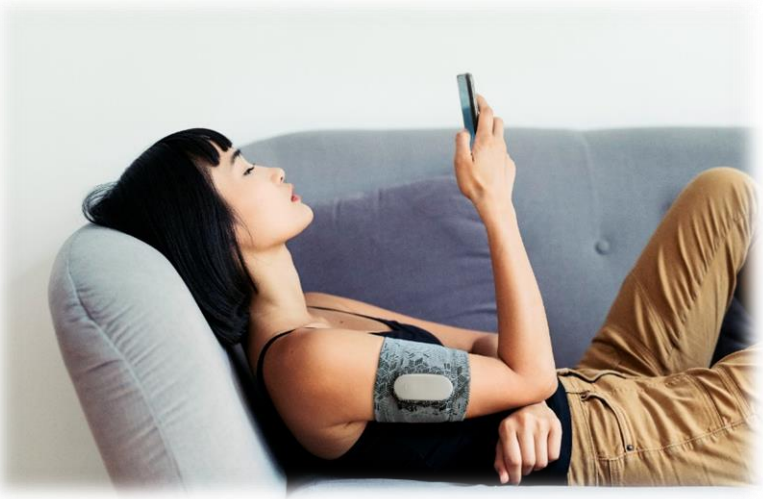
theranica
CONNECTED HEALTHCARE

Nerivio Migra®

A 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 Rx Only

2AOH8-NM

Table of content

1. INTRODUCTION

1.1. ABOUT THIS MANUAL

This manual provides the information necessary for the user to effectively use the Nerivio Migra® 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 Migra® is a wearable, battery-powered medical device for the acute treatment of migraine with or without aura. Nerivio Migra® is controlled by a mobile application. The Nerivio Migra® 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 Migra® is intended for self-administration at the onset of a migraine episode.

The Nerivio Migra® system includes several main components:

1. The Nerivio Migra device. The device is placed on the arm and produces electrical signals. The device is good for 12 treatments of 45 minutes.
2. Flexible arm sleevelet. The sleevelet 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
4. Travel bag

The external side of the Nerivio Migra device includes an ON button and a LED indicator that signals various modes of operation. The internal side includes the electrodes that deliver neurostimulation signals. The sleevelet holds 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 an ON button.
- Flexible arm sleevelet 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 application (app) installed on a smartphone to control and monitor the treatment (as well as provide other features).

1.4. PACKAGE CONTENT

- Nerivio Migra device
- Flexible arm sleevelet
- Travel bag
- QuickStart guide

2. GLOSSARY

App: Mobile application running on smartphone

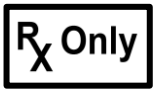
LED: Light-Emitting Diode

EMC: Electromagnetic compatibility

MAC: Media access control

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.

4. SAFETY

4.1. CONDITIONS FOR USE

4.1.1. INDICATION FOR USE

The Nerivio Migra® is indicated for acute treatment of migraine with or without aura, for 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 congenital 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 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 this 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 has not been demonstrated for subjects with chronic migraine
- The safety and effectiveness of the device has not been demonstrated 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, WIFI 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 with by other equipment utilizing RF technology, even that 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 Migra® 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 Migra® 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 or numbness in the arm or redness of the skin, which should disappear shortly after the end of the treatment.

Refer to Theranica's website at http://theranica.com/clinical-data/ 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 painless (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 application must be installed, and the device should be connected to the app. ***Make sure the Bluetooth connection on your smartphone is enabled.***

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

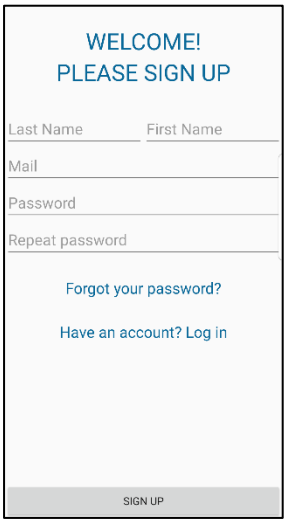
Do not use the device if the package was damaged during shipment

6.1.1. DOWNLOADING AND INSTALLING THE APPLICATION

Step 1: Verify that your phone operating system is compatible with the Nerivio Migra app (Android versions 6 to 9 and iOS versions 9 to 12.1.4).

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

Step 3: Open the application. When the app is opened for the first time, you will need to confirm the privacy policy and end-user license agreement (EULA). Scroll down the privacy policy/EULA page and touch "Confirm". You will then be asked to create an account. Follow the app instructions. This login 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.

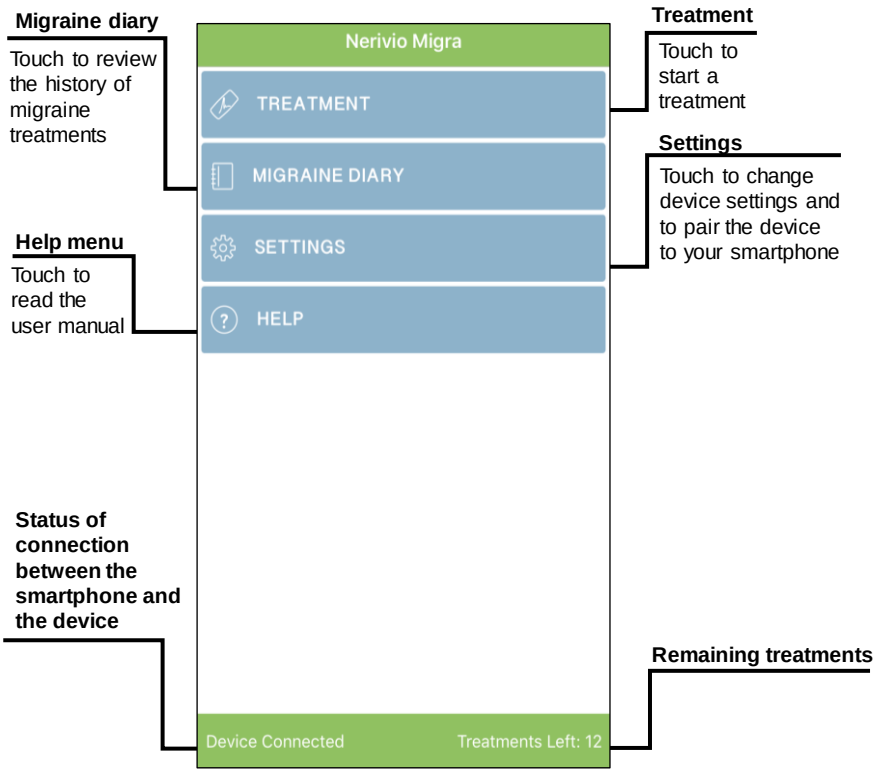


Step 4: A quick introduction will be presented. Read it by swiping the screens to the left and touch “Done” when finished. You can skip it by touching “Skip intro”.

Step 5: As you begin using the app, it may ask for permissions. Please allow these permissions so that the app works properly.

6.1.2. THE APP HOME SCREEN

The home screen provides access to information about your migraine treatments and the Nerivio Migra system.



The home screen includes:

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

Migraine diary – This section enables you to review and edit your migraine symptoms.

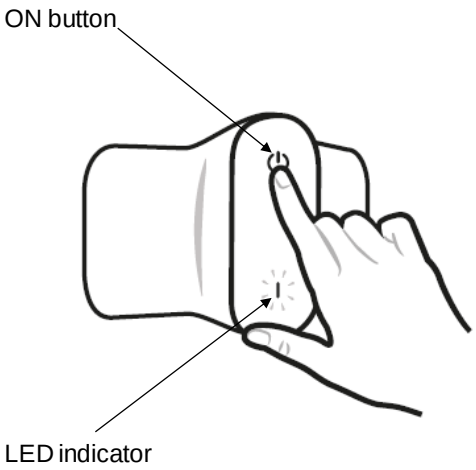
Setting – This section provides access to some of the technical aspects of the app:

About- select this to view the software version
Profile – select this to view your account details
Connect - select this option to connect the device to the Nerivio Migra app
Log out- select this to log out of your account

Help – This section provides access to the Nerivio Migra user manual and to instructional videos that explain how to connect the device to the app and how to treat a migraine episode with the device.

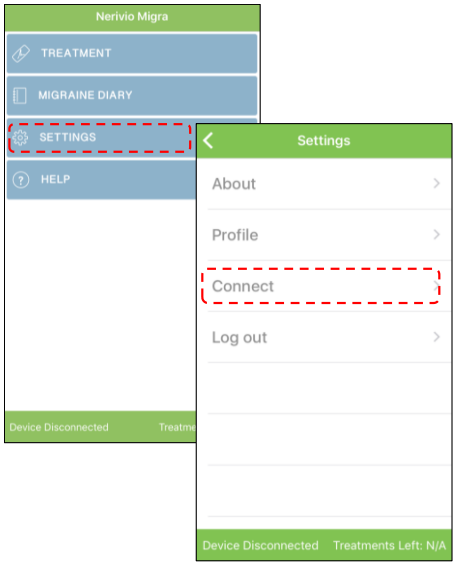
6.1.3. CONNECTING THE DEVICE TO THE APP FOR THE FIRST TIME

Step 1: Turn on the device using the ON button located at the external part of the device. A slow flashing (mostly on) green light indicates the device is on.

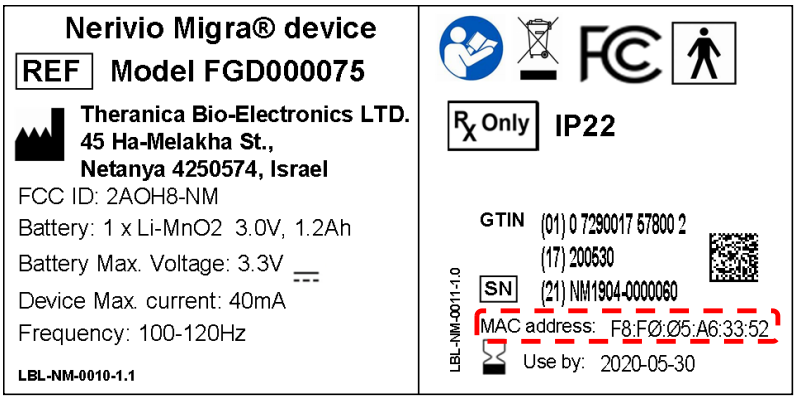


Check the device for damages. If the device is damaged return it to the manufacturer or contact customer support

Step 2: In the home screen touch “Settings” and then touch “Connect”. The device and the smartphone should be in proximity of less than 1 inch. When the device is successfully connected to the app, there will be a fast flashing green indicator light on the device. The connection status can be viewed in the app on the bottom left corner of the screen.



If a connection has not been established, make sure that Bluetooth is enabled in your smartphone. The app may prompt you to connect manually using the device MAC address. Locate the MAC address on the device label located on the protective film and on the package and follow the app instructions.



Step 3: After the connection has been established**,** the app will prompt you to enter a personal PIN code required for the initial pairing (for example, 1111 or 1234). Remember the PIN code for future use.

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 5 minutes

when no treatment was initiated, it automatically shuts down. Turn it back on to start a treatment.

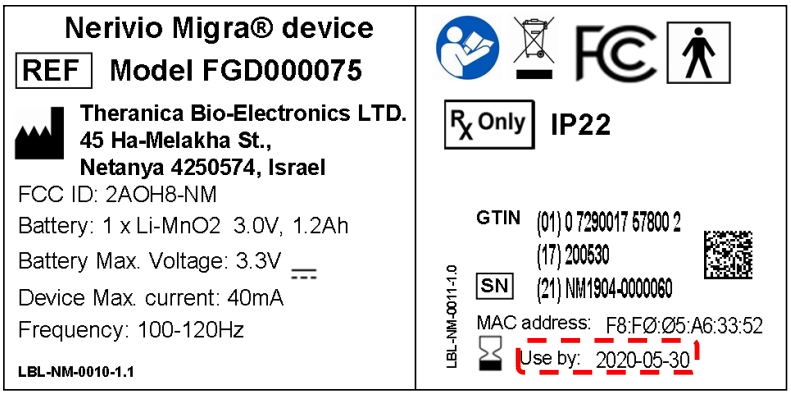
6.2. TREATING A MIGRAINE EPISODE

The treatment should be performed at the onset of a migraine episode and takes 45 minutes. 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).

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.

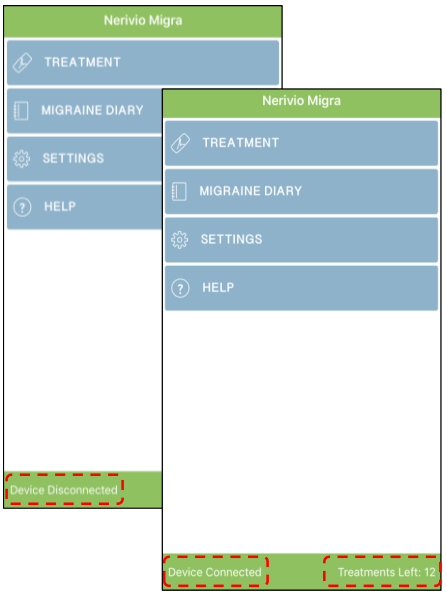


Do not use the device past expiration date

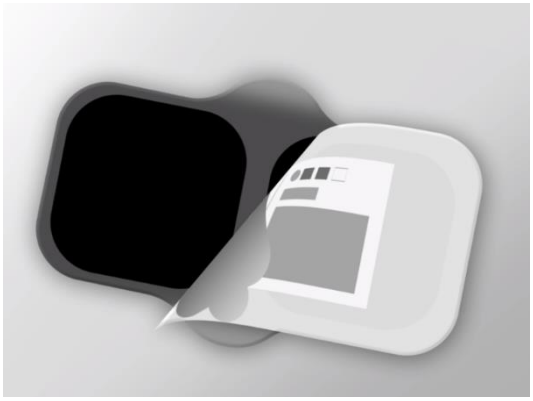
Step 2: Make sure that your arm skin is clean, dry and free from lotion.

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.

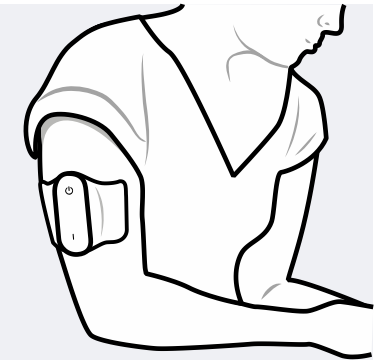
Step 4: Open the app and confirm the device is connected successfully. The connection status can be viewed in the app on the bottom left corner of the screen. Also verify that there is at least one remaining treatment on the bottom right corner of the app screen.



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: Wrap the sleevelet around the device on your arm to 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

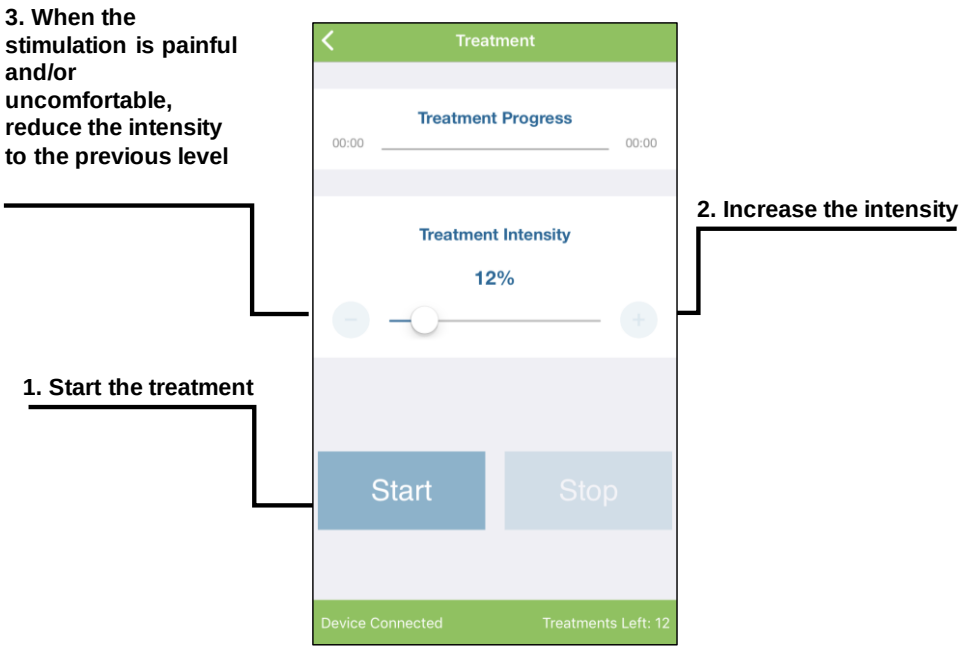
It is important to use the device only when positioned correctly on the arm. The device should be located midway between the elbow and the shoulder, on the outer side of the arm.

Step 8: To start the treatment, touch “Treatment" in the main menu of the home screen.

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 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, contact customer support**

Step 9: Touch “Start” to begin the treatment and then set the treatment intensity level, so it feels strong yet comfortable and painless.



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.

For effective and convenient treatment, the intensity level is individually set so it feels strong yet comfortable and painless

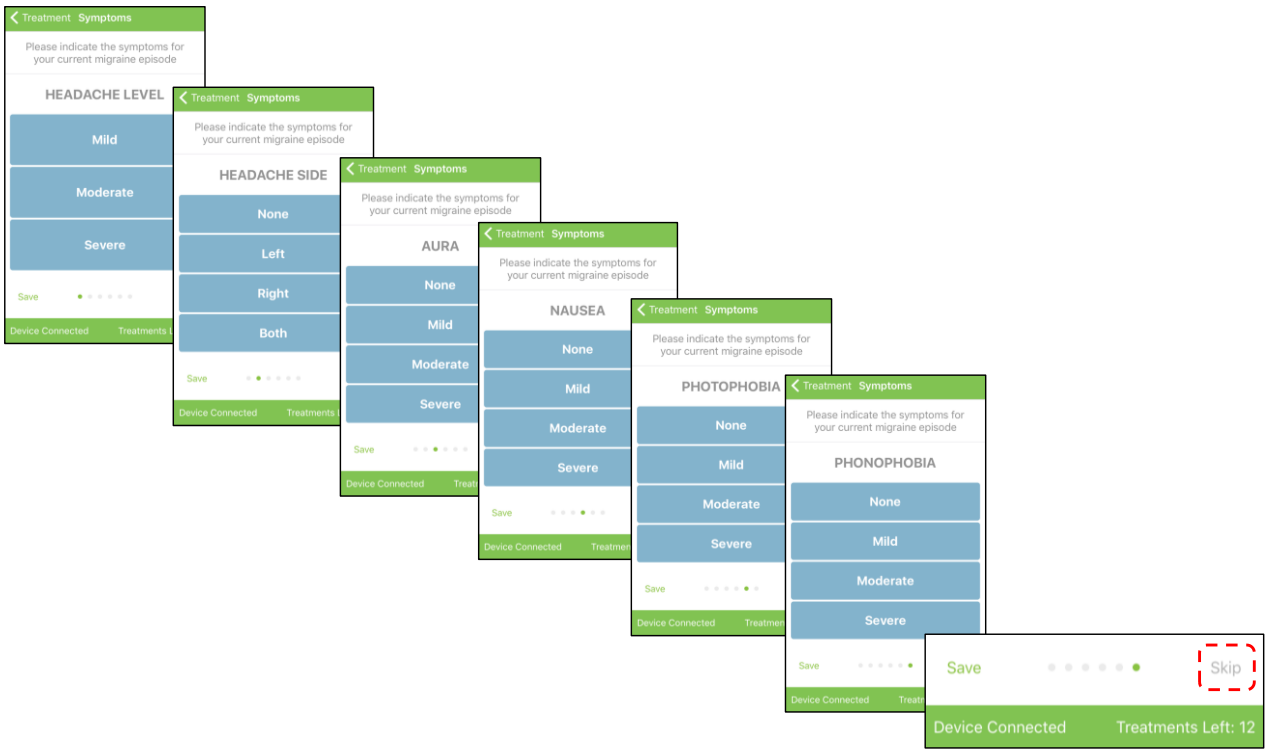
You should monitor the activity of the device throughout its operation

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.

Step 10: 60 seconds 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.

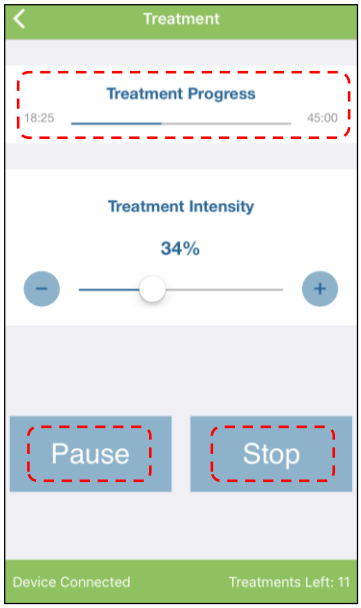


6.2.1. TREATMENT IN PROGRESS

The progress of the treatment can be monitored by the treatment progress bar and by the specified amount of time that has passed out of the total treatment duration time (45 minutes).

You can pause the treatment session for 5 minutes by touching ‘Pause’. Press ‘Resume’ to restart. Each session can only be interrupted 3 times. If a treatment is not resumed within 5 minutes, it will be stopped automatically.

The treatment can be stopped early at any time by touching “Stop”. Do not remove the device before the treatment has ended or has been stopped.



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 using the “Stop” button or remove the device from your arm.

Note that 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.

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 “Stop” button does not respond, you can remove the device from your arm

6.2.2. TREATMENT COMPLETED

Step 1: When the treatment is completed, remove the sleevelet 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 store it for next use.

Step 4: Close the app.

Note that 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 the 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. In the home screen touch “Migraine diary” to review your migraine symptoms. The migraine diary can also be accessed via the web. Type http://theranica.com/userlogs/#/ in your web browser and enter your login details. To view your login details in the app, touch “settings” and then touch “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 sleevelet can be machine washed at 80°F or 30°C. No bleach products should be used. Do not tumble dry.
- To minimize moisture loss, when unused, the electrodes should be covered by 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 life of the electrodes varies depending on skin conditions, skin preparation, storage and climate.

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 and before product expiration date, 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 ON button was not held long enough	Press the ON 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
	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” 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

The treatment screen of the app is not responding	No communication between the app and the device	See “what to do” in the problem of “No communication between the app and the device”
	The device is turned off	If the LED is off, turn on the device
	Device malfunction	Contact customer support at support@theranica.com
	The app is not working	Restart the app

8.2. MAIN ERRORS AND MESSAGES

Errors and messages displayed on the screen	What it may mean	What to do
Bluetooth is off	The Bluetooth connection of your smartphone is disabled preventing from your smartphone to connect to the device	Enable Bluetooth connection in your smartphone
The device is not properly placed on your arm. Place the device on the arm as described in the QuickStart guide or user manual.	The device is not properly placed on the body	Make sure the protective film was removed from the electrodes The device should be placed directly on the arm and not on your shirt
Device malfunction. The device is shutting down. Please wait, turn it back on and try again	Device malfunction	Turn the device on. For further support, contact customer support.
There are no remaining treatments on this device. Please replace the device or order additional units if required	No remaining treatments	The device cannot be used. Replace the device or order a new device.
Unable to start a treatment (error code is: 0X20B). Please contact customer support at support@theranica.com	Device malfunction or no remaining treatments	Contact customer support at support@theranica.com

Unable to connect using proximity. Do you want to enter device MAC address?	The device could not be paired with the app by mere proximity	Enter device mac address for manual paring. Locate the mac address of the device on the label in the external part of the device. The mac address includes 12 letters and digit separated by colons in the format of: xx:xx:xx:xx:xx:xx. Enter it to the MAC address field without the colons.
The device is shutting down since no treatment is performed. Turn it back on to start a treatment	The device was on for over 3 minutes and no treatment was performed	Turn on the device
Device not found	The mac address entered is incorrect	Re-enter the correct device mac address.
	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 1-2 meters
Invalid device MAC address	The device MAC address field has been left empty or the MAC address has been entered in the wrong format	Locate the mac address of the device on the label in the external part of the device. The mac address includes 12 letters and digit separated by colons in the format of: xx:xx:xx:xx:xx:xx. Enter it to the MAC address field without the colons.
The OS version on your device is newer than supported by the current version of the Nerivio Migra app. To ensure flawless functionality, please upgrade the app as soon as possible via App store	Incompatible mobile phone OS and app versions	Update the app

8.3. LED STATUS

LED indication	Status
Flashing very rapidly (5 times per second)	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 Migra® device.

The service lifetime of the Nerivio Migra® 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)

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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%-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. MINIMAL SMARTPHONE REQUIREMENTS

- At least 4.0 inches multi-touchscreen with at least 640 x 1136 pixels (~326 ppi pixel density) resolution

- 800MHz or more CPU, internal memory of 512kB or more, and internal storage of at least 4GB
- BT4.0 and above connectivity capabilities
- Supported operating system - iOS versions 9-12.1.4 and Android versions 6-9.

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 Migra® 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 Migra device and create a potentially unsafe situation.

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

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

Electromagnetic immunity IEC 60601-1-2			
Immunity Test	**IEC 60601-1-2 test level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
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 Migra®, 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
			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.			

Electromagnetic immunity IEC 60601-1-2
[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 Migra is used exceeds the applicable RF compliance level above, the Nerivio Migra® 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 Migra.

14.4. RECOMMENDED SEPARATION DISTANCES

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

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