Nerivio Migra 1

USER MANUAL

REVISION 1.0

Revision History

Revision	Date	Reason for Change
1.0	09-Jan-2018	Initial release

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0344 **2AOH8-NM1**

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1. INTRODUCTION

1.1. ABOUT THIS MANUAL

This manual provides the information necessary to operate Theranica's Nerivio Migra 1. **Please read and understand this manual before operating the device.** If any part of this manual is unclear, contact Theranica's Customer Support for clarification.

Please contact your local Theranica distributor/representative for translated versions.

1.2. THERANICA NERIVIO MIGRA 1 PRODUCT OVERVIEW

Nerivio Migra 1 (NM1) is a wearable, battery-powered device for the acute treatment of migraines with or without aura. NM1 is operated via a mobile application. The device is worn on a user's upper arm and delivers transcutaneous electrical nerve stimulation by applying weak electrical pulses, to achieve migraine pain inhibition by invoking conditional pain modulation (CPM). Treatments with the NM1 are intended to be self-administered by the user at onset of a migraine attack.

The Nerivio Migra 1 is a fully integrated unit similar in appearance to a sports armband. The device includes an armband, electronic circuitry and battery contained in a plastic case, and a pair of electrodes covered with hydrogel (figure 1). The device is comprised of 3 main components:

1. Armband with attached electrodes
2. Electronics case
3. Software including Firmware and Mobile Application software to be run on a mobile platform

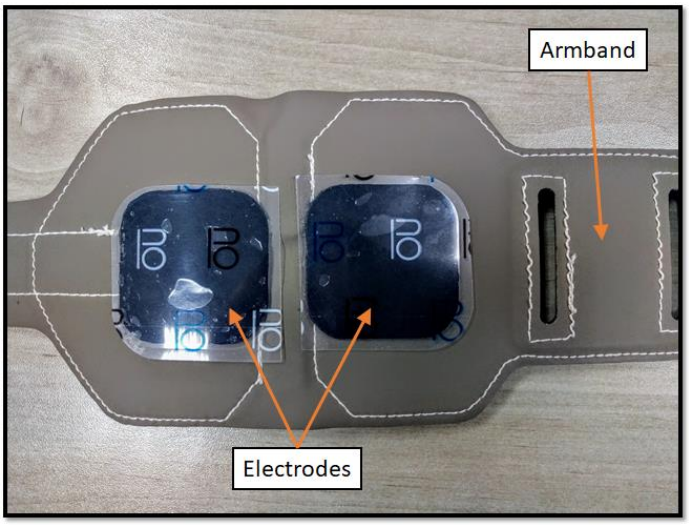

Figure 1 - View of inner part of the NM1

The external part of the armband looks as follows (Figure 2):

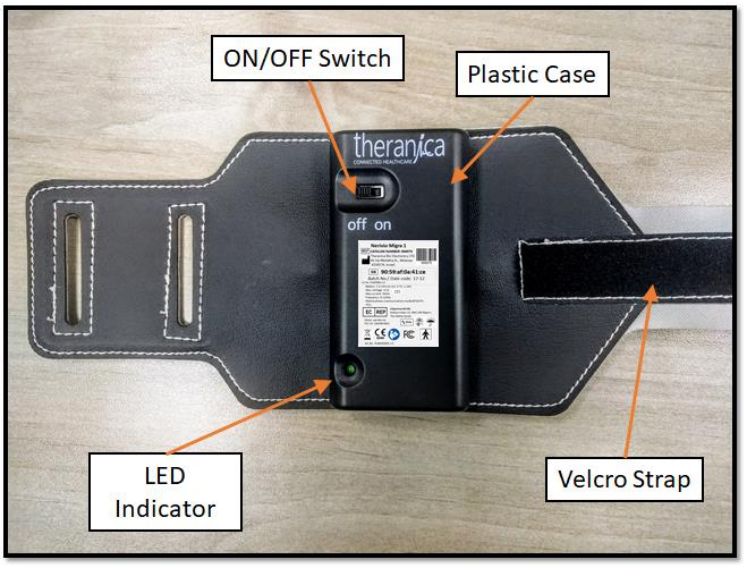

Figure 2 - View of external part of the NM1

The outside of the plastic case contains an ON/OFF switch and LED indicator, signaling various modes of operation.

The device is operated and controlled via mobile application software which is installed and run on a mobile platform such as a mobile phone or tablet. The application software operates and controls the device, retrieves operational records from the device and stores the data for further retrospective processing.

This mobile application software allows user control over adjustable stimulation parameters such as stimulation intensity, start and abort of stimulation program as well as shows indications for connection state, progress bar for stimulation duration, battery level, and user notifications.

1.3. PRODUCT FUNCTIONS

The main functions of the NERIVIO MIGRA 1 are:

a) Battery-powered; battery is internal, integrated, non-rechargeable
b) Integrated electrodes, providing the electrical stimulation to the skin
c) Main control unit, activated (and deactivated) by a designated ON/OFF switch
d) Arm band for strapping and securing the electrodes to the skin, for the duration of the treatment
e) Mobile application (App) running on smartphone or tablet for controlling the therapeutic treatment (as well as other features such as diary, etc.)

1.4. CONDITIONS FOR USE

1.4.1. INTENDED USE

The NERIVIO MIGRA 1 (NM1) is intended to reduce migraine pain by applying transcutaneous electrical nerve stimulation at the time of pain onset.

The NM1 is a home use device. It is to be used by an adult user (see below), over the upper arm, indoors while device is kept dry, under the user's discretion, care and the instructions set forth in this manual.

1.4.2. INTENDED USERS

NERIVIO MIGRA 1 is intended to be used by users suffering from episodic migraines, ages 18-75.

1.5. GLOSSARY

NM1: Nerivio Migra 1

App or app: Mobile application running on smartphone or equivalent

BT: Bluetooth

BLE: Bluetooth Low-Energy

LED: Light-Emitting Diode

ID: Identification

2. SAFETY

2.1. GENERAL WARNINGS, CAUTIONS AND NOTES

The following icons are used throughout this user manual:

	Warning: A condition that could cause serious injury or death to a patient and/or operator if instructions are not followed.
	Caution: A condition that could cause possible damage to equipment or cause the system to function inaccurately.
	Note: Indicates important user information regarding the use of the system.

	**DO NOT USE BEFORE READING AND UNDERSTANDING THIS MANUAL**
	**DO NOT USE THE DEVICE IF YOU NOTICED THAT THE PACKAGE WAS DAMAGED DURING SHIPMENT**
	**DO NOT APPLY OR USE THE DEVICE WHILE DRIVING, CYCLING, OR OPERATING ANY VEHICLE OR MACHINERY**
	**DO NOT APPLY OR USE THE DEVICE WHILE SLEEPING**
	**DO NOT APPLY OR USE THE DEVICE IF THE ELECTRODES BECOME EXCEEDINGLY DIRTY OR DAMAGED,**
	**DO NOT DISASSEMBLE, CRUSH, SHORT-CIRCUIT OR INCINERATE THE NM1'S BATTERY. THIS COULD CAUSE A FIRE, INJURY, BURNS, OR OTHER HAZARDS.**
	**DO NOT APPLY OR USE THE NM1 DEVICE IN ANY OTHER LOCATION EXCEPT THE UPPER ARM**
	**DO NOT APPLY OR USE THE NM1 DEVICE ON WET SKIN**
	**DO NOT APPLY OR USE THE NM1 DEVICE ON OPEN WOUNDS**
	**DO NOT APPLY OR USE THE NM1 OVER THE HEART OR CHEST AREA**
	**DO NOT TRANSFER THE NM1 DEVICE BETWEEN USERS DUE TO RISK OF CROSS-CONTAMINATION. THE NM1 IS DESIGNED FOR A SINGLE USER USAGE ONLY**

	**DO NOT USE THE NM1 DEVICE IN CONJUNCTION WITH ANY OTHER MEDICAL EQUIPMENT OR DURING ANY MEDICAL TREATMENT**
	**DO NOT USE SOAP, ALCOHOL, SUBMERGE IN WATER, OR SCRUB WITH ABRASIVE MATERIAL**
	**KEEP THE DEVICE AWAY FROM DRINKS, SINKS, SHOWERS, BATHTUBS, RAIN, AND OTHER MOISTURE SOURCES. MOISTURE CAN CAUSE ELECTRIC SHOCK OR UPSET LIKE ANY OTHER ELECTRONIC DEVICE**
	**DO NOT ATTEMPT TO RECHARGE OR DETACH THE BATTERY IN ANY WAY.**
	**DO NOT USE THE NM1 UNDER MAGNETIC RESONANCE IMAGING (MRI) ENVIRONMENT**
	**THE DEVICE AND BATTERY MUST BE DISPOSED OF IN ACCORDANCE WITH LOCAL LAW AND/OR CODE CONCERNING ELECTRICAL AND ELECTRONIC EQUIPMENT. DO NOT DISCARD TO STANDARD TRASH BIN.**
	**KEEP THE USER MANUAL AVAILABLE FOR FUTURE REFERENCE, IF REQUIRED**
	**CHECK DEVICE EXPIRED DATE BEFORE YOU APPLY OR USE THE DEVICE**
	**CLEAN THE SKIN WITH WATER AND SOAP TO REMOVE ANY LOTIONS, SKIN OILS, MAKE-UP AND DEAD SKIN PRIOR USAGE**
	**MAKE SURE THAT THE DEVICE IS POSITIONED CORRECTLY ON THE ARM BEFORE THE START OF OPERATIONS**
	**ADJUST THE INTENSITY OF THE PULSES UNTIL THEY ARE WELL-FELT BUT NOT PAINFUL**
	**IN CASE THAT THE ELECTRODE PICKS UP SMALL AMOUNTS OF DEBRIS, USE A DROP OF WATER ON YOUR FINGER TO GENTLY RUB THE DEBRIS OFF THE ELECTRODE**
	**AT THE END OF THE TREATMENT, REMOVE THE DEVICE AND RE-PLACE THE ELECTRODES COVER (THE TRANSPARENT MYLAR LINER THAT COVERED THE ELECTRODES PRIOR USAGE) ON THE ELECTRODES AND KEEP THE DEVICE IN ITS ORIGINAL RESEALABLE PACKAGE TO PREVENT LOSS OF MOISTURE.**
	**KEEP THE ACTIVE DEVICE AWAY AS POSSIBLE FROM RF EMITTED DEVICES (E.G MICROWAVE, ROUTERS, WI FI DEVICES) TO REDUCE THE RISK OF INTERFERENCE WITH YOUR BLUETOOTH CONNECTIVITY**

	**IN CASE OF IRRITATION, RUSH OR ANY OTHER SYMPTOMS OF SKIN REACTION TO THE DEVICE, STOP THE TREATMENT IMMEDIATELY AND CONSULT YOUR PHYSICIAN**
	**CHECK THE LED INDICATOR TO ENSURE THE DEVICE IS WORKING**
	**CHECK THE BATTERY CASE FOR BATTERY LEAKAGE OR DAMAGE**
	**STORE THE DEVICE ACCORDING TO THE RECOMMENDED CONDITIONS DESCRIBE IN THE USER MANUAL**
	**CLEAN THE DEVICE ACCORDING TO THE CLEANING INSTRUCTIONS IN THE USER MANUAL**
	**FOR EFFECTIVE TREATMENT IT IS RECOMMENDED TO AVOID USING OTHER ELECTRICAL DEVICES NEXT TO THE NM1, WHILE USING THE NM1**

2.1.1. SAFETY

I. Clean the device (except electrodes, see section 2.1 for specific electrodes instructions) with a soft cloth.

II. Placement of the electrodes near the thorax may increase the risk of cardiac fibrillation. The NM1 should not be applied across the head, directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus), or on the chest, upper back or crossing over the heart. Use the device only in the location described in this manual

III. The device should not be used adjacent to or stacked with other equipment. An exception to proximity of other devices shall be the smartphone (or another device such as a tablet) running the controlling SW application.

2.1.2. CONTRAINDICATIONS

I. The device is contraindicated for subjects with Pulmonary Edema or Congenital Heart Failure (CHF)

II. The device is intended for us by a single person only; do not pass/re-use electrodes between users.

2.1.3. BATERRY DISCHARGE INFORMTION

I. Even though the battery is marked ‘rechargeable’ it is not rechargeable for this device. The device is intended to be used until the battery runs out. With proper battery care (remember to turn off the device after each treatment) it will last longer.

II. If the LED does not blink when the switch is set to ‘ON and the application cannot connect to the device, turn the switch first ‘OFF’ and then ‘ON’ and try again. If the LED still does not blink and connection is not possible it means the battery is depleted. Contact the clinic where you have obtained this device or contact the manufacturer.

3. LABELS AND SYMBOLS

3.1 SYMBOLS

Explanation of symbols:

Symbol	Description
	Consult instructions for use
	Year of Manufacturing
	Special Requirements for Waste of Electrical and Electronic Equipment (WEEE Directive)
	Compliance with Medical Device Directive 93/42EEC
	Manufacturer
	Type B applied part (IEC60601-1)
	Catalog Number
	Serial Number
	Authorized Representative in the EU
	Keep the device dry

4. USING THE SYSTEM

4.1. INSTALLATION, PLACEMENT AND OPERATION

For your first-time use, please download and install the “NM1 CE” application via the Google Play (depending on your device). After installation, it’s recommended to create a shortcut to the App in one of your home screens (figure 3):

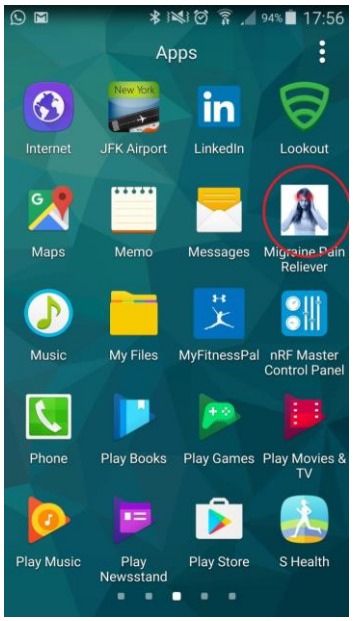

Figure 3 - App's Icon

4.1.1. RUNNING THE APP

Start the application. The following screen appears (figure 4):

Figure 4 - Welcome Screen

click on the button ‘**Sign In’** to move to the next screen.

4.1.2. CONNECTING TO THE DEVICE (NM1) [FIRST TIME]

Turn on the device by moving the switch to the 'ON' position. Make sure the device is working (LED is on and blinking).

Enter the ID of the device (found on a label on the front of the device) into the field marked in red under the "Device ID" and then click on the "Connect" button (figure 5):

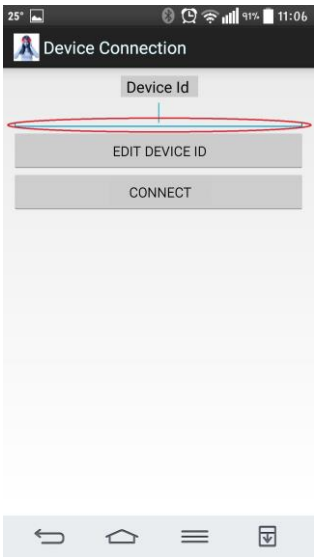

Figure 5 - Connection Screen

The application is now trying to connect to the NM1 via Bluetooth communication. If the connection is successful, the message "connected" will be shown on the screen and the main menu will be displayed (as described in the next section).

If at this stage the Bluetooth function of your phone (or tablet) is not enabled, a message appears on the screen requesting to approve the application to activate the Bluetooth communication. You must confirm by clicking "Yes" to continue (figure 6):

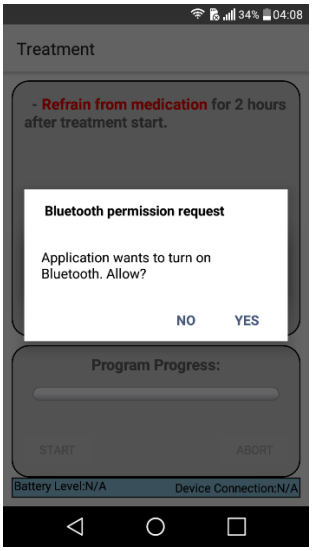

Figure 6 - App Asking for BT Permission

4.1.3. MAIN MENU

The main menu allows the activation of three different functions, listed below. You can always return to the main menu screen by pressing the "back" button (found in any Android device, marked in red in figure 7).

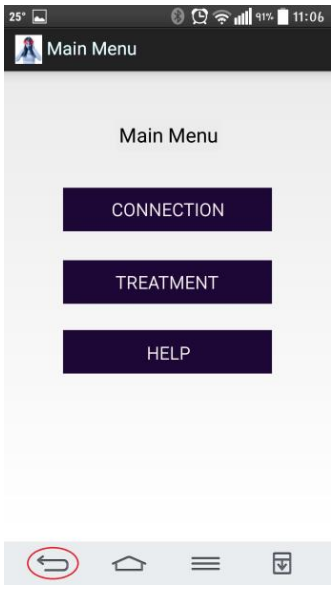

Figure 7 - Main Menu

4.1.4. CONNECTION MENU

Clicking on the "Connection" button enables going back to the screen that manages the device's connectivity. You can disconnect the device by clicking on the "DISCONNECT" button or alternatively, change the ID number of the device by clicking on the "EDIT DEVICE ID" (figure 8):

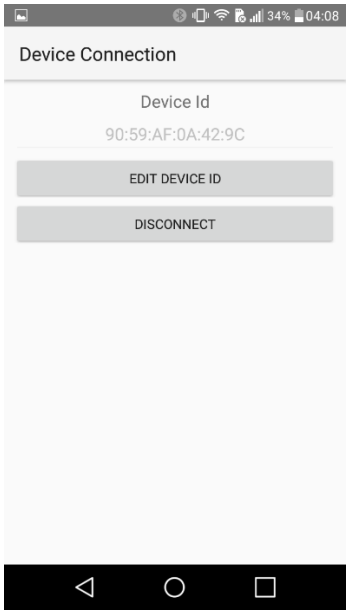

Figure 8 - Connection Menu

It is recommended to avoid as much as possible modifying the settings on this screen, and/or making unnecessary connections and disconnections to the device. If the device is offline, there is no need to go into this screen.

4.1.5. TREATMENT MENU

Open the package of the NM1. Take out the NM1 device and identify the inner and external parts of the NM1 as indicated in figures 1 and 2.

⚠	**DO NOT USE THE DEVICE IF YOU NOTICED THAT THE PACKAGE WAS DAMAGED DURING SHIPMENT**

Remove the two plastic liners (covers) from the two electrodes and place them (the liners) in a safe place, allowing you to re-place them once the treatment is complete (see section 4.1.7).

Place the NM1 on your arm in a way that the electrodes are in contact with your skin, and the battery is facing out. as shown in the following figure 9:

Figure 9 - Armband Position over the Arm

⚠	**DO NOT APPLY OR USE THE NM1 DEVICE IN ANY OTHER LOCATION EXCEPT THE UPPER ARM**
⚠	**DO NOT APPLY OR USE THE DEVICE WHILE DRIVING, CYCLING, OR OPERATING ANY VEHICLE OR MACHINERY**
⚠	**DO NOT APPLY OR USE THE DEVICE WHILE SLEEPING**
⚠	**DO NOT APPLY OR USE THE DEVICE IF THE ELECTRODES BECOME EXCEEDINGLY DIRTY OR DAMAGED,**
⚠	**DO NOT APPLY OR USE THE NM1 DEVICE ON WET SKIN**
⚠	**DO NOT APPLY OR USE THE NM1 DEVICE ON OPEN WOUNDS**
❗	**CLEAN THE SKIN WITH WATER AND SOAP TO REMOVE ANY LOTIONS, SKIN OILS, MAKE-UP AND DEAD SKIN PRIOR USAGE**
❗	**MAKE SURE THAT THE DEVICE IS POSITIONED CORRECTLY ON THE ARM BEFORE START OF TREATMENT. THE DEVICE SHOULD BE LOCATED MIDWAY BETWEEN THE ELBOW AND THE SHOULDER, ON THE OUTER SIDE OF THE ARM.**

Verify that the LED is on after turning on the device. If the LED is still off, please contact the supporting person from the hospital or TBD.

To start the treatment, click on “TREATMENT" in the main menu (figure 10):

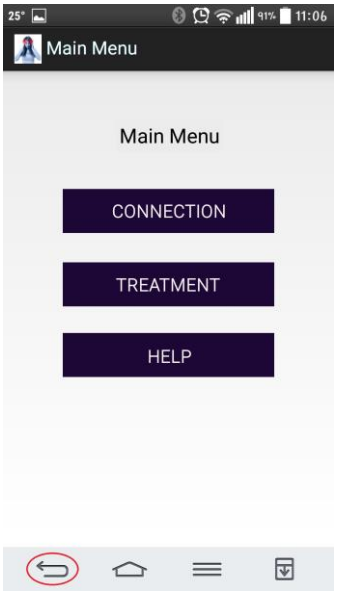

Figure 10 - Click on TREATMENT

Once in the “Treatment” screen, click on the “START” button to begin the treatment (figure 11):

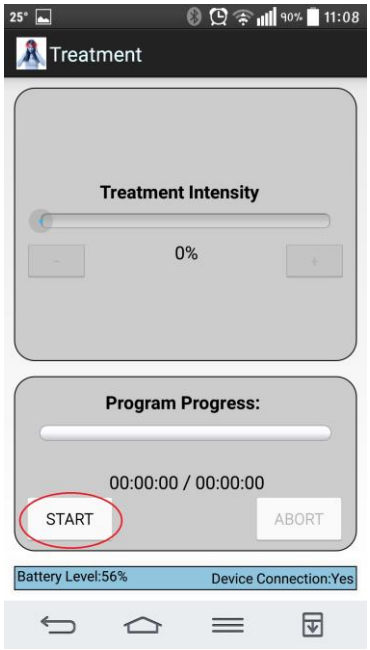

Figure 11 - Treatment Screen, Start Button

The device now starts transmitting electrical pulses onto your skin. Other important functions in the screen are (figure 12):

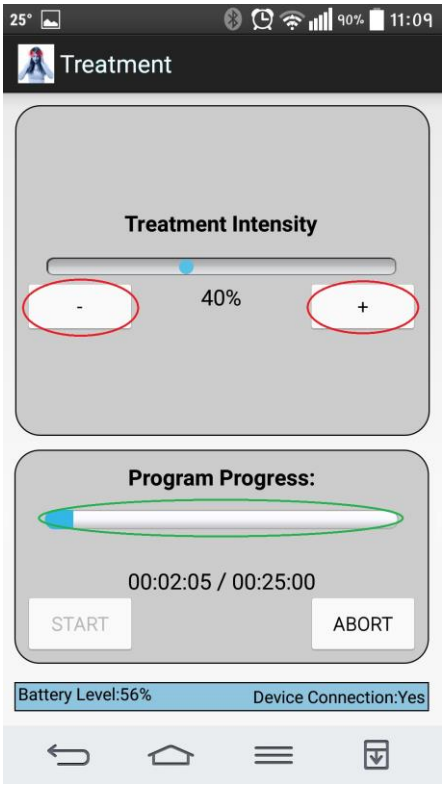

Figure 12 - Treatment Progress

I. Treatment Intensity: Indicates on a scale between 0 and 100 the output power of the device. You can increase or decrease the intensity of the pulses using the buttons - "+" or the "-" (marked in red in the picture above). Each press changes the intensity accordingly, but note that for optimal user experience, a long/continuous press is not allowed.

II. Treatment Progress: Represented both by the progress bar (highlighted in green in the image above), and by specifying the amount of time that has passed out of the total time.

III. Aborting the Treatment: Can be achieved at any time during the treatment by pressing the “ABORT” button. If you decide to abort the treatment, you will be sent back to the main screen

	CHECK THE LED INDICATOR TO ENSURE THE DEVICE IS WORKING
	DO NOT USE THE NM1 DEVICE IN CONJUNCTION WITH ANY OTHER MEDICAL EQUIPMENT OR DURING ANY MEDICAL TREATMENT
	KEEP THE DEVICE AWAY FROM DRINKS, SINKS, SHOWERS, BATHTUBS, RAIN, AND OTHER MOISTURE SOURCES. MOISTURE CAN CAUSE ELECTRIC SHOCK OR UPSET LIKE ANY OTHER ELECTRONIC DEVICE
	DO NOT USE THE NM1 UNDER MAGNETIC RESONANCE IMAGING (MRI) ENVIRONMENT

	ADJUST THE INTENSITY OF THE PULSES UNTIL THEY ARE WELL-FELT BUT NOT PAINFUL
	KEEP THE ACTIVE DEVICE AWAY AS POSSIBLE FROM RF EMITTED DEVICES (E.G MICROWAVE, ROUTERS, WI-FI DEVICES) TO REDUCE THE RISK OF INTERFERENCE WITH YOUR BLUETOOTH CONNECTIVITY
	IN CASE OF IRRITATION, RUSH OR ANY OTHER SYMPTOMS OF SKIN REACTION TO THE DEVICE, STOP THE TREATMENT IMMEDIATELY AND CONSULT YOUR PHYSICIAN

The Treatment screen also provides indications for the connectivity to the NM1 device and the status of the battery; these are shown at the bottom part of the screen (figure 13):

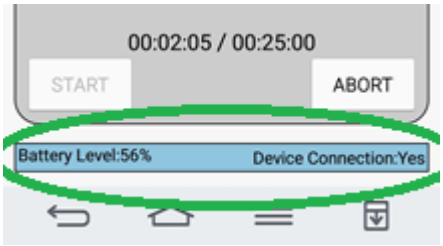

Figure 13 - Battery and Device Connection Status

4.1.6. HELP MENU

Clicking on ‘Help’ from the Main menu will display a brief version of this user manual, including operating instructions with use of the application and the device (see figure 14):

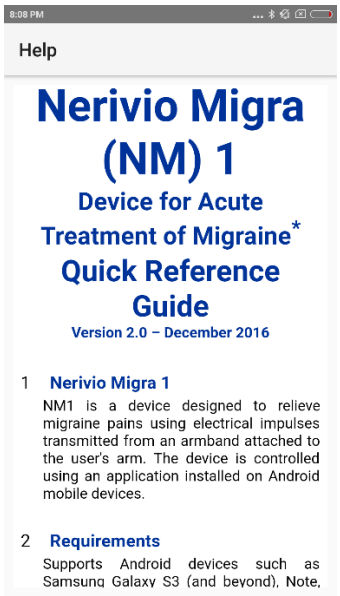

Figure 14 - Information Under the 'Help' Menu

4.1.7. AFTER COMPLETING THE TREATMENT

Once the treatment is complete, and the user wishes to store the NM1 till the next treatment, follow these steps:

I. Make sure the treatment has ended – either by reaching the program's completion or by clicking on the "ABORT" button.

II. Exit the application

III. Turn off the device by moving the switch on the NM1 to the 'OFF' position. Make sure the LED is off.

IV. Release the NM1 strap and remove it from your arm.

V. Re-place the liners on the electrodes.

	**PLACE THE ELECTRODES COVER (THE TRANSPARENT MYLAR LINER THAT COVERED THE ELECTRODES PRIOR USAGE) ON THE ELECTRODES AT THE END OF THE TREATMENT AND KEEP THE ELECTRODE IN ITS ORIGINAL RESEALABLE PACKAGE TO PREVENT LOSS OF MOISTURE.**
	**IN CASE THAT THE ELECTRODE PICKS UP SMALL AMOUNTS OF DEBRIS, USE A DROP OF WATER ON YOUR FINGER TO GENTLY RUB THE DEBRIS OFF THE ELECTRODE**
	**STORE THE DEVICE ACCORDING TO THE RECOMMENDED CONDITIONS DESCRIBE IN THE USER MANUAL**

5. TROUBLESHOOTING

Before addressing the troubleshooting table, please check and confirm the following:

1. Set the ON/OFF switch to OFF and then ON. Check that the LED turns ON.
2. Make sure that Bluetooth is enabled on your phone or tablet
3. Make sure that the device still has adequate battery left in it (use the application to check, as described in figure xx)

If the above is not helpful, proceed to 5.1.

5.1. BASIC TROUBLESHOOTING

Condition	Possible Cause	Recommended Action
No communication between App and NM1	NM1 is turned OFF	Turn on the device
No communication between App and NM1	Bluetooth is turned OFF on the phone or tablet	Turn on the Bluetooth feature on your phone or tablet and try to reconnect
No communication between App and NM1	Wrong device ID	Go into the “Connection” menu and re-enter the device ID
No communication between App and NM1	Phone and device are too far apart	Bring the phone and device to a range of 1-2 meters
No communication between App and NM1	NM1 is in shutdown (after being left ON for more than 5 minutes while not in treatment)	Turn the device OFF and then ON again
Stimulation is not felt	Treatment not started or aborted	Go to the “Treatment” screen and click on the “START” button
Stimulation is not felt	Stimulation intentisty is too low	Go to the “Treatment” screen and click on the “+” button until you feel the stimulation
The intensity can’t be changed (increased or decreased) or treatment can’t be aborted	Phone and device are too far apart	Bring the phone and device closer together (1-2 meters). If still no communications (and commands don’t work), turn the device OFF and/or remove the armband.
The treatment cannot start or stop	ON/OFF button is stuck	Stop treatment by app or remove the device

6. CLEANING, MAINTENANCE AND SERVICE

In order to clean the NERIVIO MIGRA 1 system, please note the following:

I. Clean the NM1 with a dry cloth, except for the electrodes area

II. After usage, if the electrode picks up small amounts of debris you may use a drop of water on your finger to gently rub the debris off the electrode

III. The Mylar liner must be returned in the end of the usage and to placed it in the original, resealable package to prevent loss of moisture7

In order to maintain the NERIVIO MIGRA 1 system, please note the following:

- When not in use, make sure the switch is in the 'OFF' position
- When not in use, make sure the electrodes are properly covered by their liners; Gently remove the liners from the electrodes as you begin to use the device and return the liners back in the end of the treatment to maintain the electrodes.
- When not used, store the device in an indoor environment, room temperature and away from direct sunlight
- Keep the device in the room environment
- Do not expose the device to moisture and/or high humidity
- If exposed to moisture/humidity - dry the device as quickly as possible
- If the electrodes become exceedingly dirty or damaged, please do not use the device and contact Theranica representative for product maintenance.

	**DO NOT USE SOAP, ALCOHOL, SUBMERGE IN WATER, OR SCRUB WITH ABRASIVE MATERIAL**

6.1. Obtaining service:

Contact the Theranica Nerivio Migra 1 representative:

Theranica Bio-Electronics Ltd.

Address: 45 Ha-Melakha St., (Entrance 3 second floor, Poleg Industrial Park) Netanya 4250574, Israel
Contact: info@theranica.com
Web: www.theranica.com
Fax: +972-72-390-9762

7. OPERATING SPECIFICATIONS

Note: Unless otherwise indicated, all specifications are subject to change without notice. Specifications and test methods will be made available upon request.

7.1. ENVIRONMENTAL

7.1.1. OPERATING ENVIRONMENT

Operating temperature range:	+10 º to +40º C (50'F-104'F)
Relative humidity range:	30%-75%

7.1.2. ENVIRONMENTAL CONDITIONS OF TRANSPORT AND STORAGE BETWEEN USES

Operating temperature range:	+10 º to +40º C (50'F-104'F)
Relative humidity range:	30%-75%

7.1.3. TRANSPORT AND STORAGE ENVIRONMENTAL CONDITIONS

Temperature range:	+5 º to +50º C (41'F-122'F)
Relative humidity range:	Up to 85%, with no condensation
Atmospheric Pressure:	70-106 kPa

7.1.4. ELECTRICAL

Battery type:	Lithium-Ion Rechargeable, 3.7 V, 1.05 Ah
Operation Voltage:	3.7V, 1.05 Ah
Charger Input:	N/A – battery is not rechargeable in device
Charger output:	N/A – battery is not rechargeable in device
Frequency:	N/A

	THE DEVICE AND BATTERY MUST BE DISPOSED OF IN ACCORDANCE WITH LOCAL LAW AND/OR CODE CONCERNING ELECTRICAL AND ELECTRONIC EQUIPMENT. DO NOT DISCARD TO STANDARD TRASH BIN.

8. TECHNICAL SPECIFICATIONS

Number of channels	1	
Waveform	Biphasic rectangular	
Max output voltage 500Ω 2KΩ 10KΩ	 20V 60V 60V	
Max output current 500Ω 2KΩ 10KΩ	 40mA 30mA 6mA	
Maximum phase charge 500Ω	8 µC	PrimaryPhaseDuration * PeakCurrent@500Ω
Maximum average current 500Ω	1.76mA	PeakCurrent@500Ω *(2*PrimaryPhaseDuration*Frequency)
Maximum current density (peak) 500Ω	1.6 mA/cm²	PeakCurrent@500Ω / ElectrodeArea
Maximum current density (mA/cm², r.m.s) 500Ω	0.336	PeakCurrent@500Ω * SQRT(2*PrimaryPhaseDuration*Frequency)/ ElectrodeArea
Maximum average current density (abs value) 500Ω	0.0704 mA/cm²	MaxAverageCurrent@500Ω / ElectrodeArea
Maximum average	1.408mW/cm²	MaxAverageCurrentDensity@500Ω * PeakVoltage@500Ω

power density 500Ω		
Frequency	100-120Hz, average 110Hz	
Primary phase duration [µSec]	200	
Burst mode	No	
Program duration [min]	20	
Indication display	Device LED, on/off switch	Via Mobile Application
-On/Off status	Yes (LED, switch position)	No
-Wireless connection	No	Yes
-Low battery	No	Yes
-Current level	No	Yes (stimulation intensity)
-Output mode	No	Yes (stimulation time bar)
-Time to cut-off	No	Yes (stimulation time bar)
Power source	Battery (Model LP-503562-1S-3; size 35 x 63 x 4.8 mm)	
Processor control	Yes	
Wireless control	Yes	
Automatic overload trip	Yes, hardware limiter for max current and voltage	
Automatic no load trip	No	
Automatic shut off	Yes, timer	

User override	Yes
Electrode compliance with 21 CFR 898	Yes
Electrode cable	No

Notes:

1) For any impedance up to, and including, 1.5kΩ, the parameters above will as for the impedance of 500Ω.
2) For any impedance greater than 1.5kΩ the output voltage will remain at its maximum limit of 60v and the output current will degrade to 60v/impedance.

9. APPLICABLE STANDARDS

The following list of standards applies to the system:

- EC/EN 60601-1: 2012, 3.1 Ed., Medical electrical equipment, part 1: General requirements for basic safety and essential performance.
- IEC/EN 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for safety – collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC/EN 60601-1-6:2010 AMD:2013, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-11:2015 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62304:2006/AC:2008, Medical Device Software – Software Lifecycle Processes.
- IEEE 1028-1997, IEEE Standard for Software Reviews.
- EN ISO 14971:2012, Implementation of Risk Management for Medical Devices.
- ISO 62366 -1:2015 – Medical Devices – Part 1: Application of Usability Engineering to Medical Devices.
- ISO 15223-1:2012, Labeling and Marking Symbols for Medical Devices
- EN 1041:2008: Information supplied by the manufacturer of medical devices
- ISO 14971:2007: Application of risk management to medical devices
- IEC 60601-2-10 Edition 2.0 [2012]: Requirements for the safety of nerve and muscle stimulators
- IEC 62304 [2006 + AMD:2015]: Software Life Cycle of Application Processes
- Council Directive 93/42/EEC concerning medical devices when they bear the following CE marking of conformity

10. EMC STATEMENT

NOTES

The NERIVIO MIGRA 1 requires special precautions with regard to electromagnetic compatibility.

It must be installed and prepared for use as described in this manual.

Certain types of mobile telecommunication devices such as mobile telephones may interfere with the NERIVIO MIGRA 1.

The recommended separation distances in this paragraph must therefore be complied with.

The NERIVIO MIGRA 1 must not be used near or on top of another device. If this cannot be avoided, it is necessary – before clinical use – to check the equipment for correct operation under the conditions of use.

ELECTROMAGNETIC EMISSIONS

- The Nerivio Migra 1 is intended for use in the electromagnetic environment specified in the following tables. This is not a life-sustaining device.
- The user and/or installer of the unit must ensure that it is used in such an environment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The [DEVICE NAME] is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions Test: CISPR 11	Group 1	The **[DEVICE NAME]** 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	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

10.1. ELECTROMAGNETIC IMMUNITY

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The **[DEVICE NAME]** is intended for use in the electromagnetic environment specified below. The customer or the user of the **[DEVICE NAME]** device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 test level**	**Compliance Level**	**Electromagnetic Environment- Guidance**
Electrostatic discharge(ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	□2 kV for power supply lines □1 kV for input/ Output lines	Not Applicable Not Applicable	
Surge IEC 61000-4-5	□1 kV differential mode □2 kV common mode	Not Applicable Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11 For Charger only	<5 %UT (>95 %dip in UT) for 0.5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	Not Applicable Not Applicable Not Applicable Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The **[DEVICE NAME]** is intended for use in the electromagnetic environment specified below. The customer or the user of the **[DEVICE NAME]** device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 test level**	**Compliance Level**	**Electromagnetic Environment- Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the **[DEVICE NAME]**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	$d = 1.17\sqrt{P}$ 80 M Hz t o 800 MHz $d = 2.3\sqrt{P}$ 800 MHz t o 2.5 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 R F 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 **[DEVICE NAME]** is used exceeds the applicable RF compliance level above, the **[DEVICE NAME]** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **[DEVICE NAME]**.			

10.2. RECOMMENDED SEPARATION DISTANCES

Recommended separation distances between portable and mobile RF communications equipment and the [DEVICE NAME]

- The [DEVICE NAME] is intended for use in an electromagnetic environment in which radiated radiofrequency disturbances are controlled.
- The user and/or installer of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radiofrequency communications equipment (emitters) and the [DEVICE NAME], according to the maximum output power of the equipment, as recommended in the table below.

	Separation distance according to the frequency of transmitter (m)	
Rated maximum output power of transmitter (W)	**80MHz to 800MHz $d = 1.17\sqrt{P}$**	**800MHz to 2.5GHz $d = 2.3\sqrt{P}$**
0.01	0.12	0.23
0.1	0.37	0.73
1	1.17	2.3
10	3.7	7.3
100	11.7	23

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 1 At 80 MHz and 800 MHz, the separation distance for 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.

11. CLASSIFICATION

Classification information regarding NERIVIO MIGRA 1:

- INTERNALLY POWERED ME EQUIPMENT
- TYPE BF APPLIED PART
- ENCLOSURE IPX0
- CONTINUOUS OPERATION

12. FCC RADIO FREQUENCY INTERFERENCE STATEMENT

FCC Registration Number (FRN): 0027054477.

This equipment has been tested and found to comply with the limits for a 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 particular installation. If this equipment does cause harmful interference to radio or television reception, which can 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 receiving antenna.

• Increase the separation between the equipment and receiver.

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

• Consult the dealer or an experienced radio/TV 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.

13. DISPOSAL OF PRODUCT

To dispose of a broken or defective unit, send the unit back to the manufacturer or consult your local waste management professional. Be sure to dispose of dead batteries as required by local waste disposal rules. Never throw batteries into a fire or a garbage bin.

System should be disposed appropriately (i.e., according to federal, state, and local regulations) after use.

- Do not disassemble, puncture, modify, drop, throw, or cause other unnecessary shocks to batteries.
- Do not dispose of batteries in a fire or trash incinerator, or leave batteries in hot places such as an automobile under direct sunlight.
- Do not place batteries into a microwave oven, or into any other high-pressure container.
  Do not immerse batteries in water or otherwise get them wet.
- Do not short circuit batteries; for example, do not carry loose batteries in a pocket or purse with other metal objects, which may inadvertently cause a battery to short circuit.

Please dispose of used batteries properly, following local regulations. Do not incinerate.

This symbol means the product must not be discarded as household waste, and should be delivered to an appropriate collection facility for recycling. Proper disposal and recycling helps protect natural resources, human health and the environment. For more information on disposal and recycling of this product, contact your local municipality, disposal service, or the shop where you bought this product.