Relivion® MG

PMI
PHYSICIAN INTERFACE USER MANUAL

For Physicians and Clinical Teams

IMPORTANT NOTICE

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RX ONLY

℞ Only

Federal (USA) law restricts the Relivion® MG 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.

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.

USER MANUAL PURPOSE

The Relivion MG PMI is an optional Interface that enables physicians to remotely follow up on their patients' migraine headache status and their self-administered treatments that were performed using the Relivion MG device.

For more information about the Relivion MG device and the patients using the Relivion MG device and the Relivion MG mobile app, you may refer to the Relivion MG Patient User Manual.

This user manual describes the web-based Relivion MG Patient Management Interface (PMI) to be used by physicians and their clinical teams.

This user manual provides the necessary instructions for operating the optional Relivion MG PMI's Physician Interface.

IMPORTANT!

To ensure proper usage, you should review this entire user manual carefully before using the PMI.

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

Table of Contents

1 INTRODUCING RELIVION® MG

The following describes how physician and clinical teams can use the Relivion MG web-based Patient Management Interface (PMI) to remotely follow up on their patients' migraine headache status and self-administered Relivion MG treatments.

RELIVION MG PMI

The Relivion MG is a non-invasive medical device that transfers mild electrical pulses to branches of the Trigeminal (Supraorbital and Supratrochlear) and Occipital nerves in order to treat migraine headaches. Patients can use the Relivion MG device to self-administer treatments.

The Relivion MG PMI is an optional Interface for the Relivion MG device.

The Relivion MG PMI consists of the following –

- Physician Interface (web-based interface)
- Relivion MG Application (patient mobile app)

A complete description of how the Relivion MG mobile app operates is provided in the *Relivion MG Patient User Manual*.

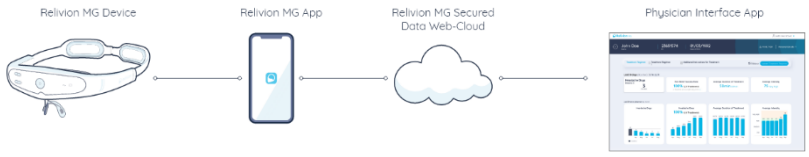

Figure 1: Relivion MG PMI Communication Flow

NOTE

Keep your web security applications (e.g., antivirus, firewall) up-to-date.

RELIVION® MG PHYSICIAN INTERFACE

A physician can prescribe the Relivion MG device to a patient in order to treat their migraine headaches as per the device indications for use. The patient can then acquire the Relivion MG device and download the Relivion MG mobile app from the Apple / Google store to their smartphone. The Relivion MG device communicates with the Relivion MG mobile app on the patient's smartphone via a Bluetooth link. The mobile app automatically reports details on treatments performed using the Relivion MG device, such as treatment schedule, intensity and duration, to the patient's physician. The app also encourages the patient to answer guided questions on the mobile app about their migraines and symptoms before and two hours after treatment.

Even though the Relivion MG device can be used without the optional Relivion MG mobile app, it is highly recommended to use it because of its benefits, as described below.

The Relivion MG device communicates with the Relivion MG mobile app on the patient's smartphone via a Bluetooth link.

The Relivion MG mobile app automatically transfers data via a secured cloud web-based Physician Interface in order to enable the physician to review the data collected by the Relivion MG mobile app from the Relivion MG device, as well as various other data and insights. This includes information about the treatments self-administered by the patient (including schedule, intensity and duration), as well as information entered by the patient describing their migraine, the treatment and its aftereffects.

If you are a physician, it is highly recommended to encourage your patients to use the optional Relivion MG mobile app in order to enable the following benefits –

- You can remotely track the patient's self-administered Relivion MG treatments, such as the treatments' schedule, frequency, intensity level and duration.
- You can remotely review a data insight regarding the patient's treatment and migraine headache status.
- You can remotely change your recommendation for a patient's self-administered treatments at any time. A new recommendation will automatically appear on the patient's Relivion MG mobile app's home screen.
- The patient sees the migraine treatment regimen that you recommend on their Relivion MG mobile app home screen.
- The patient can describe their migraines, the treatment and its aftereffects by answering guided questions on the mobile app that provide you with data regarding their migraine headache status.
- The patient can see treatment instructions, as well as the Relivion MG device's connectivity and battery status.

WORKFLOW – RELIVION® MG PHYSICIAN INTERFACE

The following is the workflow for using the Relivion MG PMI's Physician Interface –

- OPENING THE RELIVION MG PHYSICIAN INTERFACE
- RECOMMENDING RELIVION MG TO A PATIENT
- REVIEWING A PATIENT'S DATA

OPENING THE RELIVION® MG PHYSICIAN INTERFACE

In order to start using the Relivion MG Physician Interface, contact Relivion Customer Care at support@relivion-medical.com. The Neurolief Customer Care team will create an account for the clinic as well as a user account based on your profession (physician or clinical team member). You will then receive an email to validate your account. Follow the instructions in the email to verify your username and password.

To open the Relivion MG Physician Interface –

1 Browse to the Relivion MG Patient Management Interface (PMI) in a standard web browser at the following link: pmi.relivion-medical.com. We recommend you use Google Chrome or Safari.

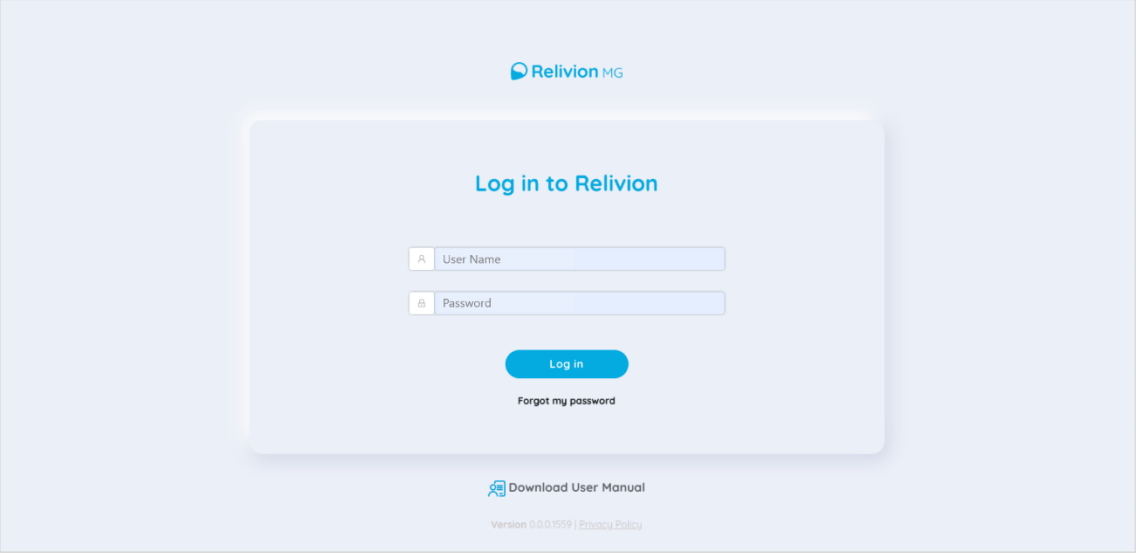

Figure 2: Logging into the Relivion MG Physician Interface

2 Enter the username and password and click the **Log in** button.

Under the **All Patients** tab, the Relivion® MG PMI lists all the Relivion MG patients associated with your clinic. If you are a physician, you can see the Relivion MG patients that are assigned to you by going to **My Patients** tab.

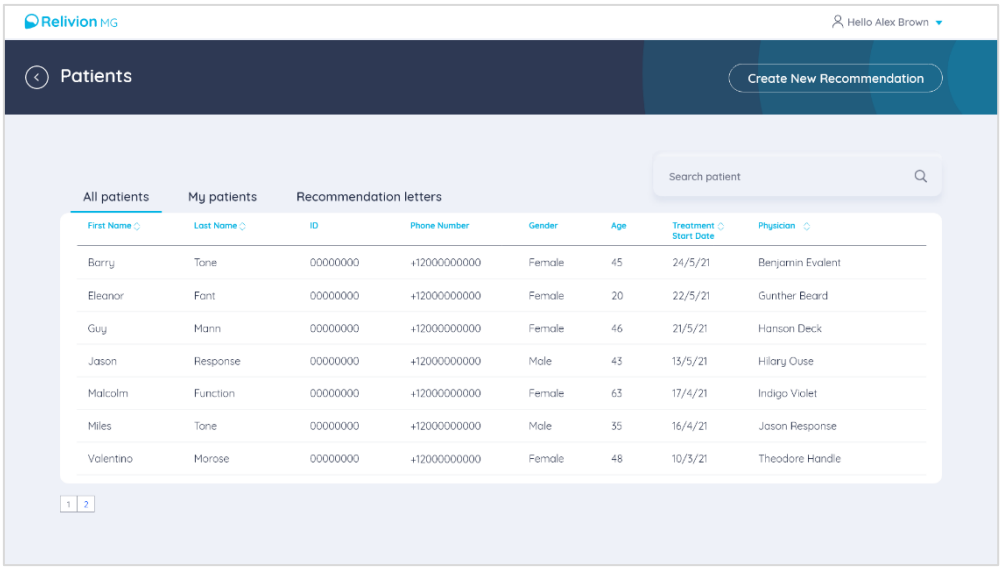

Figure 3: Your Clinic's Relivion MG Patient List

NOTE

Selecting a specific patient enables you to see more details about that patient, their headache status and the data of their treatments, as described on page 13.

RECOMMENDING RELIVION® MG TO A PATIENT

The PMI allows the physician to issue a recommendation letter. The following describes how to issue a recommendation for a Relivion MG device to a patient using the Relivion MG Physician Interface.

To recommend a Relivion MG device to a new patient –

1 Click the **Create New Recommendation** button at the top right of the page, as shown above in Figure 3. The following displays –

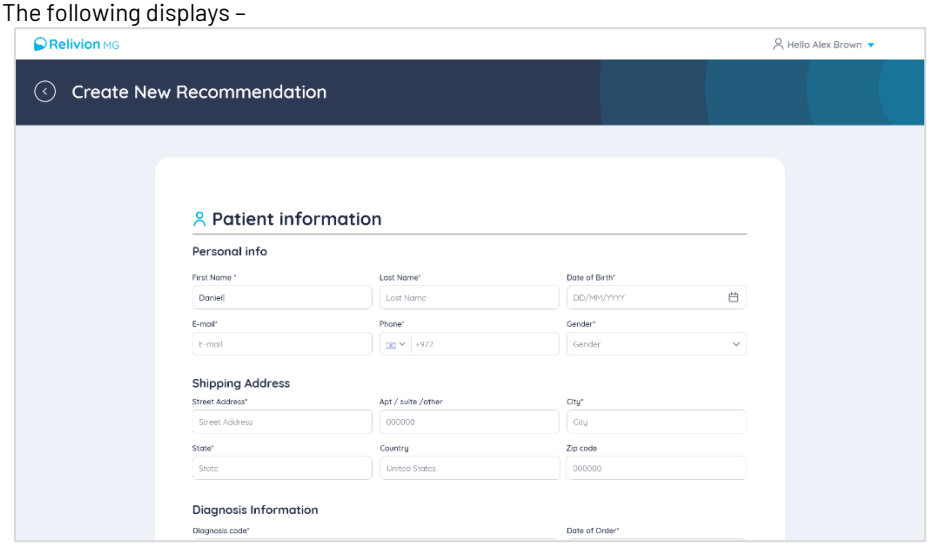

Figure 4: Creating a Relivion MG Recommendation for a New Patient

If a physician is completing the recommendation, the physician's name is automatically entered in the **Physician Details** section. If this section is completed by a clinical team member, the associated physician name should be selected from the clinic's physicians list. Once completed, the recommendation must be signed by the associated physician.

2 Fill in the **Patient's Personal Info** and **Shipping Address** in the **Patient Info** section**.** Entering their cell phone number is mandatory, because this will be used to associate the patient with your clinic after the patient registers with the Relivion MG mobile app.

3 In the **Diagnosis Information** section, select a diagnosis code from the Diagnosis Codes list.

4 In the **Training** section, select the type of training that the patient is going to undertake.

5 In the **Treatment Recommendation** section add the physician's treatment recommendations:

- In the **Treatment Duration** field, specify how many minutes the patient should self-administer each treatment for. The patient will be notified by the app once the treatment reaches the recommended time.

NOTE

The treatment session automatically ends after 60 minutes. The Relivion® MG beeps (nine times), the status indicator light stops blinking and the device turns off.

The treatment intensity is on a scale of 1-100. The instruction to the patient is to continue to increase the intensity up to the highest comfortable level. The stimulation should be strong but not painful.

- In the **Estimated Length of Needs** field, specify the period the physician recommends the patient use the Relivion MG device for – 12 months, 24 months, 36 months, 99-Lifetime, or Other.
- In the **Additional Instructions for Treatment** field, enter a free text description of the physician's instructions to the patient.

  These instructions will appear in the homepage of the patient's Relivion MG mobile app, after you complete this recommendation.

6 Click the **Save** button to generate and display a PDF file of this recommendation to acquire a Relivion MG device. A unique code (ID) is assigned to each recommendation. You can then print and sign it in order to use it as a recommendation for the patient.

This recommendation now appears in the **Recommendation Letters** tab, as shown below. This tab lists all the patients who have been issued a recommendation letter by your clinic.

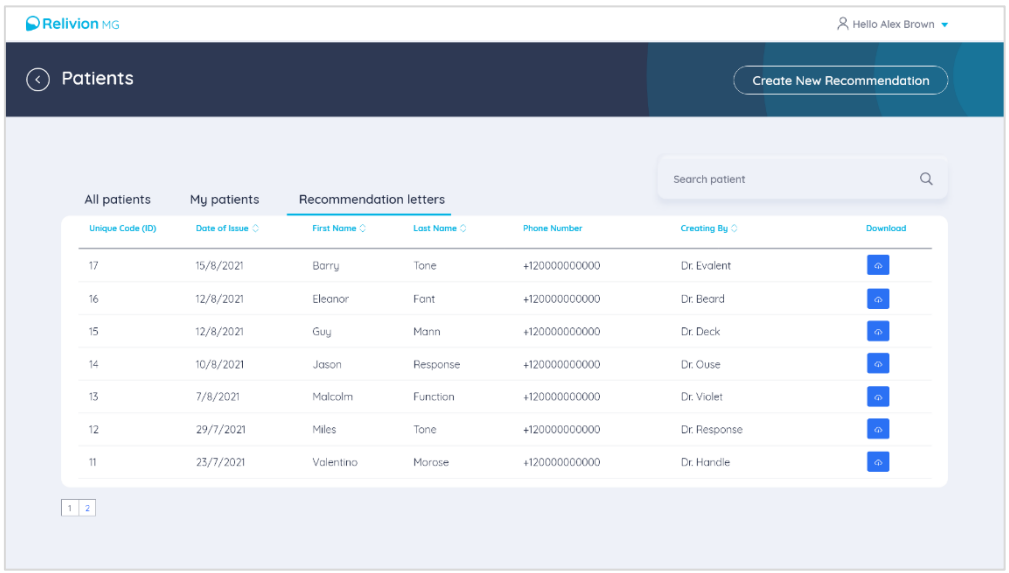

Figure 5: Recommendation Letters List

7 The patient will automatically be added to the clinic's Patient List and will be assigned to their associated physician after the following has been completed –

- The patient has acquired a Relivion MG device.
- The patient has downloaded the Relivion MG mobile app.
- The patient has completed the Relivion MG mobile app's sign-up process, which involves filling in their phone number.
- The patient has been contacted by a Neurolief Customer Care representative who linked the patient to your clinic.

After all these stages have been completed, the patient appears in the **All Patients** tab as well as in the associated physician's **My Patients** tab, as shown below –

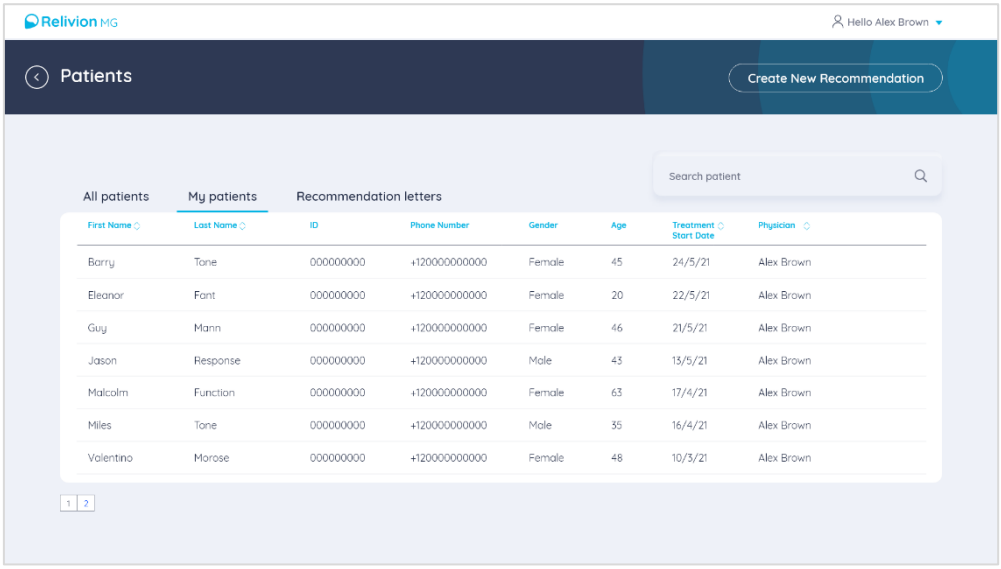

Figure 6: Your Clinic's Relivion MG Patient List

REVIEWING A PATIENT'S DATA

The Relivion® MG mobile app transfers data about patients' treatments performed using the Relivion device. Additionally, the Relivion MG mobile app collects data on the migraine status from patients by guiding them through various questions. This data is transferred to the Relivion MG PMI web-based Physician Interface to be reviewed by the physician.

The Relivion MG Physician Interface displays a variety of data and insights regarding the self-administered treatments performed by each patient, as well as the data that they reported about the treatment, their migraine and the aftereffects.

To review a patient's data –

1 Find the patient in the patients list by scrolling through the list or typing their name in the **Search Patient** field. For example, as shown below –

Figure 7: Search for a patient

2 Click on the patient's row to display their details, as shown below –

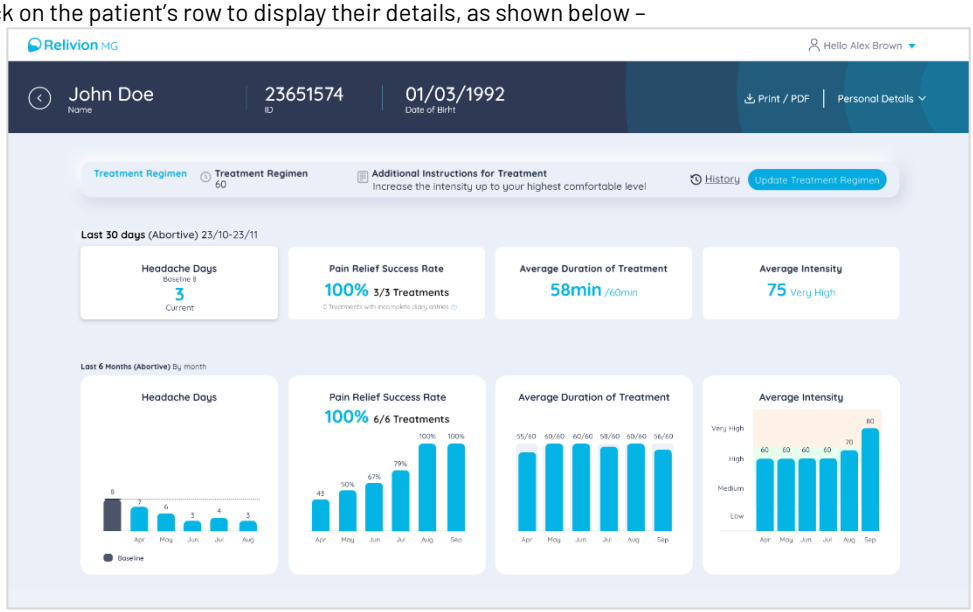

Figure 8: Patient's Details

PATIENT DETAILS

The top part of this page shows the patient details, as well as the **Treatment Regimen** that the physician recommended. You can click on the **Personal Details** option on the right to expand the **Patient Details** view, as shown above.

You can modify the patient's details by clicking the **Edit Patient's Personal Details** button on the right.

PRINT / PDF

You can print or export to PDF the patient treatment summary by clicking the Print / PDF button. The summary includes the patient's personal details, the current treatment regimen and all the data that is shown in the patient's page.

TREATMENT REGIMEN

The **Treatment Regimen** section of this page enables the physician to view and update the recommendation for the patient's treatment regimen if desired. A clinical team member can view the current and previous regimens but cannot update them.

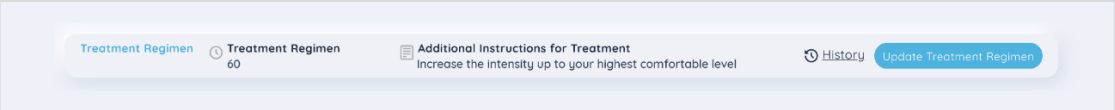

Figure 9: Treatment Regimen

The Relivion MG specifications are provided in Table 1: *Relivion® MG Device Technical Specifications*.

The Relivion® MG treatment has a maximum treatment duration of 60 minutes. Patients can only adjust the treatment duration and stimulation level.

1 Treatment duration can be adjusted within the range of up to 60 minutes.

2 Intensity level can be adjusted on a scale of 1-100.

The physician interface default regimen is for a 40-minute treatment session.

- The device automatically turns off after 60 minutes. The physician's current recommendation is displayed on the left.
- For physicians only: To modify your recommendation, click the **Edit Treatment Regimen** button on the right. After you save the new recommendation, the patient will be notified and it will appear on the main screen of the patient's Relivion MG mobile app.
- To display the history of the patient's regimen updates, click the **History** option on the right.

LAST 30 DAYS

This section shows data about the patient from the last 30 days –

Figure 10: Last 30 Days Data

- **Date Range –** Specifies date range covered by the data – the 30-day period leading up to the current date.
- **Number of Treatments with Incomplete Diary Entry –** Specifies the quantity of self-administered treatments that the patient performed (during the previous 30 days) without answering the guided questions before and/or after treatment.
- **Headache Days –** Specifies the total number of reported migraine headache days during the previous 30 days. The total number of headache days equals the sum of headache days treated using the Relivion® MG device plus the reported headache days that were not treated by the device.

  The **Baseline** value specifies the number of headache days the patient reported to have during registration. If the patient reported an incorrect baseline value during the onboarding process, the physician or clinical team member can correct this by editing the patient's details.
- **Pain Relief Success Rate –** On the Relivion MG mobile app, patients are requested to specify their level of pain on a scale (no pain, mild, moderate or severe) before and after treatment. If the patient specified an improvement in their pain level of at least one level it is considered a success. The **Pain Relief Success Rate** field shows the percentage of pain level improvement for the patient during the previous 30 days. The example above shows that **3/3** treatments were successful (meaning **100%**).
  - Note –**Treatments with incomplete diary entries** are not included in the statistics.
- **Average Duration of Treatment –** The bold number specifies the actual average treatment time (in minutes) for treatments administered by the patient during the 30-day period. In this example, it is **58** minutes. The number next to it in a smaller font size (in this example, 60 minutes), indicates the most recent treatment recommendation. This average does not include the time of the **Treatments with incomplete diary entries** (described above).
- **Average Intensity –** The number specifies the average intensity of treatments that the patient administered during the 30 days. This average does not include the intensity of the **Treatments with incomplete diary entries** (described above). Underneath there is a legend describing the patient's treatments' categorical intensity on a scale of low (0-20), medium (21-50), high (51-70) and very high (71-100).

LAST 6 MONTHS

This section shows the same type of information as described above for the last 30 days, except that this information is for the last six months of abortive treatments presented per month.

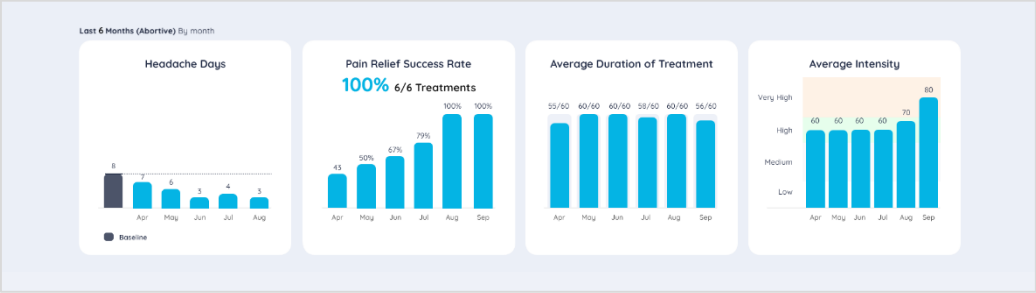

Figure 11: Last 6 Months, Data from Abortive Treatments

The explanation below describes how it differs from the 'Last 30 days' description above –

- **Headache Days** – Specifies the number of days that the patient had a headache in each month of the last six months.

  The horizontal line and the furthest left column (in gray) represent the **Baseline** value (the number of headache days the patient reported to have during registration).
- **Pain Relief Success Rate** – Specifies the success rate of treatments in each month of the last six months.
- **Average Duration of Treatment** – Specifies the monthly average number of minutes that the patient administered treatment during the last six months. The larger bright rectangle indicates the most recent recommendation for treatment.
- **Average Intensity** – Specifies the monthly average intensity of treatments that the patient administered during the last six months on a scale of low (0-20), medium (21-50), high (51-70) and very high (71-100).

LAST 6 MONTHS (ALL TREATMENTS)

Additionally, the following information shows the total use of the Relivion® MG device by the patient during the last six months, per month.

Figure 12: Last 6 Months, data of all treatments

- **Total Treatment Days** – Specifies the number of days that the patient used the Relivion MG device in each month of the last six months.
- **Number of treatments according to time of day** - Specifies the total number of treatments completed by the patient in a month during the Morning (4am-12pm), Afternoon (12pm-6pm) and Night (6pm-4am).
- **Average Total Treatment Time** - Specifies the monthly average number of minutes that the patient administered treatment in each month of the last six months.
- **Average Total Treatment Intensity** - Specifies the monthly average intensity of treatments that the patient administered during the last six months on a scale of low (0-20), medium (21-50), high (51-70) and very high (71-100).

RELIVION® MG PHYSICIAN INTERFACE INSIGHTS

The Physician Interface displays insights based on the data collected by the Relivion MG mobile application about a patient. Such as -

The patient's most common migraine day, the patient's most common triggers, the patient's most common pain areas.

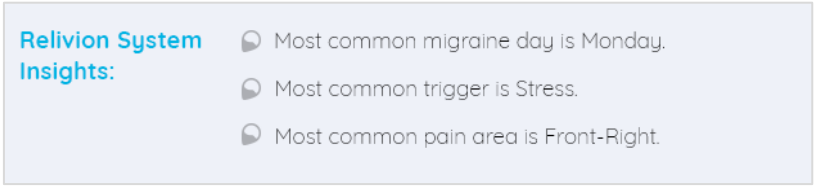

Figure 13: Insights

TREATMENT CALENDAR

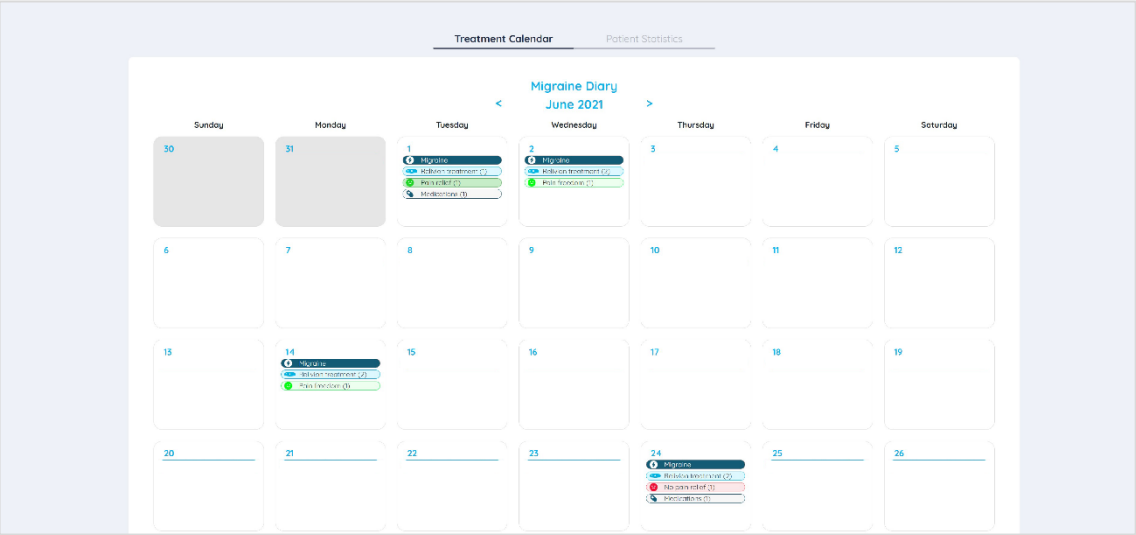

Figure 14: Treatment Calendar

Provides a calendar view of the events of each calendar day, such as –

Migraine	Indicates any migraine recorded that day (manual report or a treatment)
Relivion Treatment (#)	Total number of treatments that were administered that day
Pain Freedom (#)	Total number of treatments that day that were reported as No Pain after treatment
Pain Relief (#)	Total number of treatments that day after which a relief in pain level was reported, excluding No Pain
No Pain Relief(#)	Total number of treatments that day after which no relief was reported
Unknown Result (#)	Total number of treatments that day with missing details regarding the pain level before or after treatment
Medications (#)	Number of medications taken that day

PATIENT STATISTICS

This area shows the following data as reported by the patient using the Relivion® MG mobile app -

- **Medication Days** - Specifies the quantity of days on which the patient reported taking medication (i.e., painkillers or antiemetics) in each month of the last six months (regardless as to whether they performed a treatment with the Relivion MG device).
- **Migraine Severity -** For each month, the number of migraine attacks categorized by their maximal pain level: Mild, Moderate, Severe.
- **Triggers** – Specifies the percentage of migraine attacks for which the patient reported a specific trigger as the cause for their migraine.
- **Pain Area(s)** – Displays a heatmap showing the patient's most common pain areas.

Figure 15: Patient Statistics

2 TECHNICAL SPECIFICATIONS

This chapter describes the technical specifications of the Relivion MG device and the Relivion MG PMI.

Table 1: Relivion® MG Device 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	• **@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/In^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	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
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	0.12 lb / 90 g
Device Lifetime	
Lifetime	5 years
Software application (mobile app, for patients)	
iOS version	12.0 or later
Android	8 and above

Table 2: Relivion®MG PMI Physician Interface Technical Specifications

Operating System	Windows, Mac, Linux
Web Browser	Chrome, Safari
RAM Software	500 MG of free RAM
Display	1920 x 1080 minimum resolution

A SAFETY INFORMATION

The following section provides important safety information that must be observed while patients use 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 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 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 1 above).
- 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.
- Use this device only with Neurolief electrode pads and the Neurolief power supply and charging cable 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 the 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 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 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 sleep disorders.
- Sedative effect during or after treatment.
- Dizziness during or after treatment.
- Headache/migraine.

B RELIVION® MG SYSTEM SYMBOLS

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

Table 3: System Symbols

Symbol	Description
	Consult instructions for use
	Class II equipment
	Manufacturer
	Manufacturing date
	Authorized representative in the European Community / European Union
	European Conformity
	European Conformity (Notified Body 2797)
	Caution. See Instructions for Use
	Type BF applied part (front and back electrodes)
	Serial number
	Catalog number

Symbol	Description
	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 use
	Keep away from sunlight
	Do not use if package is damaged
	Atmosphere pressure limitation
	Humidity limitation
	Fragile, handle with care
	Medical device
	Caution
	Home Use
	USB DC wiring

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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