



USER MANUAL

For Patients

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RX ONLY

R_x Only

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

The Relivion MG transcutaneous electrical nerve stimulator 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.

SUMMARY OF CLINICAL DATA

The safety and effectiveness of the Relivion MG device for the treatment of migraine with and without Aura was demonstrated in a prospective, randomized, parallel-group, sham-controlled clinical trial- the RIME study. The study included 131 patients (109 females and 22 males) experiencing migraine attacks with or without aura. Patients were enrolled at 12 sites in the US and Israel. Baseline demographics were consistent with the migraine population in terms of age, gender, etc. 83% (109/131) of the participants were females. The mean age was 40.3 years (SD=12.7). The mean age of migraine onset was 18.6 (SD=8.54) years and ranged from 4 to 50. 62.6% (82/131) of the subjects had migraine without aura, 37.4% (49/131) had migraine with aura, 26.7% (35/131) of the subjects were using migraine preventive medication at baseline.

The primary outcome was the proportion of subjects reporting reduction of migraine headache pain (i.e. pain relief) 2 hours after treatment initiation from severe or moderate to mild or no pain, or from mild to no pain. Pain relief at 2 hours post-treatment was found statistically significantly higher in the active group than in the sham group: 60% of subjects in the active group compared to 37% in the sham group met the primary endpoint (p value=0.0180), group difference: 23%. Therefore, the study was deemed successful. Furthermore, the active arm was superior to the sham arm for all 3 study secondary endpoints, as follows:

- Pain Freedom rate at 2 hours post-treatment initiation without use of rescue medication (46.00% vs. 11.86% for active and sham arms, respectively, p-value: <0.0001).
- Improvement in MBS 2 hours post-treatment initiation without use of rescue medication (80.56% vs. 60.00% for active and sham arms, respectively, p-value: 0.0466).
- Reduction in pain level – 1-hour post-treatment initiation without use of rescue medication (-0.6 (-28.7%) vs. -0.3 (-14.4%) for active and sham arms, respectively, p-value: 0.0121).

In addition, the active arm was superior to the sham arm in the following additional parameters:

- Complete MBS Freedom 1- and 2-hours post-treatment initiation without use of rescue medication.
- Pain Freedom at 1-hour post-treatment initiation without use of rescue medication.
- Pain and MBS Relief at 1- and 2-hours post-treatment initiation without use of rescue medication.
- Complete Symptoms Free (pain and MBS)- 1- and 2-hours post-treatment initiation without use of rescue medication.
- Sustained 2-24 hours headache Pain Relief and Pain Free without use of rescue medication.
- Pain Relief and Pain Free consistency of response across multiple treated episodes.

With respect to safety, 21 AEs were reported in 10 subjects, 8 in the active arm (incidence: 11.94%, 8/67), and 2 in the sham arm (incidence: 3.13%, 2/64). None of the adverse events were serious, 7 AEs were considered moderate (4 in the active arm and 3 in the sham arm), and the other 14 were mild. 16 AEs were considered as at least possibly related to the study device (7 in 5 subjects randomized to active arm; 9 in 2 subjects in the sham arm). All the reported AEs were fully reversible and resolved without intervention. The nature of the observed events in the active group was anticipated and very similar to other nerve stimulators for migraine, including adverse events that are directly related to the neuromodulatory action of the device such as transient scalp numbness sensation, tingling and twitching. The rate and severity of events were as anticipated and similar to other available devices.

You may ask your doctor for more information regarding the clinical study.

USER MANUAL PURPOSE

This user manual provides the necessary instructions for safely operating the Relivion MG 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.

SYSTEM SYMBOLS

Table 1: System Symbols

Symbol	Description
	Consult instruction for use
	Patient information website
	Class II equipment
Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Manufacturer
	Country of manufacture and manufacturing date
	Authorized representative in the European Community / European Union
	Importer
	European conformity
	Type BF applied part (front and back electrodes)

Symbol	Description
	Serial number
	Batch code
	Catalog number
	Operating conditions
	Keep dry
	IP rating. Indicates the degree of protection. The Relivion MG device is protected from limited dust ingress and from water spray from any direction.
	RF transmitter
	Waste Electrical and Electronic Equipment Directive (WEEE)
	Single patient - multiple use
	Single use
	Keep away from sunlight
	Do not use if package is damaged
	Atmosphere pressure limitation
	Humidity limitation
	Fragile, handle with care
	Medical device

Symbol	Description
	Caution
	Home use
	USB DC wiring

SAFETY INFORMATION

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

Contraindications

- Subjects with a metal implant or shrapnel in their head, except for dental implants, should not use the device.
- Subjects with recent (less than three months) brain or facial trauma should not use the device.
- Subjects with skin abrasions on the forehead or occiput at the contact area of the Relivion MG 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 use the device in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms) that may not operate properly when the electrical stimulation device is in use.
- Apply treatment only to intact, clean and 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 6).
- 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 MG 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. Small parts, such as the disposable pads, may be a choking hazard for small children.
- Keep the device out of reach of pets.

- Use this device only with Neuro Relief electrode pads and the Neuro Relief power supply and charging cable supplied with the device. Do not use any accessories, detachable parts and materials that are not provided by Neuro Relief.
- If the device does not function as described in this user manual, stop using it and contact Customer Care.
- The Relivion MG device is designed for use by and on a single adult person. For hygiene reasons, the device should not be shared.

Adverse Reactions

Relivion MG has few reported adverse reactions, which have been demonstrated in clinical trials to be minor and fully reversible with cessation of device use. If adverse reactions persist, stop using the device and consult your physician.

- Unpleasant sensation during treatment (for example Pressure sensation on the stimulation position).
- Scalp numbness sensation during and after treatment (Paresthesia).
- Persistent tingling sensation after the treatment ends.
- Pain.
- Nausea.
- Skin reaction (for example irritation, lesion, burn) beneath the 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 (Somnolence), fatigue, or disruption in sleep patterns. Sedative effect during or after treatment.
- Dizziness during or after treatment.
- Headache/migraine.

CONVENTIONS USED IN THIS USER MANUAL

NOTE



Notes provide additional important information.

TIP



Tips indicate helpful information for using the Relivion MG.

WARNING!



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

Table of Contents

1 INTRODUCING RELIVION MG.....	12
1.1 WHAT IS RELIVION MG?.....	12
1.2 THE RELIVION MG KIT	13
1.3 RELIVION MG DEVICE.....	14
2 GETTING READY	15
STEP 1. CHARGING THE RELIVION MG	15
STEP 2. ADJUSTING RELIVION MG DEVICE TO FIT YOUR HEAD	18
STEP 3. USING THE RELIVION MG APPLICATION.....	22
3 USING THE RELIVION MG DEVICE	31
OPERATING BUTTONS AND INDICATORS	31
STEP 1. PREPARING FOR TREATMENT.....	33
STEP 2. PERFORMING TREATMENT.....	39
4 USING THE APPLICATION.....	42
HOME SCREEN	42
TREATMENT DAYS LOG	42
MIGRAINE DAYS LOG	42
MIGRAINE DIARY	43
MIGRAINE REPORT SUMMARY	44
MESSAGES.....	45
MENU.....	46
5 TROUBLESHOOTING AND MAINTENANCE.....	48
TROUBLESHOOTING.....	48
CLEANING AND MAINTENANCE.....	50
DISPOSAL.....	52
6 TECHINCAL SPECIFICATIONS	53
A ELECTROMAGNETIC COMPATIBILITY	55
ELECTROMAGNETIC COMPATIBILITY WARNINGS.....	58
B FCC COMPLIANCE.....	59
FCC COMPLIANCE STATEMENT.....	59

1 INTRODUCING RELIVION MG

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



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

Contact Relivion Customer Care at support@relivion-medical.com or visit the Neurolief website at <http://www.Relivion.com> if you have any questions.



It is highly recommended to set up your Relivion MG and complete an initial training treatment prior to your first migraine attack.

1.1 WHAT IS RELIVION MG?

Relivion MG is a non-invasive medical device. It transfers mild electrical pulses to branches of the Trigeminal (Supraorbital and Supratrochlear) and Occipital nerves to treat headaches.

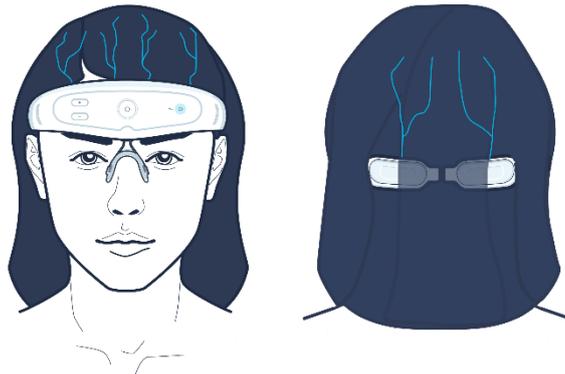


Figure 1: Relivion MG and the Targeted Nerves

Relivion MG consists of a device with integrated electrodes, designed to enable activation of the targeted nerves. The on-board electronic circuit is adapted to deliver stimulation patterns to enhance proper nerve activation. The Relivion MG device can be worn comfortably and adjusts to various head sizes and contours.

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 nerves.

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

Neurolief provides a Relivion MG mobile app that can be downloaded from the Apple/Google store to the patient’s mobile smartphone for treatment instructions, status and migraine follow-up. Even though the Relivion MG device can be fully operated and used without this mobile app, it is highly recommended to use it because of its benefits, described on page 21. The Relivion MG device communicates with the Relivion MG mobile app on the patient’s mobile smartphone via a Bluetooth link. The mobile app automatically reports treatments performed using the Relivion MG device to the physician such as treatment schedule, intensity and duration. The app also enables the patient to enter information describing their migraines, and how they feel before and two hours after treatment, by answering guided questions.

1.2 THE RELIVION MG KIT

The Relivion MG kit includes the components described in Figure 2

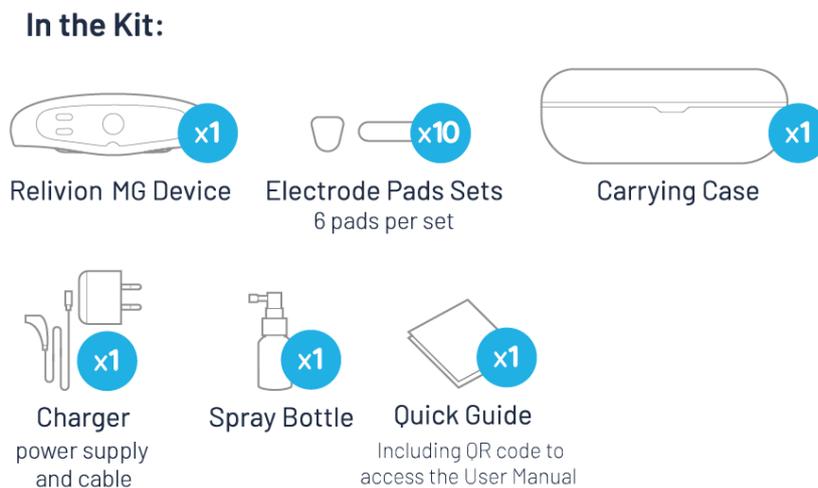


Figure 2: Relivion MG Kit

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

1.3 RELIVION MG DEVICE

The Relivion MG device can be comfortably worn on the head during treatment. It integrates six electrodes – four at the front of the device (forehead) and two at the back (occiput). It includes two flexible arms that go under the hair while the device is worn. Operating buttons, light indicators and a nose bridge are located in the front part of the device. A size adjustment mechanism is located on both sides of the device.

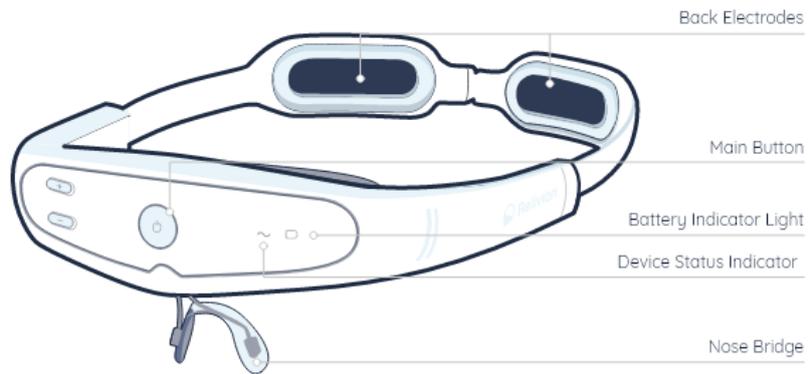


Figure 3: Relivion MG Device – Front View

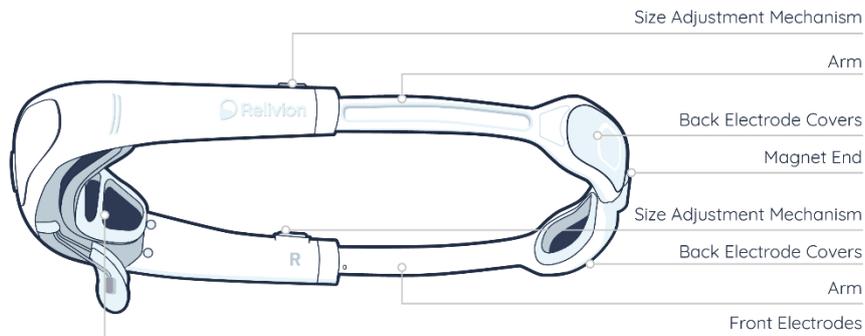


Figure 4: Relivion MG Device – Side View

Before using the Relivion MG for the first time, make sure to perform the following preliminary steps:

2 GETTING READY

- STEP 1. CHARGING THE RELIVION MG
- STEP 2. ADJUSTING THE RELIVION MG TO FIT YOUR HEAD
- STEP 3. USING THE RELIVION MG APPLICATION

TIP



It is highly recommended to perform the Relivion MG initial fitting and practice treatment prior to having a migraine attack.

STEP 1. CHARGING THE RELIVION MG

It is recommended to fully charge the Relivion MG device before first use and after each subsequent use, in order to ensure that it is always ready when needed. It takes approximately four 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.

NOTE



Only use the power supply and charging cable supplied with the Relivion MG device.

NOTE



Remember to unplug the charger from the wall outlet when it's not in use.

TO CHARGE THE BATTERY –

- 1 Plug the charging cable into the power supply and insert the power supply into a wall socket.

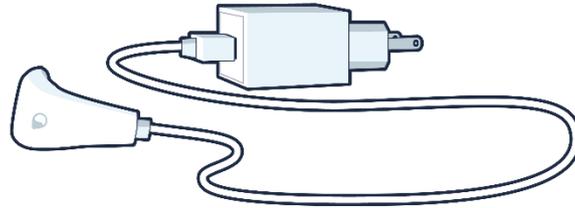


Figure 5: Relivion MG Charger Cable and Power Supply

- 2 Connect the magnetic connector of the charging cable to the charging socket on the Relivion MG. The charging socket is located on the bottom of the Relivion MG device as shown below.

NOTE



Verify that the charging socket is not wet before charging the Relivion MG.

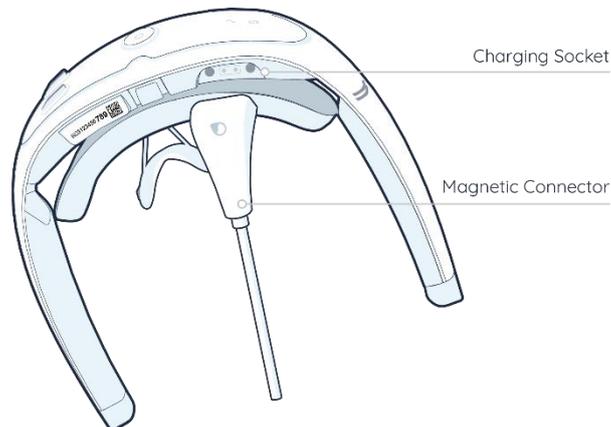


Figure 6: Charging Socket Location

- 3 Verify that the battery indicator's yellow light is on and not blinking. The yellow light blinks when the battery is low and is steady during charging.

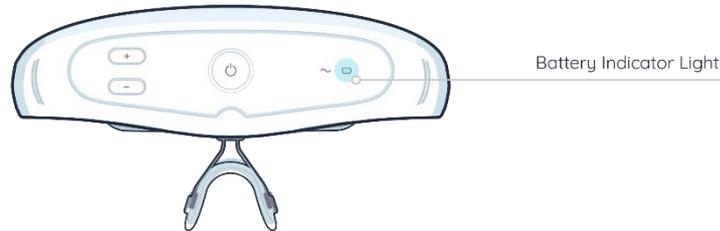


Figure 7: Battery Indicator Light on the Relivion MG device

- 4 When the Relivion MG is fully charged, the battery indicator light turns off and the status indicator's light is steady blue. When the Relivion MG device is disconnected from the charger, it turns off.

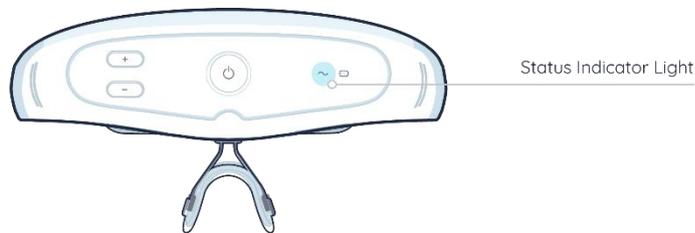


Figure 8: Status Indicator Light on the Relivion MG

NOTE



It is not possible to use the Relivion MG while it is connected to the charger.

STEP 2. ADJUSTING THE RELIVION MG DEVICE TO FIT YOUR HEAD

TO ADJUST THE RELIVION MG DEVICE TO FIT YOUR HEAD, PERFORM THE FOLLOWING STEPS–

1 Insert the electrode pads, as described below

Relivion MG comes with 10 sets of electrode pads. Each set includes six electrode pads to be placed on top of the electrodes in the device. Each set of electrode pads is provided in a separate packet.

The packet includes four pads for the front electrodes and two pads for the back electrodes.

The four pads for the front electrodes all have the same shape, but are inserted in different directions, as shown below –

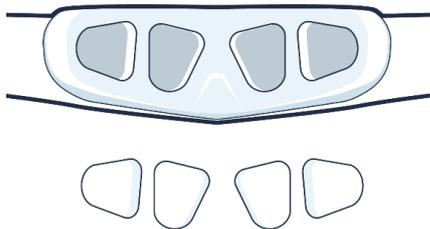


Figure 10: Front Electrode Pads

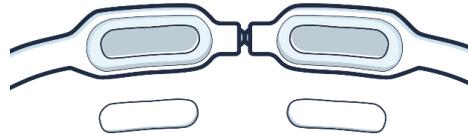


Figure 9: Back Electrode Pads

The long oval pads are for the back electrodes, as shown above. Each set of six electrode pads can be used for one treatment.

WARNING!



Be sure to place the pads correctly before using the Relivion MG.

NOTE



Only use the electrode pads provided by the manufacturer.

2 Adjust the arms of the Relivion MG device so that it fits tightly on your head and does not move

NOTE



It will take a few tries until you find the right size for your device, but this step is only required once, before using the Relivion MG for the first time.

The size of the Relivion MG device arms is determined by the numbers located on each arm.

- A. First verify that each arm size is set to size 0 (men can start from size 3)

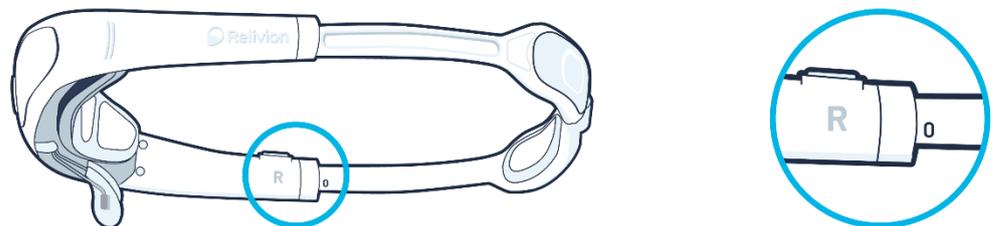


Figure 11: Size Adjustment Scale

- B. Remove all accessories from your face and your head, such as eyeglasses, hair clips, hair ties, eyebrow piercings, thick hair product, and so on.
- C. Hold the magnetic arms with your index fingers at the center of the back electrode covers. Place the magnetic ends of the arms on the front sides of your head (slightly above your ears).

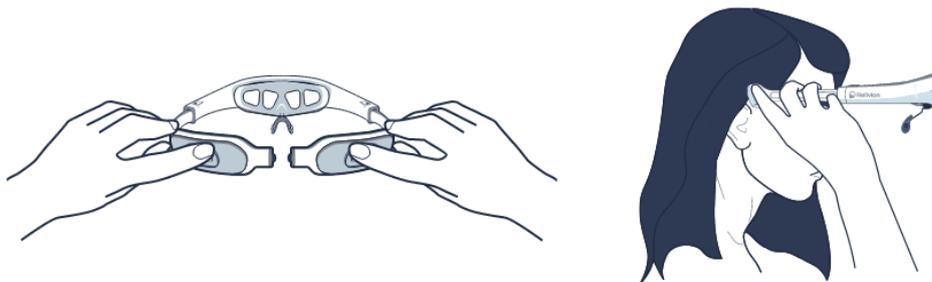


Figure 12: Placing the Device Arms on the Sides of Your Head Above Your Ears

- D. Push the Relivion MG device backwards so that the arms go underneath your hair. The magnet ends should penetrate your hair and constantly press against your scalp.



Figure 13: Pushing the Device Backwards on Your Head

NOTE



Be sure to place the arms of the Relivion MG device under your hair.

- E. If the Relivion MG size fits your head, the magnet ends should connect (you might need to apply some pressure).



Figure 14: Magnet Ends Meet at the Back of Your Head

- F. **If the magnets do not connect**, remove the device and lengthen **both** arms **by 1 unit size**. To lengthen each arm, press the size adjustment release button and extend the arm, as shown below -

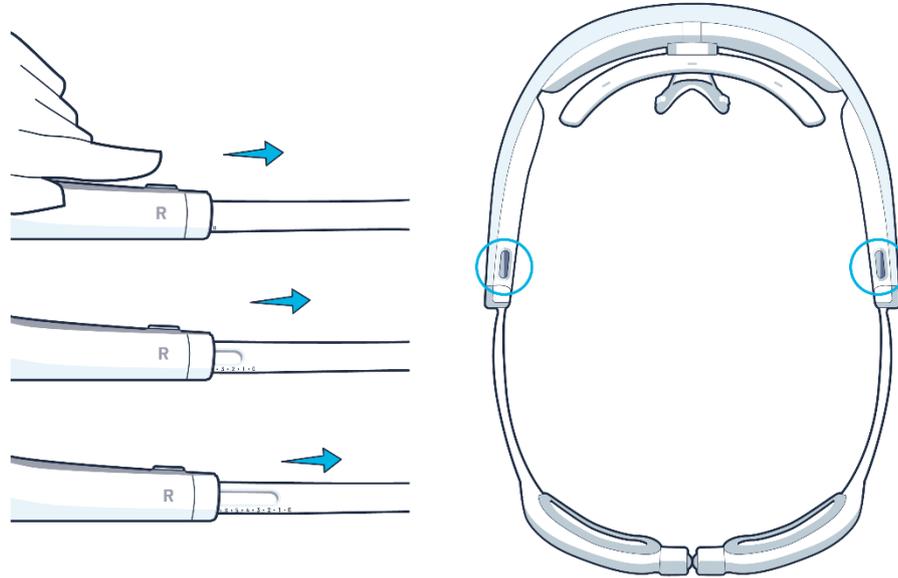


Figure 15: Extending the Device Arms

Repeat steps C to F until the magnets connect properly at the back of your head and the device is fixed tightly on your head.

NOTE



The Relivion MG device fits head circumference of 20"– 23½".

Make sure the device fits comfortably and that the magnets of both arms connect at the back of your head. If not, please contact Relivion Customer Care.

- G. While looking in a mirror, verify that the Relivion MG device is positioned properly, as follows -

- The nose bridge is centered on your nose.
- The front of the device is placed as close as possible to your eyebrows without covering them.
- The arms of the Relivion MG are above your ears and not over them.
- The magnet ends rest above the bump at the back of your head.

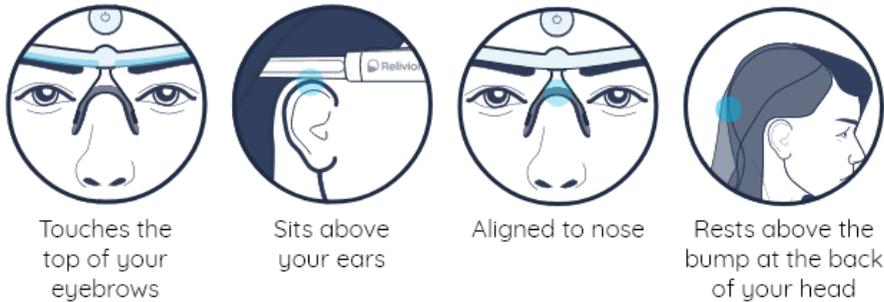


Figure 16: Proper Positioning of the Relivion MG

STEP 3. USING THE RELIVION MG APPLICATION

OVERVIEW

The Relivion MG mobile app is an app that you can download to your smartphone to access treatment instructions and updates on your device's connectivity and battery status while performing a treatment using the Relivion MG device. You can also use it to track your migraines and follow up on your treatments. Even though the Relivion MG device can be used without this mobile app, we highly recommend using it because of its benefits, as described below.

The Relivion MG device communicates with the Relivion MG mobile app on your smartphone via a secured Bluetooth low energy (BLE) link. The mobile app automatically reports treatments performed using the Relivion MG device to your physician, as well as their intensity and duration. It also enables you to enter information describing your migraine, the treatment and its aftereffects.

We highly recommend using the Relivion MG mobile app in order to enjoy the following benefits from your Relivion MG treatment –

- Receive treatment instructions.
- View Relivion MG device connectivity and battery status.
- Track your treatments, such as their frequency, intensity level, duration and so on.
- Check your recommended migraine treatment regimen.
- Record your migraines by answering guided questions.
- Enable your physician to follow your migraine status and treatment response and adjust your treatment recommendation accordingly.
- Manage a diary of headache occurrences and treatments summary.
- Track your migraines and treatments performed through the migraine report summary.

NOTE



- The Relivion MG app does not control the Relivion MG device. The device is controlled by pressing the buttons on it, as described on page 30.
- For the Relivion MG app to transfer data to the web-based physician interface, your smartphone must be connected to the Internet.
- The Relivion MG device does not store any sensitive user/patient data.
- The Relivion MG mobile app only stores your name and most recent recommended treatment regimen.

IMPORTANT – This user manual contains a detailed set of instructions. The Relivion MG mobile app provides a condensed version of these instructions, and some instructions may be omitted. Therefore, when performing this procedure for the first time, it is highly recommended to follow the instructions in this user manual, instead of relying solely on the instructions in the mobile app.

NOTE

Your smartphone must be connected to the Internet while using the app.

GETTING STARTED WITH THE RELIVION MG APP

Before launching the Relivion MG app, we recommend that you read *Chapter 1, Introducing Relivion MG* on page 10 and *Chapter 2, Getting Ready* on page 13 of this user manual.

Follow all the instructions below to set up your account on the Relivion MG mobile app so that it can communicate with your Relivion MG device. This will enable you to automatically track the treatments that you self-administered using the Relivion MG device, as described below. The Relivion MG mobile app's full set of migraine follow-up features is only available after your account is activated by Relivion Customer Care.

If you have not yet acquired a Relivion MG device, you can still launch the Relivion MG mobile app, and go through the onboarding (registration) process. You will not be able to start manually recording information about your migraines using the app's **Migraine Diary** follow-up features.

You must have a Relivion MG device before contacting a Relivion Customer Care representative.

If you already have a Relivion MG device –

When you first launch the Relivion MG app following registration, you'll be guided through the Bluetooth pairing process and will receive instructions about the Relivion MG device. If you already have a Relivion MG device, you can go directly to the instructions for launching the Relivion MG mobile app on page 23.

If you don't yet have a Relivion MG device –

You can start getting familiar with the system by launching the Relivion MG mobile app (as described below) and going through the onboarding (registration) process.

LAUNCHING THE RELIVION MG MOBILE APP

To launch the Relivion MG mobile app –

- 1 The Relivion MG app connects to the Relivion MG device via secured Bluetooth Low Energy (BLE) link. Make sure that Bluetooth is enabled on your smartphone in order to ensure the necessary connection.

Check that your smartphone is running the minimal operating system required – iOS 12 and above or Android 8 and above.

NOTE



The Relivion MG device provides sufficient Quality of Service (QoS) across its BLE internal network for its indication of use. The Relivion MG BLE internal network utilizes encryption of the data that is being transferred.

- 2 Download the free “Relivion MG” app to your smartphone from the iOS App Store or Google Play.



Figure 17: Relivion MG Mobile App

NOTE



Never try to connect the Relivion MG with any application other than the Relivion MG certified mobile app. Before downloading the app, verify that it's the official Relivion MG mobile app.

- 3 Tap the Relivion MG mobile app icon on your smartphone to launch the Relivion MG app.
- 4 Open the Relivion MG mobile app. Tap the **Sign Up** button and then follow the displayed instructions to create your Relivion MG app account and to pair the app with the Relivion MG device. Instructions for using the Relivion MG device are displayed.

The app guides you through entering general health information about yourself and your migraine characteristics, such as when they are triggered and so on. Entering this information is not mandatory. However, this information may help your physician follow your migraine status and provide you with treatment recommendations.

Note that the image on the Pairing screen (see Figure 19 below) indicates where the serial number label appears on the Relivion MG device.

Note that all the information saved within the app is securely stored in the cloud. If you change your smartphone and re-install the Relivion MG app, your information will be securely re-accessed by the Relivion MG app upon completion of the login process.



Figure 18: Relivion MG PMI Communication Flow



Figure 19: Relivion MG Device Pairing Screen

A Relivion Customer Care representative will be in touch with you by phone to activate your Relivion MG app account so that it can communicate with the Relivion MG device.

After you've successfully paired your smartphone with the Relivion MG device, you'll see the following screen. This is where you begin to familiarize yourself with your device.

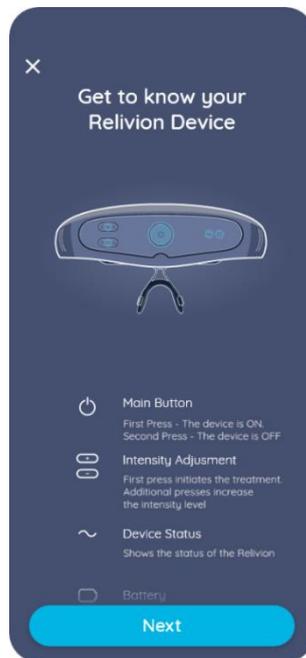


Figure 20: Relivion MG App "Get to know your Relivion device" Screen

You'll see the screen below before a Relivion Customer Care representative has been in touch and activated your account. In the meantime, click on View Tutorials button or go to More | How To Use page and follow the step by step tutorials to first learn how to adjust your Relivion MG device to fit your head properly (**Initial Fitting** tutorial) and then how to prepare for treatment (**Preparing for Treatment** tutorial). The mobile app trainings will guide you step by step and you will be asked to allow access to your camera. This will help you see how the Relivion MG is positioned on your head, just like looking in a mirror.

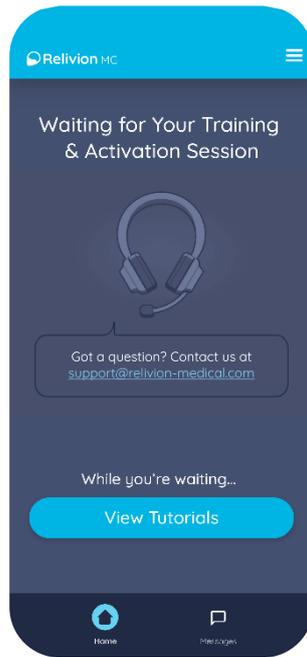


Figure 21: Waiting for Activation by a Relivion Customer Care Representative

USING THE RELIVION MG APP

After the Relivion MG mobile app is ready to use and connected to the Relivion MG device, you'll see the following screen:

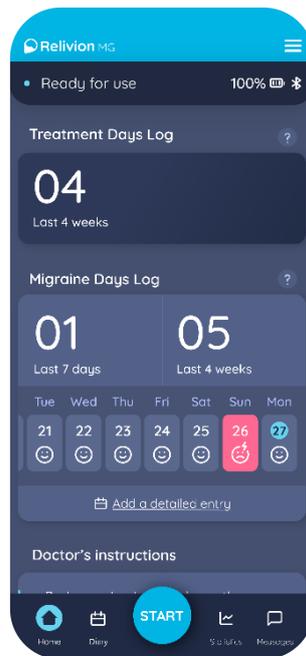


Figure 22: Home Screen

NOTE



The Relivion MG app does not control the Relivion MG device.

Doctor's Instructions

The home screen displays any treatment instructions provided for you by your physician. If your physician updates the instructions, the screen is automatically updated to show the latest recommendation.

Starting a Treatment

The Relivion MG app can be used to guide you through your treatment.

NOTE



The Relivion MG app does not activate treatment on the Relivion MG device. This can only be done manually on the Relivion MG device.

To start a treatment -

Tap the **Start** button and follow the instructions.

NOTE



Before starting a treatment, you should first prepare for the treatment (as described on page 33). To initiate the treatment, press the  button on the Relivion MG device (as described on page 39).

Manually Reporting Your Migraine

Use the following option to report a migraine which you **did not treat** by using the Relivion MG device. Reporting migraines in this manner may help your physician follow up on your migraine status.

To manually report your migraine -

Tap the **Diary** menu option and then the **Report a Migraine** button. Follow the displayed instructions to describe the migraine. The app automatically guides you through a series of questions.

Device Indications

The top of the screen shows indications about the connection between the Relivion MG app on your smartphone and the Relivion MG device, as well as the battery charge status and the Bluetooth connection. These are the indications you'll see when your Relivion MG device is connected, fully charged and the Bluetooth is connected:



Figure 23: Indications Bar – the Relivion MG is connected and ready for use

If the battery is not fully charged, the indication shows a semi-full battery icon.

If Bluetooth is not connected, the indication shows a Bluetooth not connected icon. A spinning wheel “Searching for Device” and a “Bluetooth Not Connected” icon.

If the device is not connected, you'll see these indications:



Figure 24: Indications Bar – the Relivion MG is not connected

In some cases, the Indications Bar can be expanded to show more explanations and/or troubleshooting tips.

3 USING THE RELIVION MG DEVICE

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

- OPERATING BUTTONS AND INDICATORS
- STEP 1. PREPARING FOR TREATMENT
- STEP 2. PERFORMING TREATMENT

OPERATING BUTTONS AND INDICATORS

Figure 25 shows the Relivion MG device operating buttons and indicators.

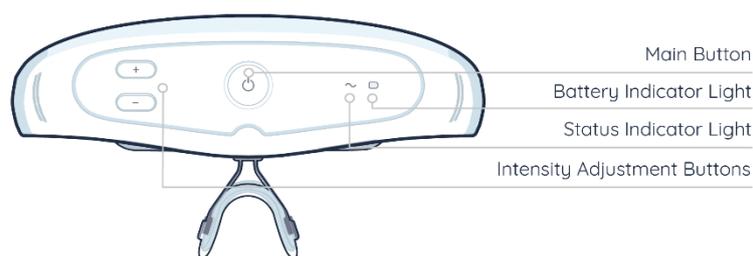


Figure 25: Relivion MG Operating Buttons and Indicators

Table 2 describes the function of each button and indicator on the front interface of the Relivion MG.

Table 2: Relivion MG User Interface Functions

Indicator Light	Description	Function
	Main Button	Press once to turn the device ON. Press again to turn the device OFF.
	Intensity Adjustment (+/-) Buttons	 – First press initiates the treatment. Additional presses or a long press increase the intensity level.  – Press or a long press decreases the intensity level.
	Device Status Indicator	Shows the status of the device, as described in Table 3.
	Battery Indicator Light	Shows the status of the battery, as described in Table 3.

NOTE



The Relivion MG shuts down automatically after 20 minutes when it is not in use.

Table 3 describes the Relivion MG device status and battery indications.

Table 3: Relivion MG 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 is active.
 Flashing Yellow	Low battery.
 Steady Yellow	Charging.
 Steady Red	Indicates a device malfunction.
 Flashing Red	Indicates an interrupted electrode contact.

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

Table 4: Relivion MG Sound Indications

Sound	Description
Button Press (Short Beep)	The device beeps whenever any button is pressed.
Minimum/Maximum Intensity (1 Error Beep)	You'll hear this sound whenever you try to go below the minimum or above the maximum device intensity.
Interrupted Electrode Contact (3 Beeps)	You'll hear this sound when there is an interrupted electrode contact.
OFF (2 Beeps)	You'll hear this sound when the device turns OFF.
End of Treatment (9 Beeps)	You'll hear this sound when the treatment automatically ends after 60 minutes.

STEP 1. PREPARING FOR TREATMENT



The Relivion MG mobile app displays the device status and indications but does not control the Relivion MG device. You control the Relivion MG using the buttons on the device.

TO PREPARE FOR TREATMENT –

- 1 Turn the Relivion MG device ON by pressing the Main button. The device beeps and the device status indicator is steady blue.

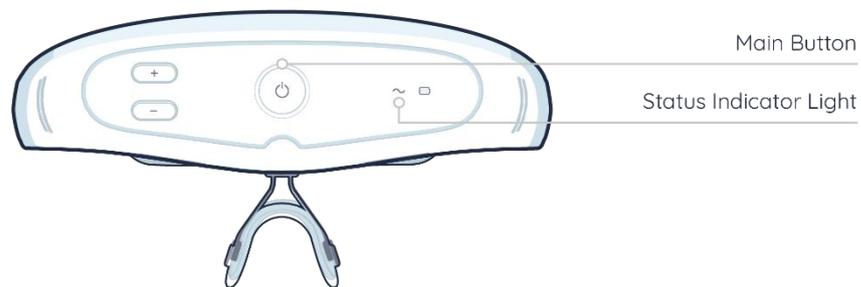


Figure 26: Turning ON the Device

- 2 On the mobile App, press the **Start** button, follow the instructions and answer the guided questions.
- 3 Remove all accessories from your face or head (e.g., eyeglasses, hair clips, hair ties, eyebrow piercings, thick hair product etc.).
- 4 Clean your forehead. You may use facial wipes or regular soap and water.
- 5 Fill the provided spray bottle with regular tap water. Use only the **Relivion water bottle** included in your kit.



Figure 27: Spray Bottle

- 6 Place the bottle nozzle **directly against the electrode pad** and press it **fully** 5 times for each of the front pads and 10 times for each of the back pads. Make sure to soak the entire surface of each electrode pad. Verify that the pad is wet enough by pressing on each electrode pad with your finger – you should see a small amount of water.

NOTE



Be sure to press the bottle cap all the way down and check that the entire surface of each electrode is soaked.

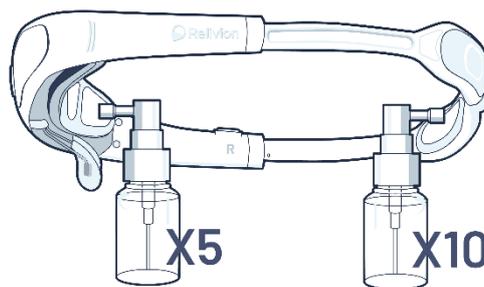


Figure 28: Soaking the Electrode Pads

WARNING!



Don't place the device under running water, as it may damage the device. Use only the provided spray bottle to wet the electrode pads.

- 7 Place the Relivion MG device on your head.** Spread the device arms and place the magnet ends at the sides of your head (above your ears). Push the Relivion MG backward so that the arms go under your hair, ensuring that the magnets constantly press against your scalp and connect at the back of your head.

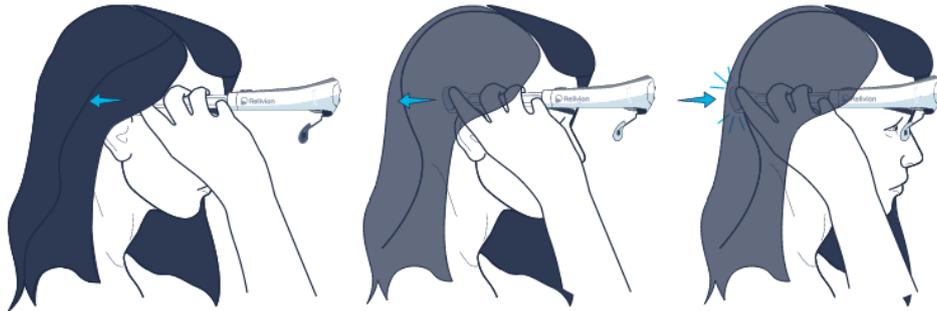


Figure 29: Placing the Relivion MG on Your Head



Figure 30: Placing the Relivion MG on Your Head (Mobile App)

- 8 The app allows you to activate the smartphone camera and use it as a mirror to verify that the Relivion MG is positioned properly as follows –
- The nose bridge is centered on your nose.
 - The front of the device is placed as close as possible to your eyebrows without covering them.
 - The arms of the Relivion MG are above your ears and not over them.
 - The magnet ends of the Relivion MG rest above the bump at the back of your head.



Figure 31: Proper Positioning of the Relivion MG

- 9 Press on the back electrode covers (see Figure 32 and Figure 33) until you feel moisture on your scalp.

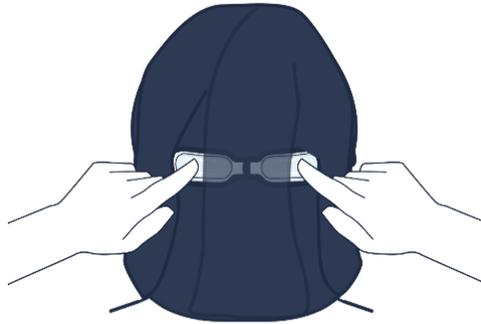


Figure 32: Pressing the Back Electrode Covers on the Head

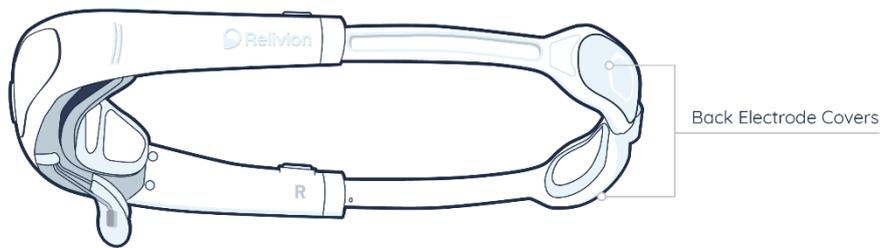


Figure 33: Back Electrode Covers

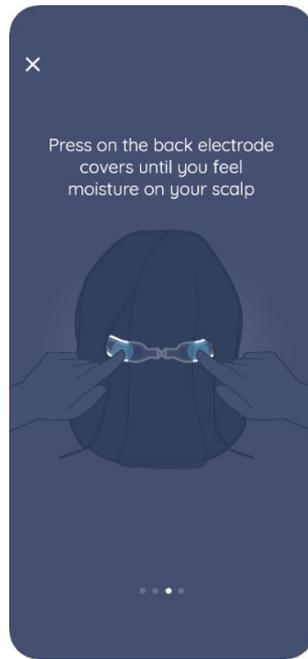


Figure 34: Pressing the Back Electrode Covers (Mobile App)

STEP 2. PERFORMING TREATMENT

NOTE



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

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

Although it is not mandatory, it is highly recommended to use the Relivion MG app to describe and report your migraines. The information you provide before and after the treatment can help your physician review and recommend your treatment regimen.

TO PERFORM TREATMENT –

- 1 If you are using the Relivion MG mobile app, start the treatment reporting procedure on the app, as described on page 32. The app will guide you through a series of questions about your migraine.
- 2 To initiate the administration of the treatment by the Relivion MG device, press the  button on the Relivion MG. The indicator light begins flashing blue.
To increase the treatment intensity, press the  button several times until you feel a tingling sensation around the electrodes. Continue to increase the intensity up to your highest comfortable level. The stimulation should be strong, but not painful.

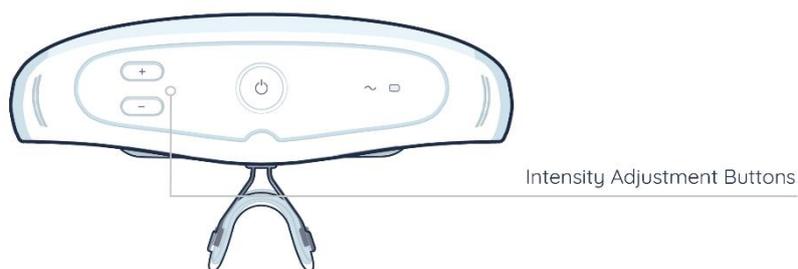


Figure 35: Initiating Treatment

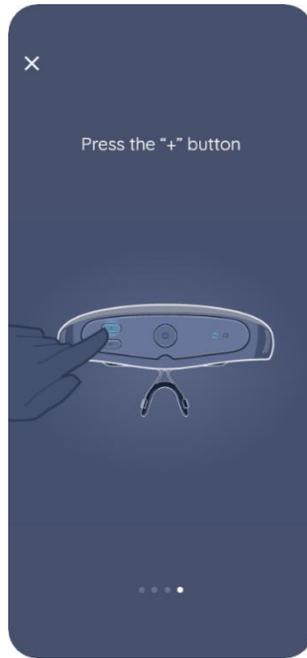


Figure 36: Initiating Treatment (Mobile App)



Figure 37: Treatment Display Screen

When using the app, after initiating the treatment, you'll see a screen showing the treatment time and the intensity level indicator.

Follow the displayed instructions -

- 3 During treatment you may feel that the sensation is weakening. This is a result of your becoming accustomed to the treatment. If so, further increase the treatment intensity by pressing the  button to the maximum comfortable level in order to optimize your treatment.

NOTE



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

- 4 If you are using the Relivion MG mobile app, you will receive a notification on the app once you have reached your recommended treatment time. You will be notified that your treatment time is up and directed to turn off the Relivion MG device (by pressing the Main button of the device). If you do not turn off the device, it will turn off automatically after 60 minutes, at which point it will beep (nine times) and its status indicator light will stop blinking and turn to steady blue.

NOTE



If you need to stop the treatment before it automatically ends, press the Main button. The Relivion MG will beep and turn off.

- 5 To remove the device, gently pull open the Relivion MG arms and remove the device from your head.
- 6 Remove the electrode pads and dispose of them at the end of each use.

TIP



Don't leave wet electrode pads in the device after use as they may damage the electrodes.

- 7 If you are using the Relivion MG mobile app, you'll see a summary at the end of your treatment session with the total treatment time.
- 8 If you are using the Relivion MG mobile app, you will receive a notification two hours after your treatment asking you to answer a series of post-treatment questions. The app will guide you through questions about the treatment and your current situation and will display a treatment summary based on your answers and device usage.

NOTE



Contact your supplier when you need additional electrode pads.

4 USING THE APPLICATION

HOME SCREEN

TREATMENT DAYS LOG

The app shows you how many treatment days you've recently had to help you stay on track with your treatment.

MIGRAINE DAYS LOG

The app provides you with a quick report option and presents the count of the reported migraines in the last days (up to 28 days). Simply tap on a date to add or remove a migraine.

Days on which you performed a treatment or manually added a migraine to your diary will be automatically displayed in the migraine log. Treatment days cannot be deleted.

By pressing on the 'Add a detailed entry' the app will direct you to the Diary screen and you can manually report a migraine (detailed migraine record).



Figure 38: Home Screen

MIGRAINE DIARY

The app allows you to track your migraines and treatments.

Treatments that are handled with the mobile app, including your answers to the questions before and after treatment, are automatically added to your Migraine Diary.

In addition, you can manually add a migraine to your Migraine Diary by tapping the **Report a Migraine** button under the **Diary** screen.

Each day with a reported migraine and/or treatment is shown in the Migraine Diary. Selecting a day and then a reported entry shows details about your pain, medication taken, triggers and treatment summary.

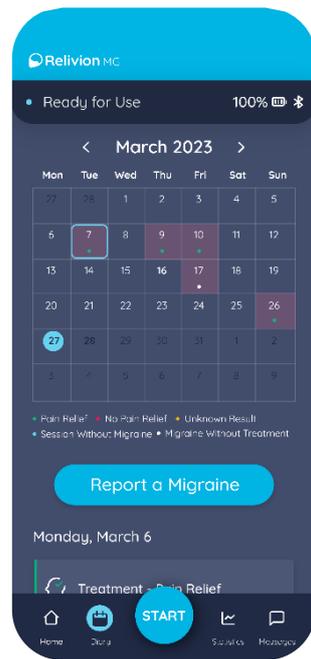


Figure 39: Migraine Diary

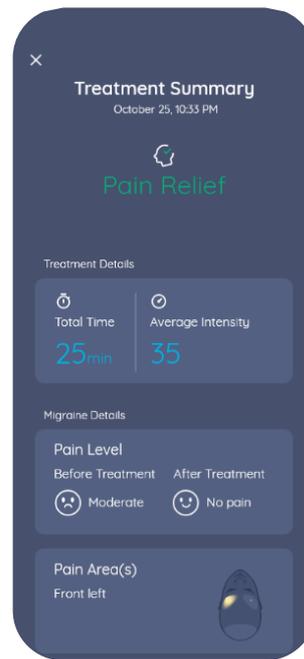


Figure 40: Treatment Summary

Your Migraine Diary will automatically be updated with your answers. If you answer that you did have a migraine that day, a migraine report will be created for the relevant date but will not contain details about the pain level, pain area and specific medications taken.

MIGRAINE REPORT SUMMARY

The app shows you some statistics on your migraines.

Details that are shown are:

- The total number of headache days you had per month over the last six months.
- The percentage of treatments with pain relief per month over the last six months. Pain is considered as relieved if you reported an improvement in your pain level of at least one level.
- The total number of days per month that you took medications for your headaches, over the last six months.
- Percentage distribution of your most common pain areas.
- Distribution of your most common triggers.



Figure 41: Migraine Report Summary

MESSAGES

The app displays messages that you may get from your physician, Relivion Customer Care and/or system messages. On the Messages screen, you'll see a list of messages. Each message has a title, message content and a date. You can identify read messages vs. unread ones and delete messages. Once there are unread messages, an icon appears next to the Messages icon in the app menu.

Messages will be presented as a popup while using the app. The popup can be closed and these messages will still appear on the Messages screen.

Some messages may suggest you take an action, such as calling Customer Care for more details and further instructions on using your Relivion MG or cleaning the electrodes.

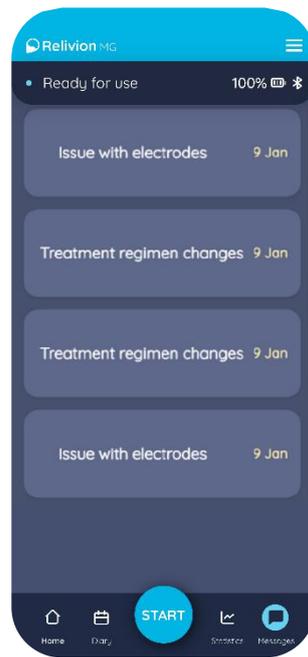


Figure 42: Messages Screen

MENU

Under the top Menu, you will find further information about your Relivion MG device and app. Under “My Profile” you will find your profile details and the Close Account option. Under “Legal” you will find the Privacy Policy and the User Agreement. For your convenience, this User Manual and some tutorials can be found under the “How to Use” section so that you can refresh your memory on how to use your Relivion MG device and app.



Figure 43: Menu Screen

5 TROUBLESHOOTING AND MAINTENANCE

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

TROUBLESHOOTING

The following section describes how to troubleshoot various issues that may arise while using the Relivion MG.

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

Table 5: Relivion MG System Troubleshooting

Problem/Symptom	Description
I initiated the treatment, heard three beeps and the treatment did not start.	This series of beeps indicates interrupted electrode contact. When the electrode is not in proper contact with your head, the status indicator light flashes red and the Relivion MG beeps. The red light will keep flashing until the electrode contact is fixed. If you are using the app, it indicates which electrodes have interrupted contact. To resolve the problem, remove the device from your head, thoroughly soak the identified electrode pads and put the device back on your head and press the back electrode covers to release moisture toward your scalp. Then, press the  button to start treatment.

Problem/Symptom	Description
	<div data-bbox="746 360 1219 842" data-label="Image"> </div> <p data-bbox="770 869 1203 898">Figure 44: Interrupted Electrode Contact</p> <p data-bbox="619 927 1342 1055">If the issue reoccurs, remove the device from your head, replace the pads, wet the pads and place the device on your head again and press the back electrode covers. Then, press the  button to start treatment.</p> <p data-bbox="619 1111 1342 1173">If the problem recurs repeatedly, remove the pads and clean the electrodes by following the cleaning procedure described in page 50.</p> <div data-bbox="831 1189 1145 1435" data-label="Image"> </div> <p data-bbox="791 1473 1182 1503">Figure 45: Front and Back Electrodes</p>
<p>The app shows Poor Electrode Contact.</p>	<p>This indicates poor electrode contact. The indication is only in the mobile app. You may continue the treatment while improving the contact by better tightening the device on your head or by pressing the back electrode covers to release moisture toward your scalp.</p>
<p>The Relivion MG device does not turn ON.</p>	<p>The battery is depleted. Charge your Relivion MG device, as described in <i>Step 1, Charging the Relivion MG</i> section on page 13.</p>
<p>The status indicator () is a steady red light.</p>	<p>Indicates a device malfunction. Contact Relivion Customer Care at +1-888-4Relivion (888-473-5484).</p>

Problem/Symptom	Description
The mobile application is unable to connect to my Relivion MG device	<p>Make sure Bluetooth is turned on in your smartphone settings.</p> <p>Make sure you correctly entered the last 3 digits of the Serial Number of your Relivion MG (the S/N label is located on the lower front side of the device, next to the nose bridge).</p> <p>Make sure your smartphone and the Relivion MG are in close enough proximity to one another (within 5 meters).</p> <p>Make sure the Relivion MG is turned ON.</p> <p>Make sure the Relivion MG is charged.</p> <p>If the issue persists, contact Relivion Customer Care.</p> <p>Note – You can use the Relivion MG device to treat your migraines even if the mobile app is not functioning.</p>

CLEANING AND MAINTENANCE

- Clean the device with a wet cloth periodically or as visibly required.
- Do not use solvents of any kind (acetone, petrolatum, etc.) on the device, except for 70% Alcohol to clean the electrodes, as described below.
- Dispose of the electrode pads at the end of each treatment. Reused pads may cause interrupted electrode contact.
- Don't leave wet electrode pads in the device after use, as it may degrade the electrode conductivity.
- When the device is not in use, make sure that the arms are not connected to one another by the magnets.

CLEANING THE RELIVION MG ELECTRODES

Over time, the device may accumulate residue on the electrodes' surface, which may lead to conductivity issues. To prevent the residue accumulation, it is recommended to clean the electrodes' surface every two months of consistent use. A periodic message in the mobile app will remind you to clean the electrodes.

To clean the electrodes, you'll need:

- Six Q-tips, one for each electrode.
- 70% Alcohol solution



Figure 46: Setup: Six Q-tips; 70% alcohol solution

Complete the following cleaning steps for each electrode:

- Pour some alcohol solution into a small container.
- Dip one end of a Q-tip in the alcohol solution.

NOTE



Keep the Q-tip soaked throughout the cleaning process.

- Gently clean the black surface of the electrode, using the soaked Q-tip, in a circular motion from the center of the electrode moving outward. Reach the external edges of the electrode, where it touches the plastic frame.
- Continue cleaning the electrode for at least 30 seconds.
- Turn the Q-tip around and use the dry end to wipe the electrode's surface. Wipe it in the same gentle, circular motion from the center to the external edges.
- Inspect the Q-tip. If you see any black residue on it, it means too much force was applied. Clean the electrodes gently.
- Inspect the electrode's surface, at the end of the cleaning steps it should look shiny.
- Repeat the cleaning steps for each of the electrodes (six), using a fresh Q-tip each time.

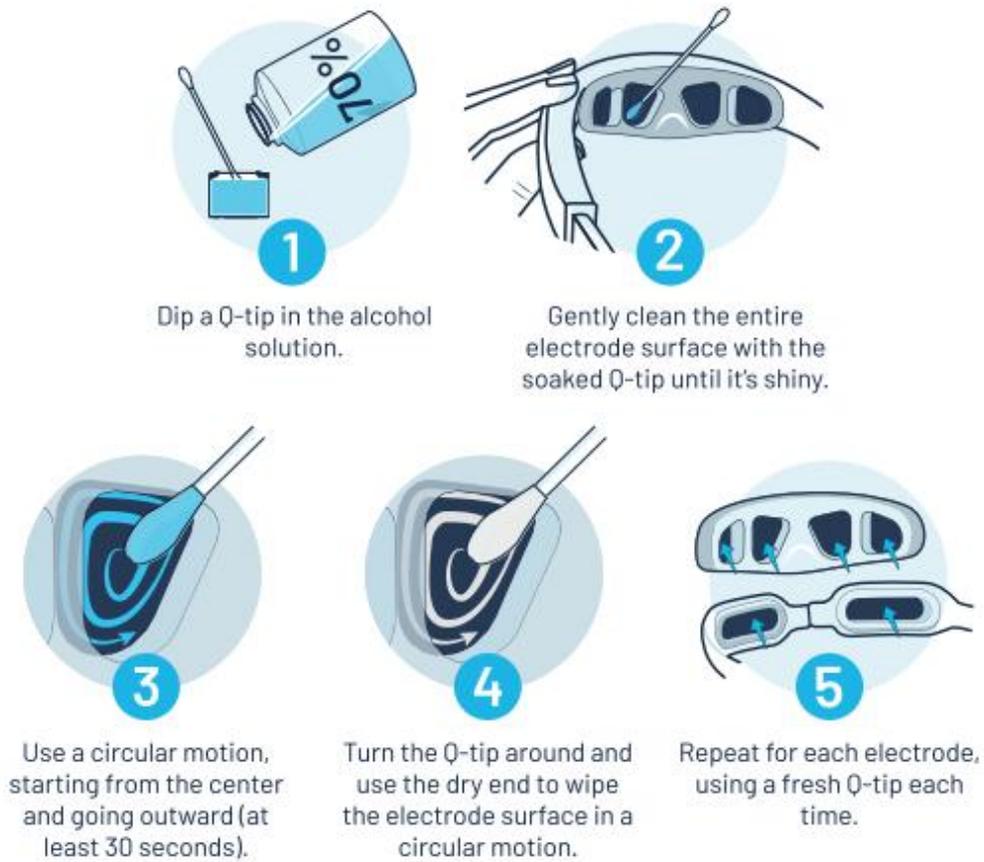


Figure 47: Electrode cleaning steps

NOTE



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

DISPOSAL

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

6

TECHINICAL SPECIFICATIONS

This chapter describes the technical specifications of the Relivion MG.

Table 6: Technical Specifications

Operating Conditions	
Temperature	+41°F to +104°F/+5°C to +40°C
Relative Humidity	15% to 90%
Atmospheric Pressure	10.1PSI to 15.3 PSI/700 hPa to 1060 hPa
IP Classification	IP54
Transport and Storage Conditions	
Temperature	14°F to +131°F/-10°C to +55°C
Relative Humidity	Less than 90% (non-condensing)
Atmospheric Pressure	10.1PSI to 15.3 PSI/700 hPa to 1060 hPa
Electrical Specifications	
Number of Stimulation Channels	3 (2 Trigeminal, 1 Occipital)
Current	Constant
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	<ul style="list-style-type: none"> • @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 (µC)	2.4 front electrodes / 4.8 back electrodes

Maximum Current Density (peak) (mA/cm ²)	0.968 front electrodes / 1.288 back electrodes
Maximum Current Density (r.m.s.) (mA/cm ²)	0.062 front electrodes / 0.082 back electrodes
Maximum Average Power Density (W/ln ²)/ (W/cm ²)	0.000077 front electrodes/0.000219 back electrodes/ 0.000012 front electrodes/0.000032 back electrodes
Maximum Rise Time	≤5 μsec
Timer	60 minutes
Power Source	
Battery Type	Rechargeable 3.7V Li-Po battery, 200 mAh
Battery Life	500 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 4.2
Security	128-bit key encryption
Device	
Number of Electrodes	6 (4 forehead electrodes and 2 occiput electrodes)
Replaceable Electrode Pads	yes, set of 6 pads per treatment
Size	Minimum Circumference (Adjusted to Smallest Head Size) – 20"/ 510mm Maximum Circumference (Adjusted to Largest Head Size) – 23½"/600mm
Dimensions	8" x 5" x 1½" / 209mm x 128mm x 39mm
Weight	0.2 lb / 90 g
Device Lifetime	
Lifetime	5 years
Software application (app)	
iOS version	12.0 or later
Android	8 and above

A ELECTROMAGNETIC COMPATIBILITY

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

Table 7: Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group1 Class B	The Relivion MG 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 Relivion MG 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 8: 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	1 kV for mains power ports	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	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	50/60Hz, 1 A/m	Not applicable	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 Vrms 150kHz to 80kHz 10 V/m from 80 MHz to 2.7 GHz	3 Vrms 150kHz to 80kHz 10 V/m from 80 MHz to 2.7 GHz	<p>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.</p> <p>Recommended separation distance</p> <p>$d = 1.17\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol –</p> 

Table 9: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Relivion MG

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.17\sqrt{p}$	80 MHz to 800 MHz $d = 1.2\sqrt{p}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.37	0.38	0.73
1	1.17	1.2	2.3
10	3.7	3.8	7.3
100	11.7	12	23

ELECTROMAGNETIC COMPATIBILITY WARNINGS

The Relivion MG 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 MG 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 MG 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: 2A09M-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 0.1" 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.



**Do you have any questions?
We're here to help.**

Contact our customer care team at +1-888-4Relivion (888-473-5484)

Or visit our website at www.Relivion.com

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