.2. CONTRAINDICATIONS

I. The device should not be used by people with congestive heart failure (CHF), severe cardiac or cerebrovascular disease.
II. The device should not be used by people with uncontrolled epilepsy
III. 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, crush, incinerate or short-circuit the battery. This could cause a fire, injury, burns, or other hazards

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 18 years of age.
- The safety and effectiveness of the device have not been evaluated in people with chronic migraine
- The safety and effectiveness of the device have not been evaluated for the preventive treatment of migraine headache

- Do not use the device past expiration date
- Check the device for damages. If the device is damaged return it to the manufacturer or contact customer support
- If the device was damaged, do not touch exposed electronics
- Do not use the device if the electrodes become significantly dirty or damaged
- Keep the device in a dry environment. Moisture may damage the device
- Do not start a treatment before placing the device on your arm
- In case of device malfunction, remove the device from your arm and contact customer support
- It is recommended that your smartphone will be protected by a password (or other security mechanism) to refrain from unwanted people to activate the device
- Interference to 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 the device should be stored in its original package
- Do not expose the device to moisture and/or high humidity. If exposed, dry the device as soon as possible
- Before or after a treatment, rub the electrodes with your finger using a drop of water to improve their adhesiveness
- Do not clean the device with soap, alcohol, submerge in water, or scrub with abrasive material
- Do not disassemble or modify the device by yourself
- Do not attempt to recharge or detach the battery
- Keep the device out of the reach of infants, toddlers, children and pets
- The device uses Bluetooth technology; it may therefore be interfered by other equipment utilizing RF technology, even if the other equipment complies with CISPR emission requirements

The device should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the Nerivio™ should be observed to verify normal operation in the configuration in which it will be used

Do not use devices which generate strong electrical or electromagnetic fields, near the Nerivio™ device. This may result in incorrect operation of the device and create a potentially unsafe situation. In order to reduce the risk of EM interference, it is recommended to keep a minimum distance of 30 cm (12 inches) between the device and other electromagnetically radiating devices. Verify correct operation of the device in case the distance is shorter. During the immunity tests the device operated normally

Adverse reactions

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

Refer to Theranica's website at https://theranica.com 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 electrodes on the arm.

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.***

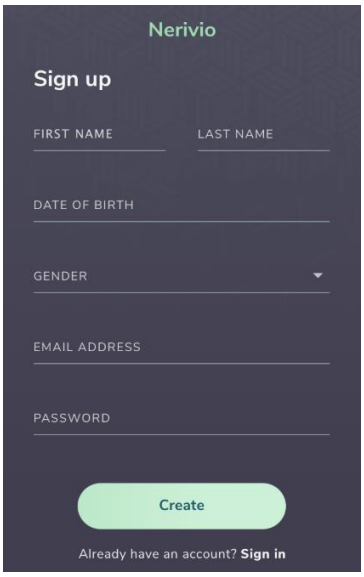
Do not attempt to perform any procedure before carefully reading all the instructions

6.1.1. DOWNLOADING AND INSTALLING THE APPLICATION

Step 1: Verify that your smartphone is compatible with the Nerivio app (refer to www.theranica.com for smartphone requirements).

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

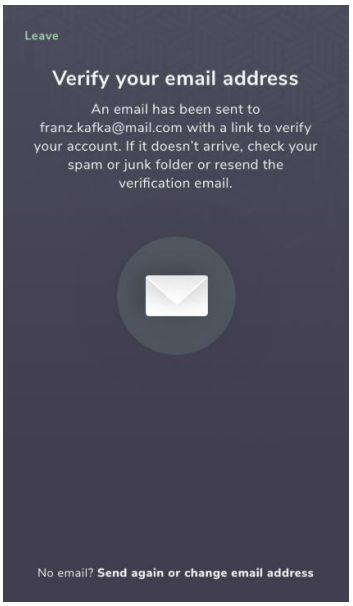
Step 3: You will be asked to create an account. Follow the app instructions. During the sign-up process, you will need to confirm the end-user license agreement (EULA). The EULA confirmation is only required when the app is opened for the first time. For safety reasons, you are advised to lock your smartphone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

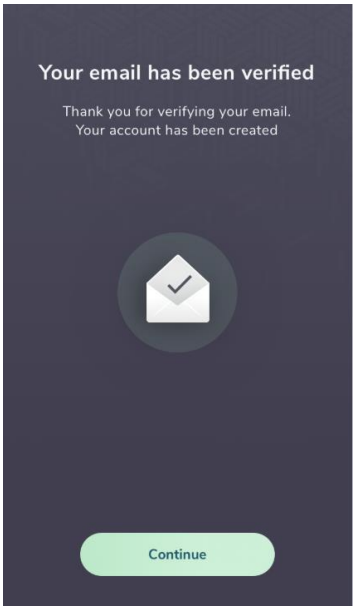


If this is the first time you are using the app, you will need to create an account in the "Sign up" screen. If you already have an account, use the "Sign in" to sign into your account

When creating an account, you will need to choose a password. The password must be at least 8 characters including at least 1 uppercase letter, at least 1 lowercase letter and at least 1 numeric digit.

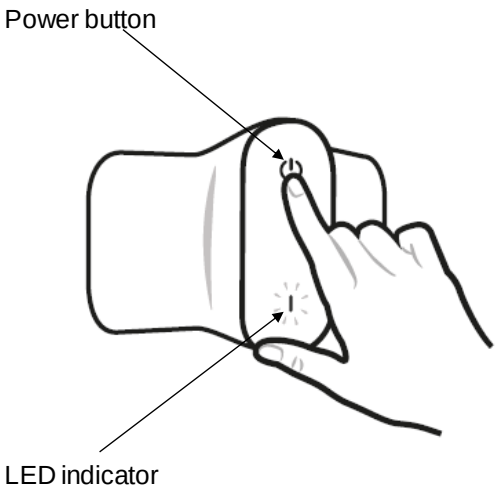
During the sign-up process, the app will send you a verification email to the email address which you have registered with. You will need to confirm this email to continue with the registration process.





6.1.2. 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 for damages. If the device is damaged return it to the manufacturer or contact customer support

Step 2: Enable Bluetooth on your smartphone. Then, open the app and connect the Nerivio™ device to the app using the app instructions. The device and the smartphone should be in proximity of less than 1 inch (~2.5 cm). As you begin using the app, it may ask for 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.

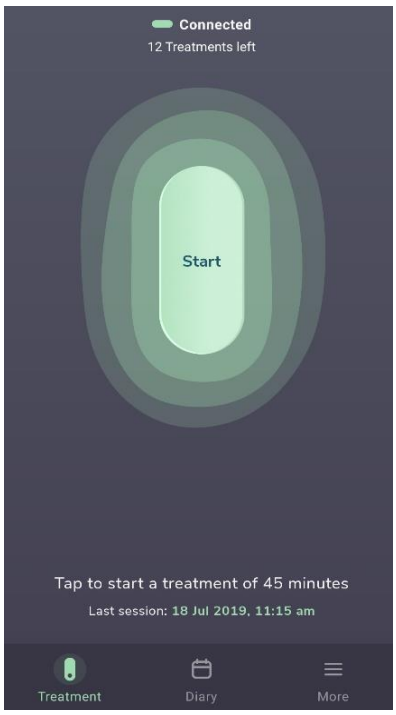
Step 3: Instruction how to treat a migraine headache with Nerivio™ will be presented. You can skip it by touching “Skip”.

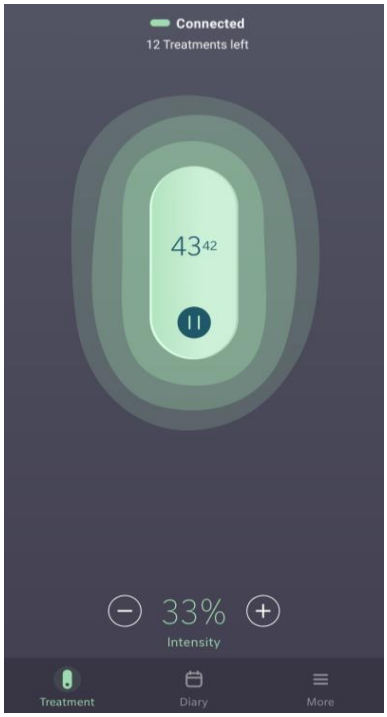
Step 4: Place the device in its original package or in the travel bag to store it for next use or start a treatment following the instructions below. If the device was on for over 10 minutes when no treatment was initiated, it automatically shuts down. Turn it back on to start a treatment.

6.1.3. THE APP SCREENS

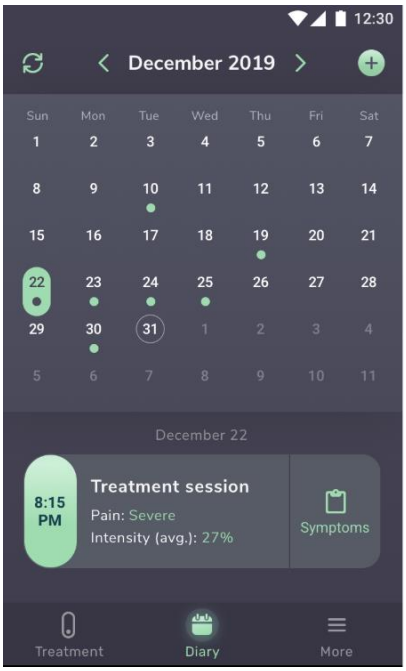
The app includes a *treatment screen (home screen)*, a *diary screen* and a *more screen*.

Treatment screen – This screen enables to initiate, control, monitor, pause and stop a treatment session.





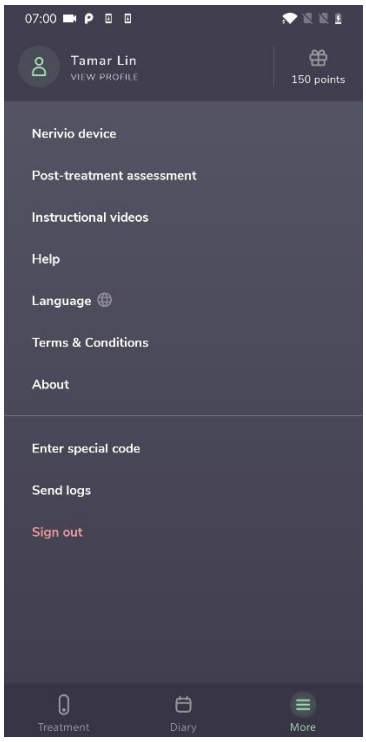
Diary screen – This screen enables you to track and edit your treatment sessions and migraine headaches.



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

View profile – Select this to view your account details
Nerivio device– Select this to order a Nerivio™ device or to connect to a different Nerivio™ device

Post-treatment assessment – Select this to report your migraine symptoms at 2 hours and at 24 hours post-treatment. When a post-treatment assessment is available, a green badge will be presented on the More menu.
Instructional videos – Select this to view instructional videos that explain how to how to treat a migraine headache with the device
Help – This screen provides access to the Nerivio™ user manual and enables to contact customer support via email.
Language – Select this to choose you preferred language.
Terms & Conditions – Select this to view the terms and conditions.
About- select this to view the app version and the connected device info
Enter special code – Select to enter a code, if applicable.
Sign out- select this to sign out of your account and to change the automatic sign out settings.



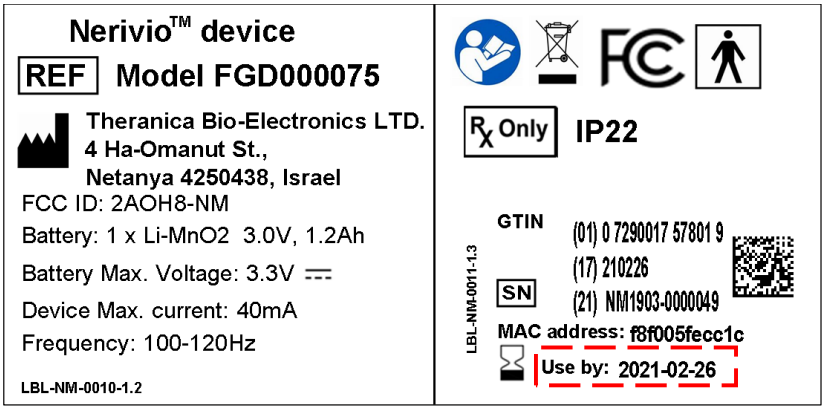
6.2. TREATING A MIGRAINE HEADACHE

The 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). The treatment duration is 45 minutes.

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

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

Step 1: Check the device expiration date on the label located on the protective film and on the package.

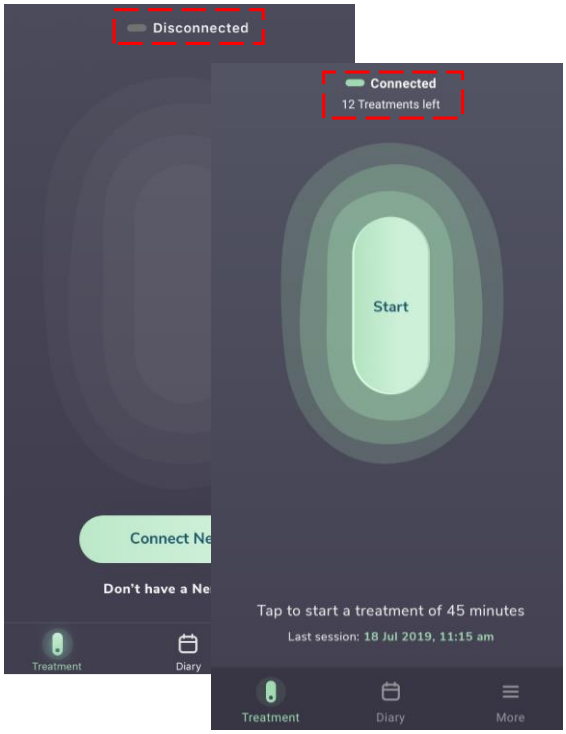


Do not use the device past expiration date

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

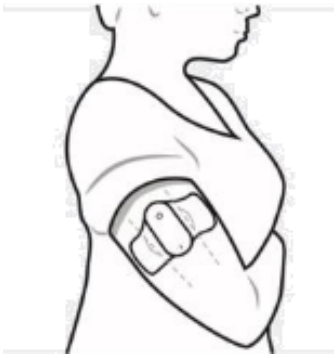
Step 3: Turn on the device. A slow flashing (mostly on) green light indicates the device is on. If the LED is still off or is solid green, please contact customer support.

Step 4: Open the app and confirm the device is connected successfully. The connection status can be viewed in the app on the top of the treatment screen. Also verify that there is at least one remaining treatment.



Step 5: Carefully remove the protective film from the electrodes and save it for storing the device and maintaining the electrode adhesiveness between uses.

Step 6: Place the device on your upper arm so that the electrodes are in contact with your skin and the LED indicator is facing outwards. The device should be located midway



between the elbow and the shoulder. Place the device directly on the skin and not on your shirt.

Step 7: Adjust the armband to your size. There are 4 sizes you can choose from (S, M, L, XL). Attach the extension to the armband for L and XL sizes.

Step 8: Insert the strap to the buckle of your size.

Step 9: Wrap the armband around the device on your arm and fasten the strap. The armband will secure the device on its location and improve the contact between the device and your skin.

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

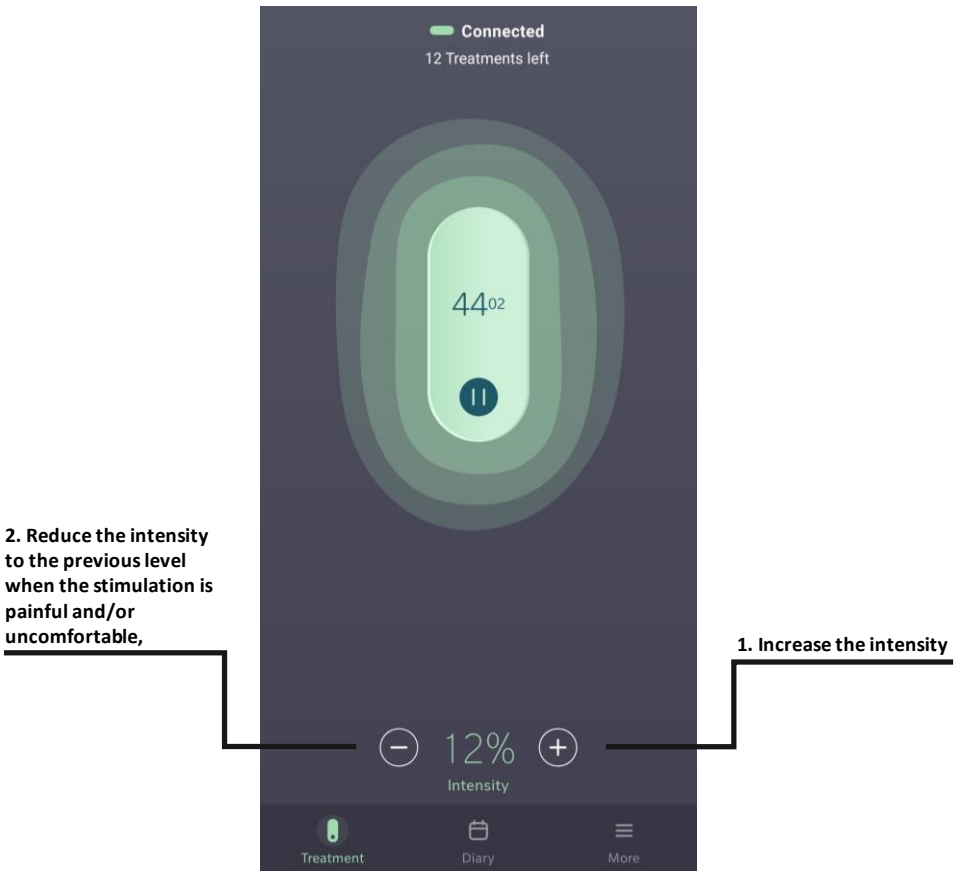
Do not use the device over skin conditions, such as open wounds or rashes, or over swollen, red, infected or inflamed areas or skin eruptions or fragile skin on your upper arm at the treatment location

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.

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 placing 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 if the electrodes become significantly dirty or damaged**
- **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 device fails 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

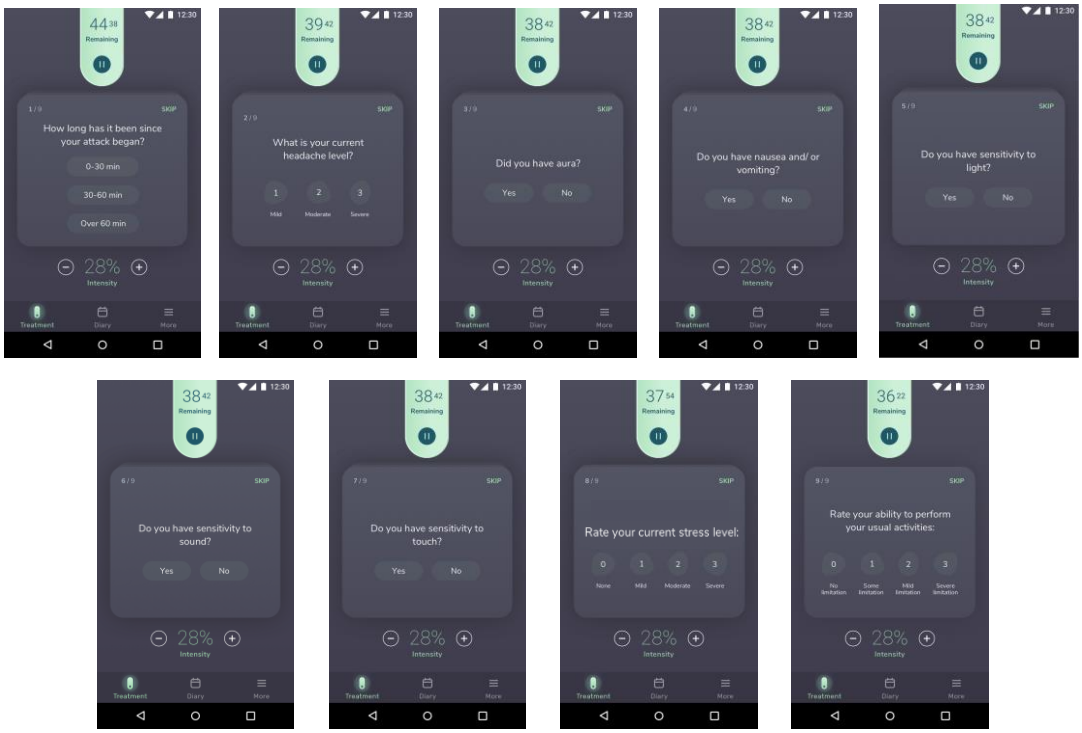
Once you find the strongest and convenient stimulation intensity level, relax and continue with the treatment. If during the treatment the sensation is not strong, if it feels uncomfortable or painful, adjust the intensity level using the "+" and "-" buttons.

- 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 on your migraine symptoms will be automatically displayed. You can record your migraine symptoms or skip this by touching “Skip”.

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



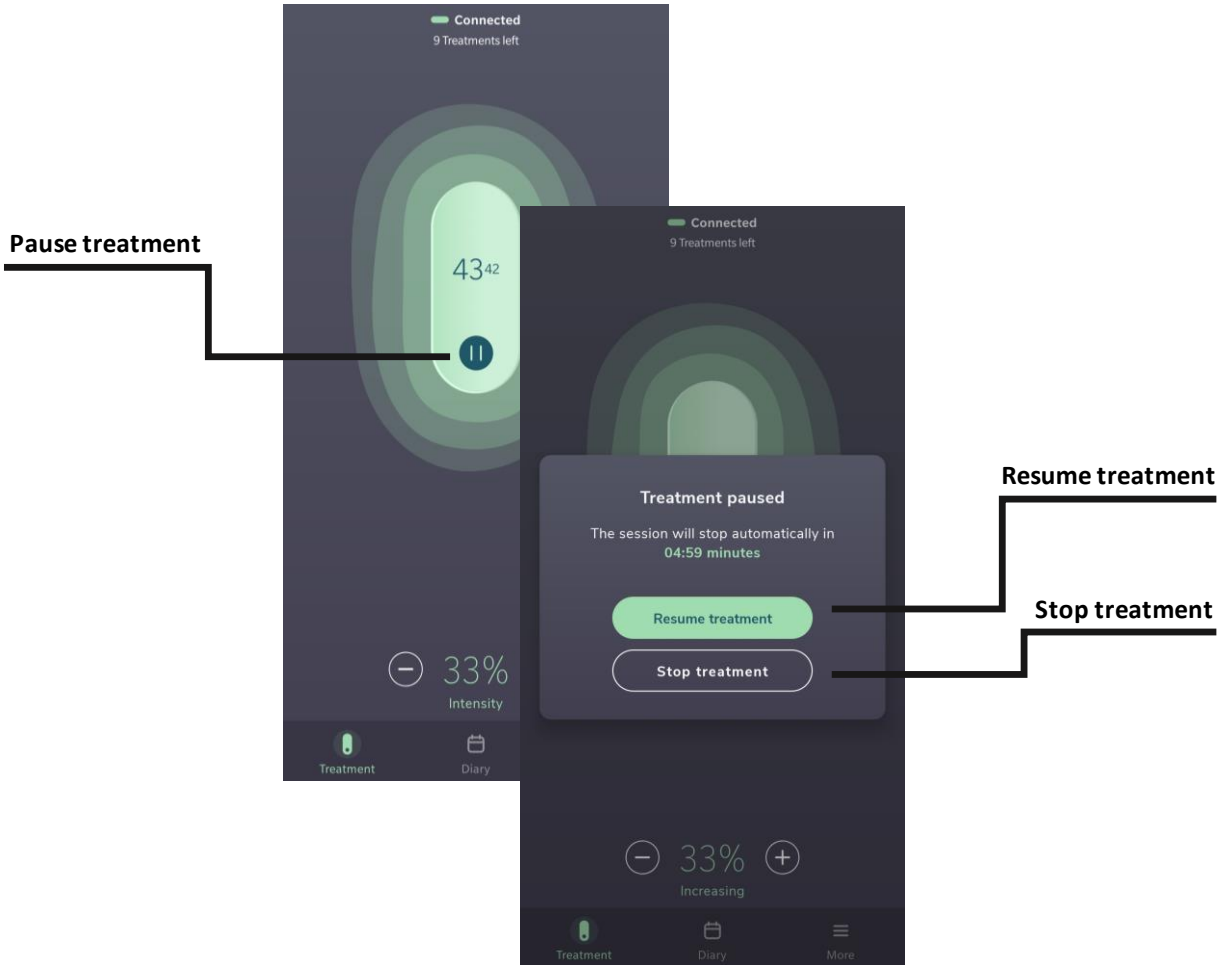
You can also record your symptoms post-treatment via notifications that will be send or in the post-treatment assessment section in the More menu.

6.2.1. 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 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 to activate 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 "Stop" button does 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 and the device 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 electrodes (the protective film is reusable).

Step 3: Place the device in its original package or in the travel bag to store it for next use.

Step 4: Close the app.

If your migraine headache is not aborted 30 minutes following treatment, you may administer additional treatments.

6.3. STORING THE DEVICE FOR NEXT USE

Once the treatment has been completed, the device needs to be stored until the next treatment.

Step 1: Verify that the electrodes are covered with the protective film.

Step 2: Store the device in its original package or in the travel bag in an indoor environment, away from direct sunlight and according to 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 the device should be stored in its original package

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

The device 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. Touch “Diary” to review your migraine symptoms.

You can also report a current migraine headache and records your symptoms in the diary even if the device is not used.

To help you track your migraine headaches, the app will provide notification to fill your symptoms at 2 hours and at 24 hours after a treatment session or a reported migraine headache. You can disable these notifications in the smartphone settings.

The migraine diary can also be accessed via the web. Type https://diary.nerivio.com in your web browser and enter your account details. To view your login details in the app, touch “More” and then touch “View profile”.

7. CLEANING, MAINTENANCE AND DISPOSAL

7.1. CLEANING AND MAINTENANCE

- The device can be cleaned with a dry cloth (except for the electrodes).
- If the electrodes begin losing adhesion, gently rubbing one or two drops of water onto the gel surface may extend usage.
- 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.
- 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

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, before product expiration date or before 12 treatments have been performed, 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 there are treatments left in your device

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@theranica.com
	The power button was not held long enough	Press the power button continuously for 2-3 seconds
The LED is flashing very rapidly (5 times per second)	There is an error message on the screen	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
	There are no treatments left in the device	Check in the app how many treatments you have left. The device is good for 12 treatments of 45 minutes. If there are no treatments left, dispose the device.
The LED is solid green	Device malfunction	Contact customer support at support@theranica.com

No communication between the app and the device	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	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 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 electrodes
	The electrodes begin losing adhesion	Gently rub with your finger one or two drops of water onto the gel surface of the electrodes
	The adhesive surface of the device is damaged	Replace the device

8.2. MAIN ERRORS AND MESSAGES

Errors and messages displayed on the screen	What it may mean	What to do
Nerivio 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 electrodes The device should be placed directly on the skin of the arm
No treatments left	No remaining treatments	The device cannot be used. Replace the device or order a new device.

Errors and messages displayed on the screen	What it may mean	What to do
Nerivio 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 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

8.3. LED STATUS

LED indication	Status
Flashing very rapidly (5 times per second)	The device is shutting down or an error occurred or there are no treatments left in the device
Solid green	Device malfunction
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

8.4. CUSTOMER SUPPORT

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

The service lifetime of the Nerivio™ is until product expiration date.

The battery operation time is 540 minutes if stored at ambient temperature of 23±2℃ (i.e., 12 treatments of 45 minutes)

Theranica Bio-Electronics LTD.

Address: 4 Ha-Omanut St.
Netanya 4250438, Israel
Email: support@theranica.com
Web: www.theranica.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%-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%-50%, 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%-50%, with no condensing
Atmospheric pressure:	70-106 kPa

9.4. ELECTRICAL PROPERTIES

Battery type:	Primary cell Li-MnO2, 3.0 V, 1.2 Ah
Maximum Voltage:	3.3V
Maximum Current	40mA
Frequency	100-120Hz
Charger Input:	N/A – the battery is not rechargeable in the device
Charger output:	N/A – the battery is not rechargeable in the device
Battery lifetime	540 minutes if stored at ambient temperature of 23±2℃.

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

Do not attempt to recharge or detach the battery

Recycle or dispose the device 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 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	100-120Hz, 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	Yes	Yes
-Wireless connection	Yes	Yes
-Low battery	No	Yes (remaining number of treatments)
-Current level	No	Yes (stimulation intensity)
-Output mode	Yes	Yes (stimulation time indicator)
-Time to cut-off	No	Yes (stimulation time indicator)
Power source	Integrated, non-rechargeable, primary cell Li-MnO2 battery Operation time: 540 minutes (12 treatments of 45 minutes).	
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.

11. SMARTPHONE REQUIREMENTS

Refer to www.theranica.com for smartphone requirements

12. POTENTIAL ADVERSE REACTIONS

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

13. CLASSIFICATION

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

14. EMC STATEMENT

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, the Nerivio™ 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™ device and create a potentially unsafe situation.

The Nerivio™ 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™ medical device conforms with the IEC60601-1-2:2014 standard for both immunity and emissions.

The Nerivio™ 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™ device. This may result in increased emissions or decreased immunity of the device.
- The Nerivio™ device should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the Nerivio™ 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™ 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™ device complies with immunity tests described below.

14.1. ELECTROMAGNETIC TEST RESULT SUMMARY

Test	**Standard**	**Class / Severity level**	**Test result**
Emission			
Radiated emission Frequency range: 30-1000 MHz	IEC 60601-1-2 section 7.1 / CISPR 11	Group 1 Class B	Complies
	ETSI EN 301 489-1 section 8.2; ETSI EN 301 489-17 section 7.1/ EN 55032	Class B	Complies
Radiated emission Frequency range: 1.0 GHz-6.0 GHz	ETSI EN 301 489-1 section 8.2; ETSI EN 301 489-17 section 7.1 EN 55032	Class B	Complies
Immunity			
Immunity from Electrostatic discharge (ESD)	IEC 60601-1-2 section 8, Table 4/ IEC 61000-4-2	8 kV contact & 15 kV air discharges	Complies
	ETSI EN 301 489-1 section 9.3; ETSI EN 301 489-17 section 7.2/ EN 61000-4-2	4 kV contact & 8 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 60601-1-2 section 8, Table 4/ IEC 61000-4-3	10 V/m, 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 60601-1-2 section 8, Table 9/ 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 radiated electromagnetic fields	ETSI EN 301 489-1 section 9.2; ETSI EN 301 489-17 section 7.2/ EN 61000-4-3	3 V/m, 80 MHz - 6 GHz, AM 80% @ 1 kHz	Complies

Test	Standard	Class / Severity level	Test result
Immunity from power frequency magnetic field	IEC 60601-1-2 section 8, Table 4/ IEC 61000-4-8	30 A/m @ 50 Hz & 60 Hz	Complies
Note: this table is formatted based on IEC60601-1-2:2014.			

14.2. ELECTROMAGNETIC EMISSIONS

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

Note: the following tables is formatted based on IEC60601-1-2:2007.

Electromagnetic emissions IEC 60601-1-2		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Nerivio™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Nerivio™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Not applicable	

14.3. ELECTROMAGNETIC IMMUNITY

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

Electromagnetic immunity IEC 60601-1-2			
Immunity Test	**IEC 60601-1-2 test level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Electrostatic discharge, ESD (IEC 61000-4-2)	Contact discharge: ±8 kV Air discharge: ±15 kV	Contact discharge: ±8 kV Air discharge: ±15 kV	The relative humidity should be at least 5%
Electrical fast transient / burst (IEC 61000-4-4)	Power supply lines: ±2 kV Longer input / output lines: ±1 kV	Not Applicable Not Applicable	
Surge on AC mains lines (IEC 61000-4-5)	Common mode: ±2 kV Differential mode: ±1 kV	Not Applicable Not Applicable	

Electromagnetic immunity IEC 60601-1-2			
Immunity Test	**IEC 60601-1-2 test level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Voltage dips, short interruptions and voltage variations on power supply lines (IEC 61000-4-11)	0% UT for 0.5 cycle 0% UT for 1 cycle 70% UT for 25 cycles 0% UT for 5 s	Not Applicable Not Applicable Not Applicable Not Applicable	
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	30 A/m	30 A/m	
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Electromagnetic immunity IEC 60601-1-2			
			Portable and mobile RF communications equipment should be used no closer to any part of the Nerivio™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF (IEC 61000-4-6)	3 V rms 150 kHz to 80 MHz	Not Applicable	$d = 1.16 \sqrt{P}$ 150 kHz to 80 MHz
	6 V rms The ISM bands and the amateur radio bands between 150 kHz to 80 MHz	Not Applicable	$d = 0.58 \sqrt{P}$ 150 kHz to 80 MHz (The ISM bands and the amateur radio bands)
Radiated RF (IEC 61000-4-3)	10 V/m 80 MHz to 2.7 GHz IEC 60601-1-2:2014 Table 9 (Up to 28 V/m at certain frequencies)	10 V/m 80 MHz to 2.7 GHz IEC 60601-1-2:2014 Table 9 (Up to 28 V/m at certain frequencies)	$d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \sqrt{P}$ 800 MHz to 2.7 GHz

Electromagnetic immunity IEC 60601-1-2			
			Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation Distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Nerivio™ is used exceeds the applicable RF compliance level above, the Nerivio™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Nerivio™.			

14.4. RECOMMENDED SEPARATION DISTANCES

Recommended separation distance between portable and mobile RF communications equipment and the NM				
Nerivio™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the users of Nerivio™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Nerivio™ 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.				

15. 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.

16. APPLICABLE STANDARDS

- IEC/EN 60601-1 edition 3.1 Medical electrical equipment, part 1: General requirements for basic safety and essential performance.
- IEC/EN 60601-1-2 edition 4.0 Medical electrical equipment- Part 1-2: General requirements for safety – collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC/EN 60601-2-10 edition 2.1 Requirements for the safety of nerve and muscle stimulators

Nerivio™

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