Neurolief
Brain Innovation

Relivion™
User Manual

Important Notice

Manufacturer

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Rx Only

Federal (USA) law restricts this device to sale by or on the order of a physician or with the descriptive designation of any other practitioner licensed by the law of the state in which he/she practices to use or order the use of the device.

Intended Use

The Relivion™ transcutaneous electrical nerve stimulator is intended for the treatment of headache and is indicated for the acute treatment of migraine with or without aura in patients 18 years of age or older. It is a prescription device to be self-used at home.

User Manual Purpose

This user manual provides the necessary instructions for safely operating the Relivion™ in accordance with its function and intended use. These instructions include –

- An explanation of the function of controls and indicators.
- The sequence of its operation.
- Maintenance and troubleshooting.

This user manual contains the following chapters –

- **Chapter 1, Introducing Relivion™,** page 9, introduces the Relivion™ device, describes its components and its package contents.
- **Chapter 2, Getting Ready,** page 13, describes the preliminary steps to be performed before using the Relivion™.
- **Chapter 3, Using the Device,** page 21, describes how to prepare, connect and use the Relivion™.
- **Chapter 4, Troubleshooting and Maintenance,** page 33, describes how to troubleshoot and clean the Relivion™.
- **Chapter 5, Technical Specifications**, page 37, describes the technical specifications of the Relivion™ device.
- **Appendix A, Electromagnetic Compatibility,** page 39, provides the electromagnetic compatibility declaration of the Relivion™.
- **Appendix B, FCC Compliance,** page 43, describes the FCC compliance of the Relivion™.

System Symbols

The following describes the symbols used in this document and for this product.

Table 1: System Symbols

Symbol	Description
	Consult instruction for use.
	Class II equipment.
	Prescription only. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Caution, see Instructions for Use.

Symbol	Description
	Manufacturer.
	Manufacturing date.
	Type BF Applied part (front and back electrodes).
	Serial number.
	Catalog number.
	Operating conditions
	Keep dry.
	IP rating. Indicates the degree of protection. The Relivion™ device is protected from limited dust ingress and from water spray from any direction.
	RF transmitter.
	Waste Electrical and Electronic Equipment Directive (WEEE).

Safety Information

The following section provides important safety information that must be observed while using the Relivion™ device.

Contraindications

- Subjects with a metal implant or shrapnel in their head, except for dental implants, should not use the device.
- Subjects with recent brain or facial trauma (less than three months) should not use the device.

- Subjects with skin abrasions on the forehead or occiput at the contact area of the headset should not use the device.
- Subjects with implanted neurostimulators or any implanted metallic or electronic device in the head, a cardiac pacemaker or an implanted or wearable defibrillator should not use the device.

Warnings

- Do not use the device while driving or in conjunction with dangerous activity during which the user must be alert and focused (for example, while operating machinery).
- Do not use the device on any other areas apart from the head.
- Do not use the device in the bath or shower.
- Do not use the device while sleeping.
- Do not to use the device in the presence of electronic monitoring equipment that may not operate properly when the electrical stimulation device is in use.
- Apply stimulation only to intact, clean, healthy skin.
- Do not use this device in locations subject to extreme high or low temperatures or humidity. Use within the temperature and humidity range according to the product's specifications (see Table 7).
- Do not use a device that shows signs of mechanical damage or loose parts.
- No modification of this equipment is allowed.
- Do not interconnect the Relivion™ device with other equipment.

Precautions

- The long-term effects of chronic use of the device are unknown.
- The safety of electrical stimulation during pregnancy has not been established.
- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
- Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
- Keep the device out of reach of children.
- Use this device only with Neurolief electrode pads and the Neurolief charger supplied with the device. Do not use any accessories, detachable parts and materials that are not provided by Neurolief.
- If the device does not function as described in this manual, stop using it and contact customer support.
- The Relivion™ device is designed for use by and on a single adult person. For hygiene reasons, the device should not be shared.

Adverse Reactions

- Unpleasant sensation during treatment.
- Scalp numbness sensation during and after treatment.
- Persistent tingling sensation after the treatment ends.
- Pain.
- Skin reaction (for example irritation, lesion, burn) beneath the stimulation electrodes. In this case, treatment should be temporarily discontinued.
- Redness of the skin under or around the electrodes. Skin redness usually disappears within several hours after treatment.
- Sleepiness, fatigue or sleep disorders.
- Sedative effect during or after treatment.
- Dizziness during or after treatment.
- Tension-type headache after treatment.
- If adverse reactions persist, stop using the device and consult your physician.

Conventions Used in This User Manual

NOTE Notes provide additional important information.

TIP Tips indicate helpful information for using the Relivion™.

WARNING! Warnings indicate conditions or practices that may result in damage to the equipment or minor/moderate injury to the patient.

Table of Contents

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1 Introducing Relivion™

This chapter introduces the Relivion™ device and describes its components and its package contents.

IMPORTANT!

To ensure safe and proper usage, you should review this entire user manual carefully before using the Relivion™ device.

Contact Neurolief customer support at +972 (9) 3730288 or visit the Neurolief website at www.neurolief.com if you have any questions.

1.1 WHAT IS THE NEUROLIEF RELIVION™?

The Relivion™ is a non-invasive neurostimulation device. It transfers mild electrical pulses to branches of the Trigeminal (Supraorbital and Supratrochlear) and Occipital nerves to treat headache.

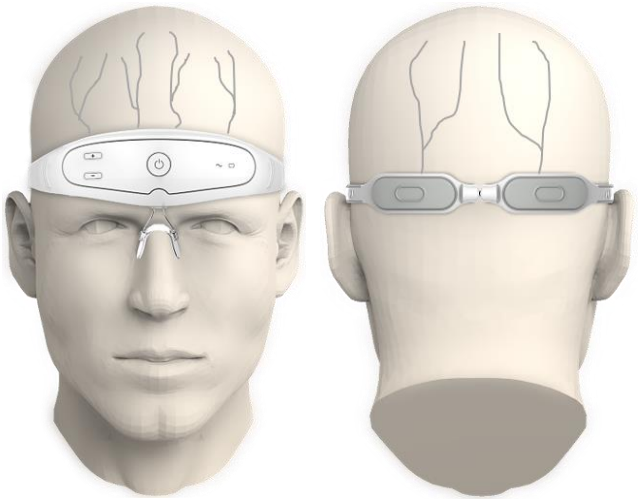


Figure 1: Relivion™ and Its Target Nerves

The Relivion™ consists of a headset with integrated electrodes, designed to enable stimulation of the target nerves. The on-board stimulation circuit is adapted to deliver stimulation patterns to enhance proper nerve activation. The Relivion™ adjusts to various head sizes and contours and can be worn comfortably. Each time it is worn, the six electrodes are placed over the underlying nerves. The four electrodes on the forehead stimulate branches of the Trigeminal nerve and the two electrodes at the back of the head stimulate the greater Occipital nerve.

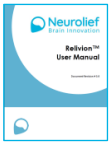
The Relivion™ incorporates an on-board user interface that enables the user to activate/deactivate the device and to adjust the stimulation intensity. It provides visual and auditory indications to indicate when the device is active/non-active and when there is a low battery.

The Relivion™ communicates via a Bluetooth link with a dedicated mobile application on the user's smartphone. The mobile application displays the device status and provides indications, such as treatment intensity level, treatment duration and battery status.

1.1 THE RELIVION™ KIT

The Relivion™ kit includes the components described in Table 2.

Table 2: Relivion™ Kit

Relivion™ System Kit Contents	
Relivion™ Device	
Charger	
Electrode Pads	
Spray Bottle (to Wet Electrodes with Water)	
User Manual	

Relivion™ System Kit Contents	
Carrying Case	

Do not use other accessories than those provided with the Relivion™ kit.

1.2 RELIVION™ HEADSET

The Relivion™ headset can be comfortably worn on the head during treatment. It integrates six electrodes – four in the front of the device (forehead) and two in the back (occiput). It includes two flexible arms that go under hair layers while the headset is worn. A simple user interface and a nose bridge are located at the frontal aspect of the headset. A size adjustment mechanism is located on both sides of the device.

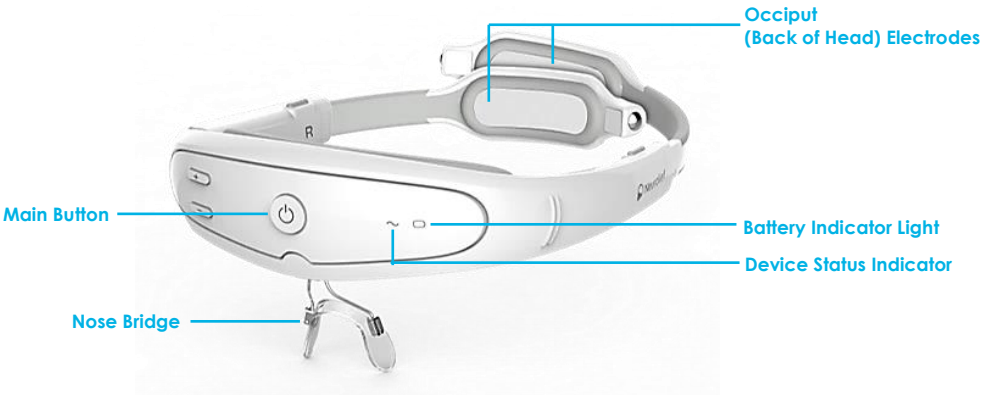


Figure 2: Relivion™ – Front View

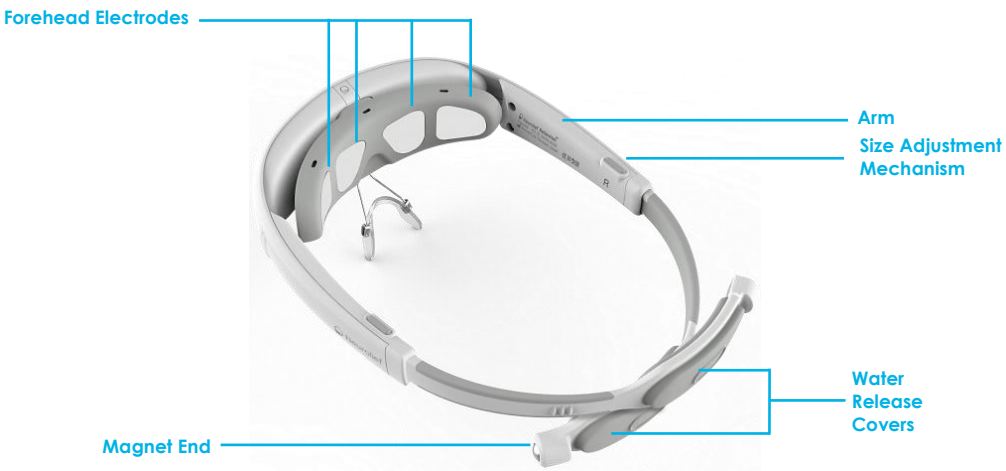


Figure 3: Relivion™ – Top View

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2 Getting Ready

Before using the Relivion™ for the first time, several preliminary steps must be performed.

Step 1	Charging the Relivion™	Section 2.1
Step 2	Adjusting the Relivion™ to Fit Your Head	Section 2.2
Step 3	Getting Started with the Relivion™ App	Section 2.3

2.1 STEP 1, CHARGING THE RELIVION™

It is recommended to charge the device before first use and after each use, in order to ensure that it is always ready when needed. It takes approximately three hours to fully charge the battery. When the battery is low, the battery indicator light blinks yellow. After the device is fully charged, it is typically sufficient for approximately five hours of treatment.

IMPORTANT! Only use the charger supplied with the Relivion™ device.

▶ **To charge the battery –**

1 Plug the charger into a wall socket.

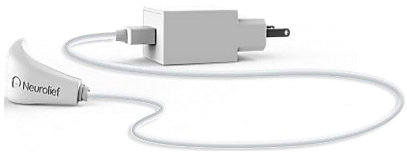

Figure 4: Relivion™ Charger

NOTE Ensure that the charger socket is not wet before charging the device.

2 Connect the magnetic connector of the charger to the charging socket on the headset. The charging socket is located on the bottom of the headset. The connector connects using magnetic force. It must be connected in the proper direction for the magnet's polarity to work properly.

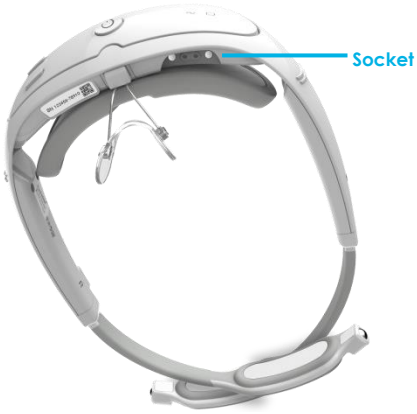

Figure 5: Charging Socket Location

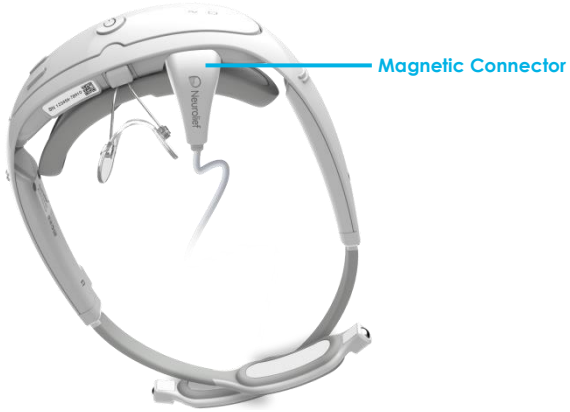

Figure 6: The Magnetic Connector Connected to the Headset

3 Verify that the battery indicator lights steady yellow. The battery indicator light blinks yellow when the battery is low and is steady yellow during charging.

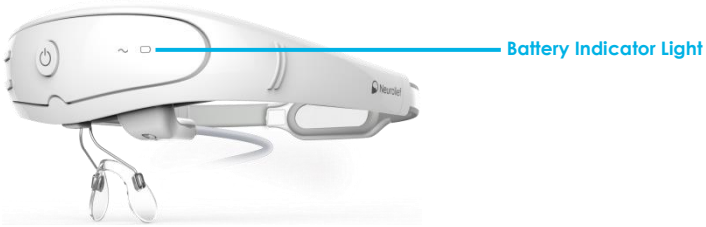

Figure 7: Battery Indicator Light on the Headset

4 When the charging process ends, the battery indicator light turns off and the status indicator lights blue. When the Relivion™ is disconnected from the wall socket, the status indicator turns off.

WARNING!
Do not use the device while charging.

2.2 STEP 2, ADJUSTING THE RELIVION™ TO FIT YOUR HEAD

Perform the procedure below to adjust the Relivion™ to fit your head.

You only need to make these adjustments once, before using the Relivion™ for the first time.

▶ **To adjust the Relivion™ to fit your head –**

1 **Insert the electrode pads,** as described below.

The device is provided with the electrode pads to be put on the electrodes. Electrode pads are provided in a plastic packet.

Six electrode pads are provided – four for the front electrodes and two for the back (Occiput) electrodes.

The four pads for the front electrodes all have the same shape, but are inserted in different directions according to the holes in the inside of the front of the headset, as shown below –

Figure 8: Front Electrode Pads

The long oval pads are for the back electrodes.

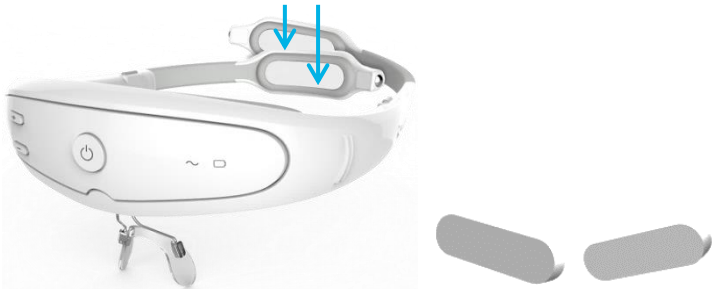

Figure 9: Back Electrode Pads

Each set of six electrode pads can be used for one treatment.

WARNING! Be sure to place the pads correctly before using the device.

NOTE Contact your supplier when you need more electrode pads.

NOTE Use only electrode pads provided by the manufacturer.

2 Adjust the arms of the headset to fit as tightly as possible on the head.

The arms of the device are set to size 5 before the device is shipped. You must first determine whether this size (size 5) provides a snug fit, or if you need to adjust the arms in order to obtain snug fit on your head. To do so, follow the steps below –

- Place the magnet ends of the arms at the sides of your head (slightly above your ears).

Figure 10: Placing the Relivion™ Arms on Your Head Above the Ears

- Push the device backwards so that the arms penetrate under your hair.

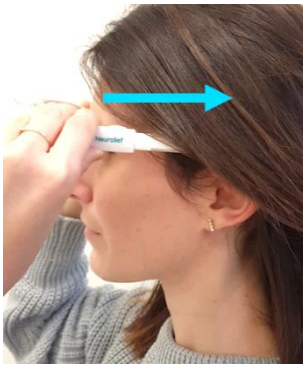

Figure 11: Pushing the Device Backwards on your Head

NOTE

Be sure to place the device arms under your hair.

- Check to see if the magnets at the ends of each arm meet at the back of your head. You should hear a click when the magnets click together.

Push the magnets together until they click.

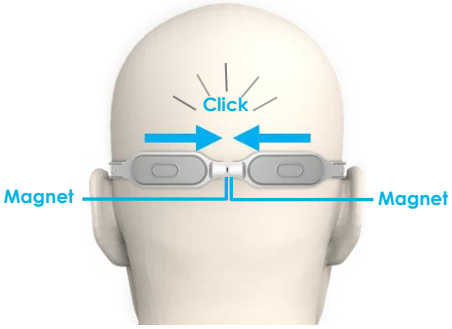

Figure 12: Magnet Ends Meet at the Back of the Head

- **If the magnets do meet at the back of the head**, then position your fingers on the back and front grips and gently pull the grips toward each other to tighten the device on your head.

Figure 13: Front and Back Grips

IMPORTANT! Make sure that the headset fits snugly and that the magnets of both arms meet on the back of the head.

- **If the magnets <u>do not</u> meet at the back of the head**, you must extend the arms to make them longer. To do so, press the release button of the size adjustment mechanism on either the left or right side and extend the arm to its maximum length. Then, repeat this action on the other arm.

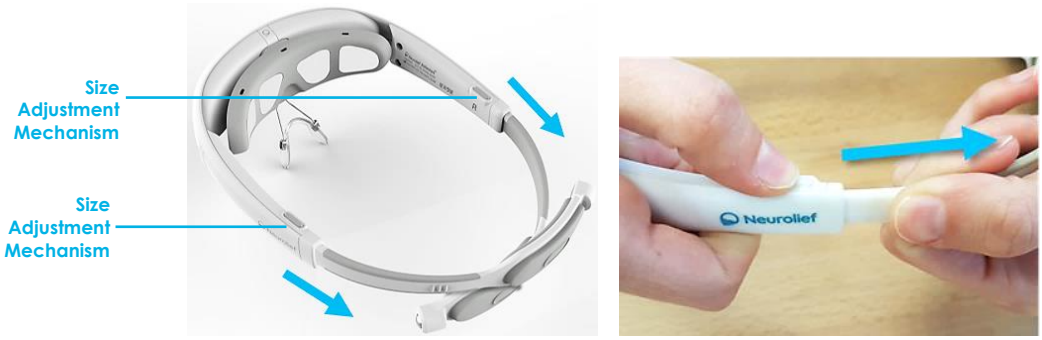

Figure 14: Extending the Headset Arms

3 **Remove the device and check the headset arms' settings (numerical scale) to ensure that they are symmetrical.** The size setting for both arms must be the same. Remove the device and check whether they are. If they are not, adjust each arm's lengths so that both are the same length, and then repeat step **2** as needed to obtain a tight fit. It may take more than one attempt to get the arm length to be identical for both arms, while obtaining a tight fit.

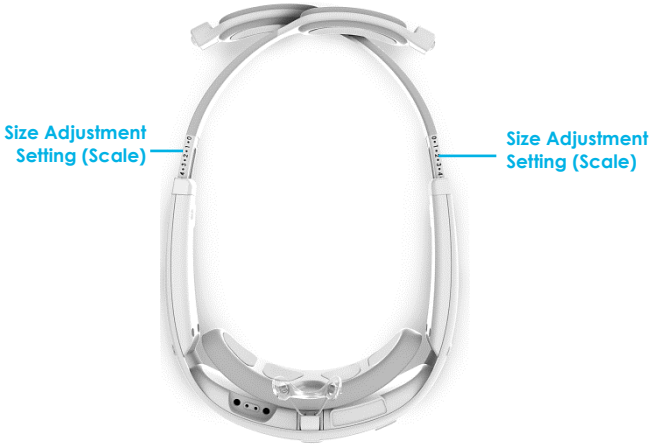

Figure 15: Size Adjustment Scale

2.3 STEP 3, GETTING STARTED WITH THE RELIVION™ APP

The Relivion™ mobile app is available from the app store. Download the app and then follow the instructions displayed in the app to register and pair the app with the Relivion™ headset. After successful pairing, the Start Treatment window displays in the app, as shown in Figure 20 on page 25.

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3 Using the Device

This chapter describes how to prepare, connect and use the Relivion™.

Step 1 — Preparing for Treatment — Section 3.2

Step 2 — Performing Treatment — Section 3.3

3.1 OPERATING BUTTONS AND INDICATORS

Figure 16 shows the Relivion™ operating buttons and indicators.

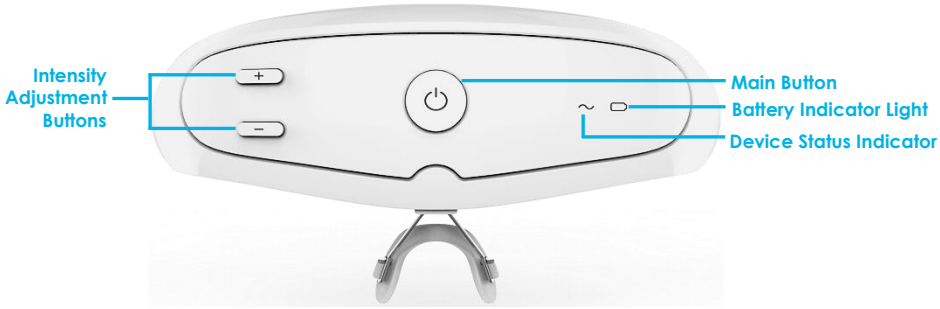

Figure 16: Relivion™ Operating Buttons and Indicators

Table 3: Relivion™ User Interface Functions

Indicator Light	Description	Function
⏻	Main button	• **First Press –** The device is ON. • **Second Press –** The device is OFF.
+ / −	Intensity adjustment (+/-) buttons	• + **–** First press initiates the treatment. Additional presses increase the intensity level. • − **–** Decreases the intensity level.

Indicator Light	Description	Function
~	Device Status indicator	Shows the status of the Relivion™, as described in Table 4.
▭	Battery indicator light	Shows the status of the battery, as described in Table 4.

Table 4 describes the Relivion™ Device Status and battery indications.

NOTE The Relivion™ shuts down automatically after 20 minutes when not being used for stimulation or when not pressing a button.

Table 4: Relivion™ Device Status and Battery Indications

Indicator Light	Description
~ Steady Blue	The device is ON, which means that the Main button has been pressed and the device is in standby mode.
~ Flashing Blue	Treatment (stimulation) is active.
▭ Flashing Yellow	Low battery.
~ Steady Red	Indicates a device malfunction.
~ Flashing Red	Indicates a faulty electrode contact.

The Relivion™ also emits sounds (beeps) to indicate its status.

Table 5: Relivion™ Sound Indications

Sound	Description
Button Press Beep (Short Beep)	The device beeps whenever any button is pressed.
Maximum Intensity Beep (Error Beep)	This sound is heard whenever you reach the maximum intensity for the device, such as after pressing the + button multiple times to increase the intensity.
Faulty Electrode Contact Beep (3 Beeps)	This sound is heard when there is a faulty electrode contact.
OFF Beep (2 Beeps)	This sound is heard when the device turns OFF.

3.2 STEP 1, PREPARING FOR TREATMENT

Important –

Complete instructions for this step are provided in this user manual. Note that some instructions may be abbreviated or not included in the mobile app. Therefore, when performing this procedure for the first time, it is highly recommended that you follow along in this user manual, instead of relying solely on the mobile app. After you are familiar with the procedure, it is recommended to use the mobile app.

NOTE The mobile app displays the device status and indications, but does not control the Relivion™. You control the Relivion™ using the buttons on the headset.

▶ **To prepare for treatment –**

1. Turn the Relivion™ ON by pressing the Main button. The device beeps, and the Device Status indicator is steady blue.

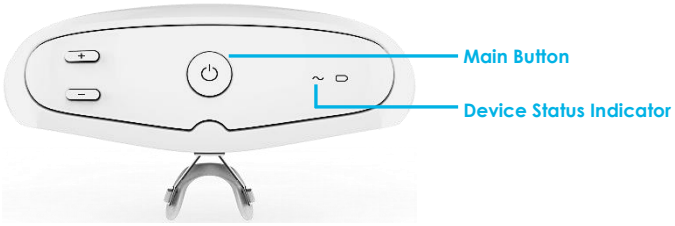

Figure 17: Turning ON the Device

The Relivion™ app connects to the Relivion™ via Bluetooth. Be sure that Bluetooth is enabled on your mobile phone to make the necessary connection.

2. Click the Neurolief icon on your mobile phone to launch the Relivion™ application.

3 Follow the on-screen instructions to log in to the mobile app and register your device.

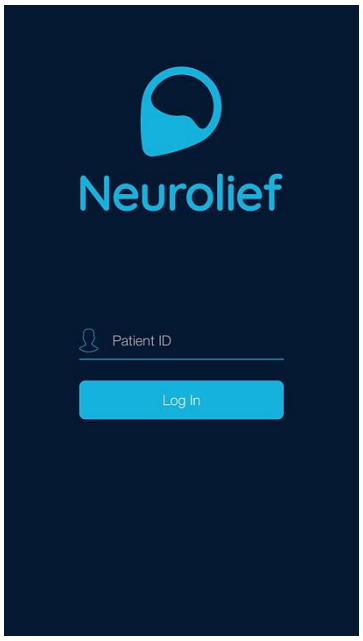

Figure 18: Login Screen

Figure 19: Device Registration Screen

Note that the image on the Registration screen indicates where the serial number label appears on the device.

After the app successfully connects to the Relivion™, the following window displays. The Device Status indicator should be illuminated on the app.

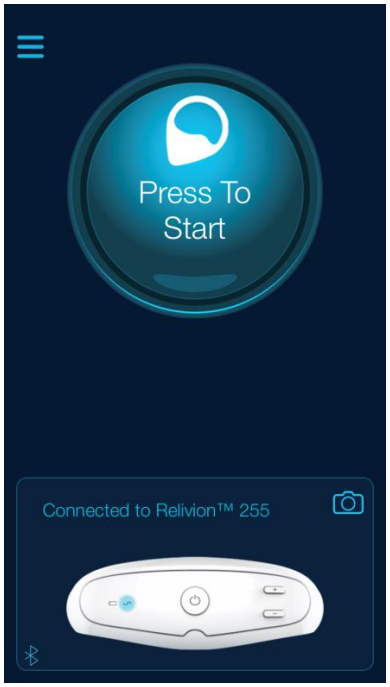

Figure 20: Successful Connection

4 Tap the **Press to Start** button on the mobile application.

5 Remove all hair clips and hair ties. Also, remove your glasses.

6 Clean your forehead. You can use facial wipes or regular soap and water.

7 Fill the provided spray bottle with regular tap water so that it is full.

Figure 21: Spray Bottle

8 Move the nozzle of the bottle up 45 degrees, and then press 8 times for each of the four pads on the front electrodes and 16 times for each pad on the two back electrodes. Be sure to wet the entire surface of each electrode pad.

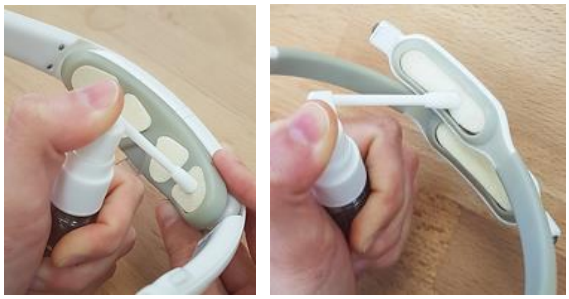

Figure 22: Wetting the Electrode Pads

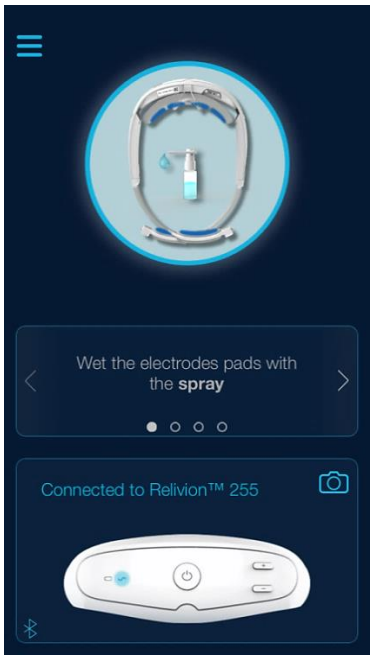

Figure 23: Wetting the Electrode Pads (Mobile App)

NOTES	Be sure to wet the electrode pads as instructed.

When using the mobile app, click the ❯ after you perform this step to move to the next screen in the mobile app wizard.

9 **Place the headset on your head.** While holding the Relivion™ arms away from one another, place the tips of the arms at the sides of your head (above your ears) and push the device backwards so that the arms penetrate under your hair and lock to each other by the magnets. You should hear a click when the magnets meet.

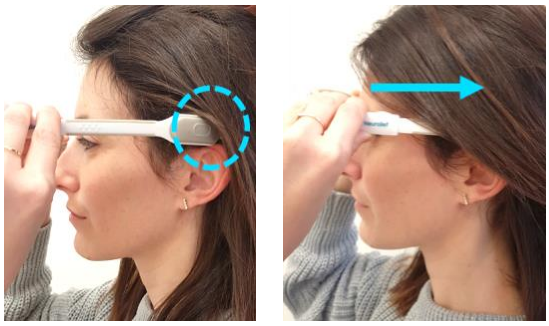

Figure 24: Placing the Device on the Head

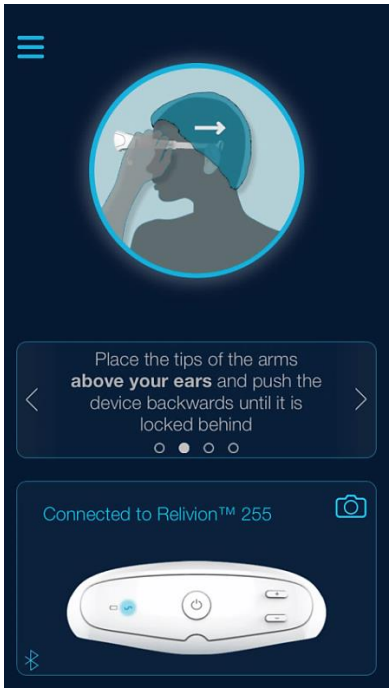

Figure 25: Placing the Device on the Head (Mobile App)

When using the mobile app, click the after you perform this step to move to the next screen in the mobile app wizard.

NOTES	Be sure to adjust the device and place it correctly before beginning treatment. Be sure to put the device on clean skin.

10 Verify the position of the headset by looking in a mirror to see that the device is positioned properly. The nose bridge should be centered on your nose and the front portion of the headset should be placed as close as possible to your eyebrows without covering them.

Figure 26: Proper Placement of Front Part of the Device

When performing this step with the mobile app, you can click the **Camera** icon on your app to view the position of the headset on your head, like when looking into a mirror.

When using the mobile app, click the after you perform this step to move to the next screen in the mobile app wizard.

9 Press the water release covers located on the back electrodes (see Figure 28) to release moisture toward your scalp.

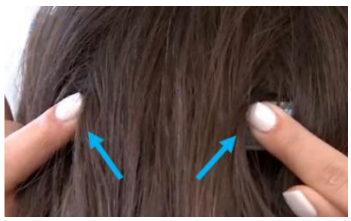

Figure 27: Pressing the Water Release Covers on the Head

Figure 28: Water Release Covers

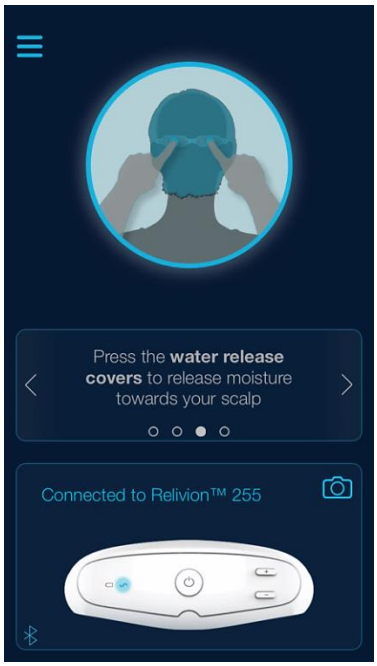

Figure 29: Pressing the Water Release Covers (Mobile App)

When using the mobile app, click the after you perform this step to move to the next screen in the mobile app wizard.

3.3 STEP 2, PERFORMING TREATMENT

Follow the procedure below to perform treatment using the Relivion™ device.

NOTE
It is not mandatory to use the mobile app to perform treatment.

▶ **To perform treatment –**

1. To initiate treatment, press the button on the Relivion™. The indicator light begins flashing blue.
   To increase the treatment intensity, press the button several times until you feel a tingling sensation in the area of the electrodes. Continue to increase the intensity until you feel a spreading tingling sensation over your forehead and occiput.

Figure 30: Initiating Treatment

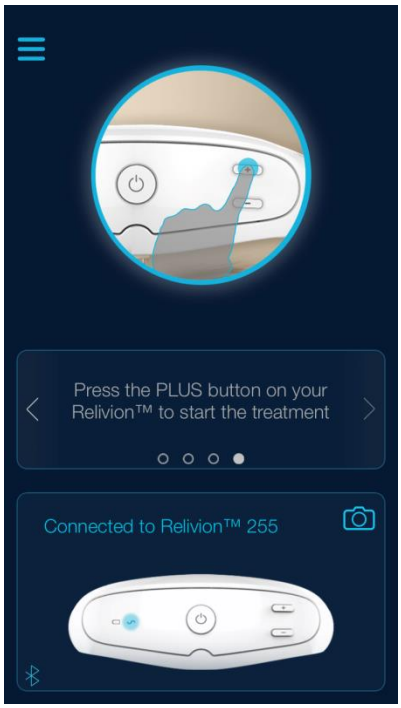

Figure 31: Initiating Treatment (Mobile App)

When using the app, after initiating the treatment you will see the treatment display screen, which shows the treatment duration, remaining operating time and the intensity bar. For effective treatment, the intensity must be increased **beyond the red section** of the intensity bar.

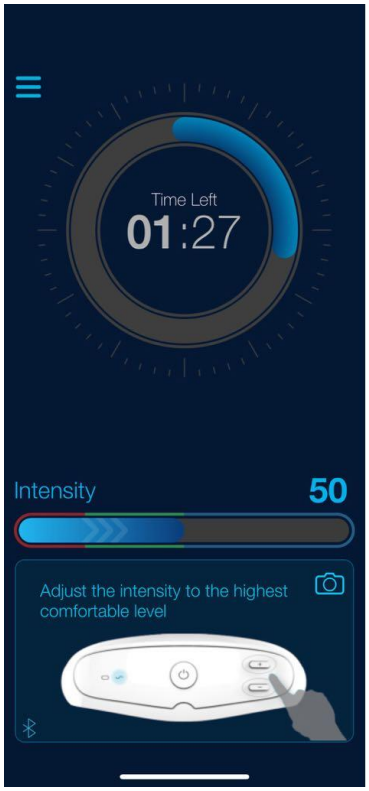

Figure 32: Treatment Display Screen

2 **Important – Continue to increase the stimulation intensity to the highest tolerable level. During treatment you may feel the sensation of the stimulation is weakening. This is a result of becoming accustomed to the stimulation. If so, further increase the stimulation intensity to the maximum tolerable level in order to maximize the therapeutic effect.**

NOTE The sensation should be strong enough to relieve the headache, but tolerable and comfortable enough for prolonged treatment.

3 The treatment automatically ends after 60 minutes. The Relivion™ beeps (nine times) and the status indicator light stops blinking and turns off.

NOTE Should you need to stop the treatment before that, press the Main button. The Relivion™ will beep and turn off.

4 To remove the device, detach the Relivion™ arms at the magnets closure and gently remove the Relivion™ from your head.

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4

Troubleshooting and Maintenance

This chapter describes how to troubleshoot and clean the Relivion™.

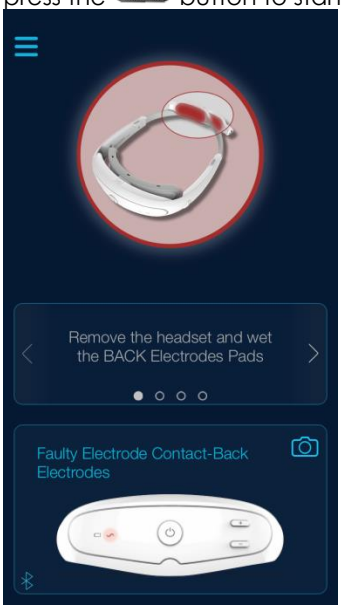
4.1 TROUBLESHOOTING

The following section describes how to troubleshoot various issues that may arise on the Relivion™.

Should a technical problem occur that is not covered below or that cannot be resolved by the suggested solutions below, contact customer support.

Table 6: Relivion™ System Troubleshooting

Problem/Symptom	Description
I initiated the treatment and heard a Faulty Electrode Contact beep (three beeps) and the stimulation does not start.	This indicates faulty electrode contact. When faulty electrode contact occurs, the status indicator light flashes red and the headset beeps –

Problem/Symptom	Description
	• If you are using the app, it indicates which electrodes have faulty contact. To solve the problem, remove the headset from your head, wet the identified electrode pads and put the headset on your head again. Then, press the + button to start treatment.  **Figure 33: Faulty Electrode Contact – Back Electrodes** • If you are not using the app, press the water release covers on the rear side of the electrodes at the back of the head to release water toward the scalp. Then, press the + button to start treatment. • If the problem recurs, remove the headset from your head, wet the six electrode pads and put the headset on your head again. Then, press the + button to start treatment. • If the problem recurs repeatedly, replace the electrode pads.

Problem/Symptom	Description
The device does not turn ON.	The battery is depleted. Charge your Relivion™ device, as described in the *Step 1, Charging the Relivion™* section on page 13.
The status indicator (~) is a steady red light.	Indicates a device malfunction. Contact Neurolief customer support.

4.2 CLEANING AND MAINTENANCE

- There are no parts that need regular service or maintenance.
- Clean the device with a wet cloth after each use.
- Do not use solvents of any kind (acetone, petrolatum and so on) on the device.
- Replace the electrode pads before each treatment.
- When the device is not used, make sure that the arms **are not connected** to one another by the magnets.

NOTE

Store the Relivion™ in its case when not in use.

4.3 DISPOSAL

- Used electrode pads should be disposed of in normal trash receptacles after each use.
- Dispose of the device according to national, state and local regulations, as the device contains a Lithium-Ion battery.

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5 Technical Specifications

This chapter describes the technical specifications of the Relivion™.

Table 7: Technical Specifications

Operating Conditions	
Temperature	+5°C to +40°C
Relative Humidity	15% to 93%
Atmospheric Pressure	700 hPa to 1060 hPa
Transport and Storage Conditions	
Temperature	-25°C to +70°C
Relative Humidity	Less than 93% (non-condensing)
Atmospheric Pressure	700 hPa to 1060 hPa
Electrical Specifications	
Number of Stimulation Channels	3 (2 Trigeminal, 1 Occipital)
Constant Current	Yes
Waveform	Symmetrical rectangular biphasic pulse, 100% compensated
Maximum Current – Trigeminal	6 mA (per channel)
Maximum Current – Occipital	12 mA
Maximum Phase Duration	330–400 µsec (fixed sequence)
Maximum Frequency	80 Hz
Maximal Voltage	• **@500 ohms –** 3 V front electrodes/6 V back electrodes • **@2,000 ohms –** 12 V front electrodes/24 V back electrodes • **@10,000 ohms –** 60 V front electrodes/100 V back electrodes
Maximum Charge per Phase	4.8 µC
Maximum Current Density (mA/cm^2, r.m.s.)	1.93 front electrodes/2.78 back electrodes

Maximum Average Power Density (W/cm^2)	0.0000116 front electrodes/0.000034 back electrodes
Maximum Rise Time	5 µsec
Timer	60 minutes
Power Source	
Battery Type	Rechargeable 3.7V Li-Po battery, 200 mAh
Battery Life	300 charge cycles
Charging Source	AC line adapter
Wall Adapter Input	100–240 VAC, 50/60 Hz, 0.3 A
Radio Transceiver Properties	
Frequency Band	2,400–2,483.5 MHz
Maximum Emitted Radiation Power	7.5dBm
Modulation	GFSK
Radio Protocol	BLE type 4.1
Headset	
Number of Electrodes	6 (4 forehead electrodes and 2 occiput electrodes)
Replaceable Electrode Pads	2 sets of 6 Contact Neurolief to order more.
Size	• Minimum Circumference (Adjusted to Smallest Head Size) – 515 mm • Maximum Circumference (Adjusted to Largest Head Size) – 600 mm
Dimensions	210 mm x 130 mm x 35 mm
Weight	150 g
Device Service Life	
5 years	

A Electromagnetic Compatibility

The Relivion is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Table 8: Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group1 Class B	The Relivion™ 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.
	Class B	The Relivion™ 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	Class A	
Voltage Fluctuations and Flicker IEC 61000-3-3:2013	Complies	

Table 9: Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	• 8kV contact • 2, 4, 8, 15kV air	• 8kV contact • 2, 4, 8, 15kV 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	Evaluated during AC/DC adapter approval	Mains power quality should be that of a typical domestic establishment.
Fast Surge Immunity IEC 61000-4-5	• 1 kV line(s) to line(s) • 2 kV line(s) to earth • 2 kV signal input/output) to earth	Evaluated during AC/DC adapter approval	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	• **0% UT –** 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° • **0% UT –** 1 cycle • **70% UT –** 25/30 cycles • **Single phase at 0° 0% UT –** 250/300 cycles	Evaluated during AC/DC adapter approval	Mains power quality should be that of a typical domestic establishment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V, 6 V 10 V/m • 3 V from 0.15 to 80 MHz • 6 V from 0.15 to 80 MHz and 80% AM at 1 kHz • 10 V/m from 80 MHz to 2.7 GHz	3 Vrms, 6 V 10 V/m • 3 V from 0.15 to 80 MHz • 6 V from 0.15 to 80 MHz and 80% AM at 1 kHz • 10 V/m from 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 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 RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol – 

Table 10: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Relivion™

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)			
	150 kHz to 80 MHz Outside ISM Bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM Bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Electromagnetic Compatibility Warnings

The Relivion™ device is approved according to electromagnetic compatibility (EMC) safety standard EN 60601-1-2. It is designed to be used in typical domestic environments –

- Radiated or conducted electromagnetic signals may impair Relivion™ essential performance, and incorrect output that exceeds the device's specifications may occur.
- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Relivion™ device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

B FCC Compliance

This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions –

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

FCC ID: 2AO9M-01

WARNING! Modifications not expressly approved by the manufacturer could void the user authority to operate the equipment under FCC Rules.

A distance of at least 0.25 cm between the equipment and all persons should be maintained during the operation of the equipment.

FCC Compliance Statement

This device 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 residential installations. 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 and television reception.

However, there is no guarantee that interference will not occur in a particular installation. If this device does cause such interference, which can be verified by turning the device off and on, the user is encouraged to eliminate the interference by one or more of the following measures:

1. Re-orient or re-locate the receiving antenna.
2. Increase the distance between the device and the receiver.
3. Connect the device to an outlet on a circuit different from the one that supplies power to the receiver.
4. Consult the dealer or an experienced radio/TV technician.

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MAN1001A Rev.1.1 (for model type RLV3)

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