Proliv™ Rx

User Manual

Neurolief
Brain Innovation

IMPORTANT NOTICE

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PRESCRIPTION ONLY

℞ Only

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

Patient's Health Care Provider (psychiatrist or physician) will review the patient's medical and depression history to help determine if the Neurolief Proliv™Rx Therapy is appropriate.

IMPORTANT

This user manual offers comprehensive and detailed instructions. The Proliv™Rx App provides a condensed version of these instructions, which may exclude certain details. If you ever have any doubts or uncertainties, we recommend referring to this user manual for guidance.

INDICATIONS FOR USE

The Proliv™Rx System provides focal external Combined Occipital and Trigeminal Afferent Stimulation (eCOT-AS) treatment. It is intended as an adjunctive treatment for Major Depressive Disorder (MDD) in adults who failed to achieve satisfactory improvement from at least one previous antidepressant medication, for patients use at home or in clinic.

The device is a prescription only device.

USER MANUAL PURPOSE

This user manual provides the necessary instructions for safely operating the Proliv™Rx system in accordance with its function and intended use. It covers:

- Explanation of controls and indicators.
- Operation sequence.
- Maintenance and troubleshooting procedures.

SYSTEM SYMBOLS

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

Symbol	Description
	Consult instruction for use
	Class II equipment
	Prescription only Federal law restricts this device to sale by or on the order of a physician/psychiatrist
	Manufacturer
	Manufacturing date and country
	Type BF Applied part (front and back electrodes)

Symbol	Description
	Serial number
	Catalog number
	Temperature limit
	Keep dry
	IP rating. Indicates the degree of protection. The Proliv™Rx 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
	Home use
	USB DC wiring

Symbol	Description
	Caution
	Consult electronic instructions for use
	UDI
	Single patient multiple use
	MR unsafe

Table 1: System symbols

CONVENTIONS USED IN THIS USER MANUAL

NOTE 

Notes provide additional important information.

TIP 

Tips indicate helpful information for using the Proliv™Rx .

WARNING! 

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

SAFETY INFORMATION

The following section details side effects observed during clinical trials of the Proliv™Rx system. It also includes warnings and precautions for Proliv™Rx system therapy; these should be reviewed and discussed with your physician or psychiatrist to determine what, if any, precautions should be taken during your treatment with the Proliv™Rx system.

The safety of the Proliv™Rx system was demonstrated in the aforementioned clinical trials.

In the MOOD trial, during the double-blind phase of the study, 74 adverse events were reported by 39 participants, 19 participants in the active arm (incidence: 30.16%, 19/63), and 20 participants in the sham arm (incidence: 32.79% ,20/61). Most adverse events reported by the active arm participants were mild (35 events), some moderate (9 events), and only 1 severe event.

In the same study phase, 31 events (out of 74) were considered related to the study device. Of these, 25 were in the active arm (20 mild and 5 moderate). Approximately 27% of the adverse events were headaches or migraines.

In the active arm, 15.87% (10/63) of study participants reported events classified as related to the study device, 9.52% of them Mild (6/63), and 6.35% Moderate (4/63). All but two events were successfully resolved. The remaining two cases of scalp itching and intermittent headaches/body aches were graded as mild and did not require follow-up.

In general, incidence of adverse events reported in the open label phase were similar to those reported in the double-blind phase by the active treatment group.

Finally, a single serious event of worsening depression symptoms was reported during the open label phase of the study.

No deaths or serious unanticipated device- related adverse events were reported among the participants who participated in the clinical study.

Adherence to the instructions for use is important to minimize the risk of adverse events.

Contraindications

The Proliv Rx System is contraindicated for use in patients with:

- A history of intracranial surgery.
- Recent traumatic brain injury (TBI) (less than three months).
- A metal implant or shrapnel in their head, except for dental implants.
- An implanted neurostimulator or electronic device in your head such as a cochlear implant or brain pacemaker.
- A cardiac pacemaker or an implanted or wearable defibrillator.
- Skin lesions, scars, or inflammation at the region of the stimulating electrodes.

Warnings

- The Proliv™Rx device **does not** represent a **substitution for your medication**.
- Apply treatment only to intact, clean, healthy skin.
- Do not use the device on any other areas **apart from the head**.

- Keep the device **out of reach of children**. Small parts, such as the disposable pads, may be a choking hazard for small children.
- 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 in the **presence of electronic monitoring equipment** that may not operate properly when the electrical stimulation device is in use.
- Do not use a device that shows signs of **mechanical damage** or loose parts.
- Do not modify this device or its accessories.
- Do not connect the Proliv™Rx device with **other equipment**.
- Use this device only with the **supplied charger**.
- Do not use **any accessories, electrode pads,** detachable parts, and materials that are not provided or recommended by Neurolief.
- Patients with active **suicidal** intent or plan should follow physician's/psychiatrist's instructions.
- If depression symptoms worsen, contact your physician.
- This device should only be used by patients whose clinical course is supervised by a medical provider.

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.
- 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 the device in the **bath or shower**.
- If the device **does not function** as described in this manual, stop using it and contact customer support.
- The Proliv™Rx device is designed for use by and on a single adult person. For hygiene reasons, the **device should not be shared**.
- Keep the device out of reach of pets.
- It is recommended that your mobile device be protected by a password (or other security mechanisms) to prevent unauthorized access to the Proliv™Rx device.

Adverse reactions

Proliv™Rx, along with similar antidepressant treatments, have the potential for certain adverse reactions, which are detailed below. Adverse reactions reported with Proliv™Rx have been demonstrated in clinical trials to be mild to moderate and most are fully reversible upon cessation of device use. If adverse reactions persist, stop using the device and consult your physician/psychiatrist.

- Unpleasant sensation during treatment (e.g., pressure sensation at the stimulation position).

- A sensation of scalp numbness (paresthesia) during and after treatment.
- Persistent tingling, stinging, itching, or burning sensation after the treatment ends.
- Pain or discomfort.
- Skin reaction (e.g., irritation, lesion, or burn) beneath the electrodes. In such cases, 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
- Depression-related adverse events:
  - Mania.
  - Suicidal ideation
  - Worsening depression

Worsening of Depression or ineffective treatment

As with any antidepressant treatment, there is a risk of your depression becoming worse before you begin to feel an improvement. Proliv™Rx Therapy may require up to 8 weeks of daily treatments before symptom improvement occurs. Make sure to discuss with your psychiatrist/physician the Proliv™Rx recommended treatment schedule. Contact your physician/psychiatrist if symptoms do not improve or if they get worse. Your physician/psychiatrist will monitor you for worsening depressive symptoms or signs or symptoms of suicidal behavior during the course of the treatment. Your family and caregivers should also be aware that if such behavioral changes appear, they should inform your physician/psychiatrist who will determine whether Proliv™Rx treatment should be discontinued and, if so, what other treatment options are available.

In the event of a medical emergency, please consult your healthcare provider on the appropriate course of action.

For more resources related to the treatment of psychiatric conditions, including recommendations for the public provided by professional healthcare organizations, please explore the American Psychological Association website (https://www.apa.org) or other relevant associations' websites.

NOTE Please report to Neurolief Ltd. and the regulatory authority of your country of any serious incident that you encounter in relation to the Proliv™Rx device.

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1 Introducing the Proliv™Rx

This chapter introduces the Proliv™Rx device and describes its components and contents.

NOTE!

To ensure safe and proper usage, please review this entire user manual carefully before using the Proliv™Rx device.

Contact Proliv™Rx Customer Care at support@prolivrx.com or visit the Neurolief website at www.Neurolief.com if you have any questions.

1.1 WHAT IS THE NEUROLIEF PROLIV™RX?

The Proliv™Rx is a non-invasive head-mounted medical device. It is designed to non-invasively trigger activation of relevant nerve branches in the head by externally applying mild electrical pulses through electrodes placed on the forehead and occiput. These activated nerves serve as conductors of the signal to the brainstem and to relevant brain regions which participate in the regulation of mood, to treat Major Depressive Disorder (MDD).

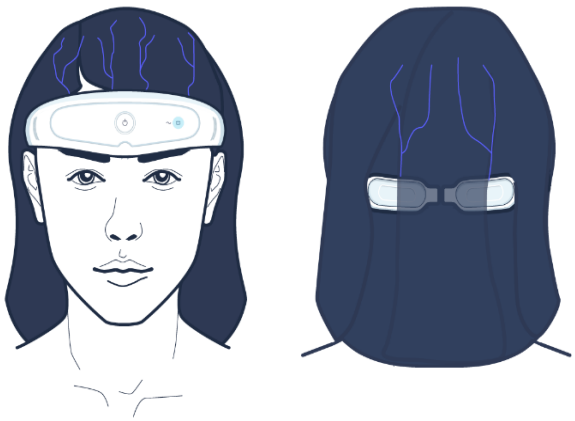


Figure 1: Proliv™Rx device and the associated nerve branches

The Proliv™Rx device consists of a headset with integrated electrodes, designed to trigger activation of relevant nerves. The on-board electronic circuit is adapted to deliver stimulation patterns to enhance proper nerve activation. The Proliv™Rx 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 trigger branches of the Trigeminal nerve and the two electrodes at the back of the head trigger the greater Occipital nerve.

The Proliv™Rx device incorporates an on-board user interface that enables the user to turn the device on and/or off. It provides visual and auditory indications to indicate when the device is on/off and battery status.

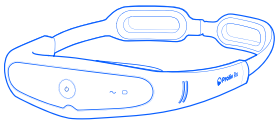
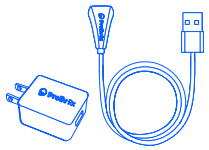
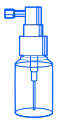
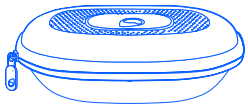
The Proliv™Rx device communicates via Bluetooth link with the Proliv™Rx dedicated mobile application on the user's smartphone. The Proliv™Rx App is required in order to operate and control the Proliv™Rx device. Therefore, the Proliv™Rx App should be downloaded from the App Store/Google Play store before initial use of the Proliv™Rx device. Once the device and mobile app are paired, you can initiate or end treatment sessions and adjust the device's intensity directly from the mobile app. Device status, indications, and alerts will be displayed on the mobile app's screen.

NOTE The Proliv™Rx device provides sufficient Quality of Service (QoS) across its BLE internal network for its intended use.

NOTE The Proliv™Rx BLE internal network utilizes encryption of the data that is being transferred.

1.2 THE PROLIV™RX KIT

The Proliv™Rx kit includes the components presented in Table 2.

Contents of Proliv™Rx kit	
Proliv™Rx Device	
Proliv™Rx Charger	
Proliv™Rx Electrode Pads (six units)	
Spray Bottle (to wet electrode pads with water)	
Proliv™Rx Quick Guide	
Proliv™Rx Carrying Case	

Contents of Proliv™Rx kit	
Proliv™Rx App	

Table 2: Contents of Proliv™Rx kit

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

1.3 THE PROLIV™RX DEVICE

The Proliv™Rx device is designed to be comfortably worn on the head during treatment. It features six electrodes – four in the front of the device (forehead) and two in the back (occiput). It includes two flexible arms that go under the hair while the device is worn. The on/off button and light indicators are positioned on the front part of the device. A size adjustment mechanism is located on both sides of the device.

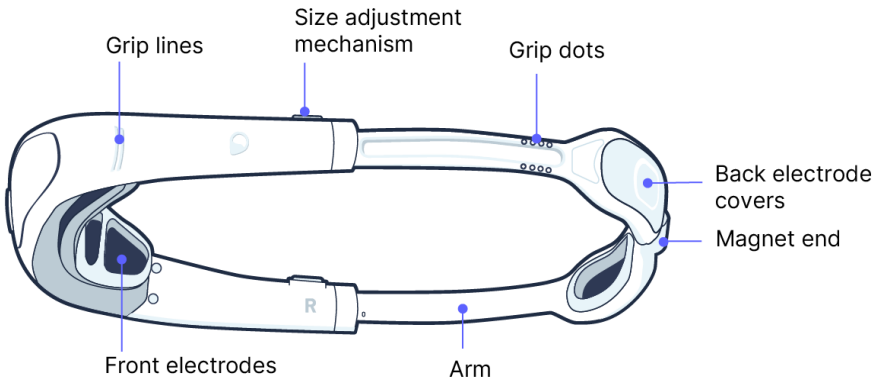


Figure 2: Proliv™Rx device – side view

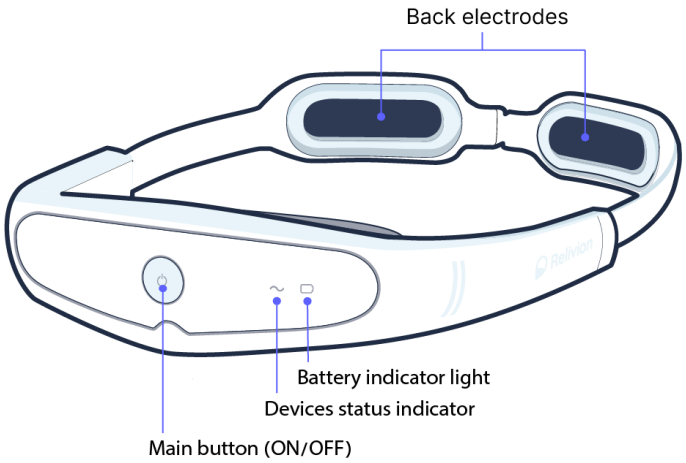


Figure 3: Proliv™Rx device front view

Indicator Light	Meaning
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.
Steady Red	Device malfunction.
Flashing Red	Poor electrode contact during treatment.
Steady Yellow	Fully charged and connected to the charger
Flashing Yellow	Battery depleted/charging

Table 3: Proliv™Rx device status and battery indications

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

Sound	Meaning
Short beep	This sound is heard when the device turns ON.
Three beeps	This sound is heard when there is a poor electrode contact during treatment.
Two beeps	This sound is heard when the device turns OFF.
Short beep	This sound is heard when the treatment automatically ends after 40 minutes.

Table 4: Proliv™Rx sound indications

NOTE

The Proliv™Rx device does not store any sensitive user/patient data.

1.4 THE PROLIV™RX MOBILE APP

The Proliv™Rx App is essential for using the product.

1 It features tutorials and troubleshooting tips to ensure the device is worn correctly.

2 It serves as a control interface for the Proliv™Rx device.

3 It offers a biweekly self-assessment questionnaire.

4 It provides history and statistics of treatment and self-assessment questionnaires that may be shared with your physician/psychiatrist.

The Proliv™Rx App includes two consecutive treatment programs designed to support your initial adjustment to the treatment and your subsequent treatment program. Your physician/psychiatrist may prescribe a treatment program aligned to your medical condition and outline it in your prescription.

The following treatment programs are available:

1 **Embark** program: Designed for new patients, this introductory program helps familiarize you with the product, daily treatment routine, and treatment sensation. This program is assigned automatically in the first week of product use. It contains two daily sessions with a gradually increased session duration and intensity level. By the end of this program, you should reach a regular session duration and attain your highest comfortable intensity level.

2 **Progress** program: This program will be automatically assigned after you complete the **Embark** program. It consists of two daily treatment sessions, each lasting 40 minutes. During this program, you should aim for your sessions to be conducted at your highest comfortable level of intensity.

2 Getting Ready

2.1 PRELIMINARY STEPS

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

1 Charge the device. It takes up to four hours to fully charge the battery. A fully charged battery is sufficient for approximately five hours of treatment. Connect the magnetic connector of the charging cable to the charging port on the Proliv™Rx device. The charging port is located at the bottom of the Proliv™Rx device.

WARNING! Only use the power supply and charging cable supplied with the Proliv™Rx device.

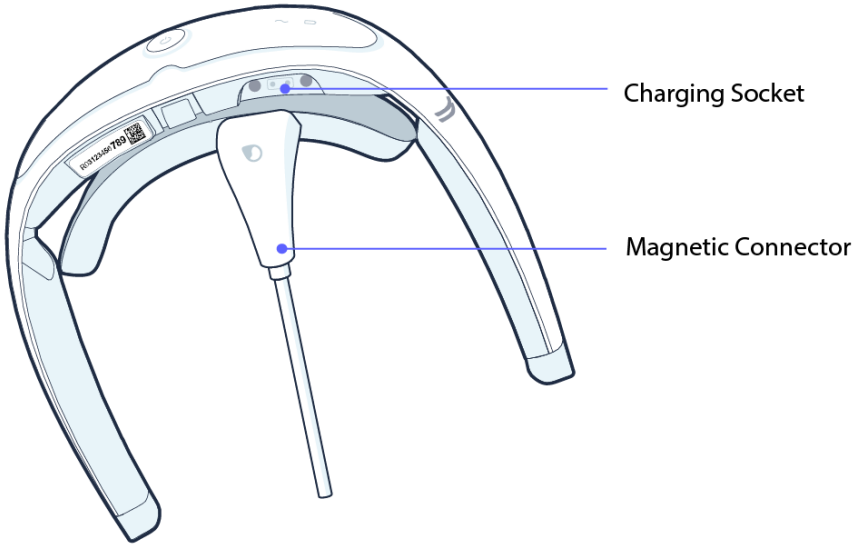


Figure 4: Proliv™Rx magnetic connector and charging port

NOTE Check the charging port and cable are not wet before charging the Proliv™Rx device.

NOTE It is not possible to use the Proliv™Rx while it is connected to the charger.

2 Download the Proliv™Rx App to your smartphone from App Store or Google Play. The Proliv™Rx App is compatible with smartphones running either Apple iOS15

and above or Android 12 and above. Never try to connect the Proliv™Rx device with a mobile application other than the Neurolief-certified application available on the Apple/Google store.



Figure 5: Proliv™Rx App

3 Open the Proliv™Rx App and follow the instructions to create your new account. A verification code will be sent to you to confirm your account.

> **NOTE** The information saved within the app is securely stored in the cloud. If you re-install the Proliv™Rx App, your information will be securely re-accessed upon login. The app only stores your registration information.

4 Pair your device with the Proliv™Rx App. Turn the device ON and make sure that Bluetooth is enabled on your smartphone. Follow the instructions in the app to pair your Proliv™Rx device.

5 Watch the mandatory self on-boarding tutorials where you'll get familiarized with the Proliv™Rx device and app. You will learn how to adjust the device to fit your head and prepare for treatment. While watching the videos, follow the steps on your own device. You may use the in-app camera as a mirror while placing the Proliv™Rx device on your head to ensure proper placement.

> **NOTE** The tutorials are always available for you on the "More" screen within the app.

6 Upon watching all the tutorials and adjusting the Proliv™Rx device to fit your head, tap on "Let's get started" to go to the treatment homepage and start your first treatment session.

2.2 ADJUSTING THE PROLIV™RX DEVICE TO FIT YOUR HEAD

The arms of your Proliv™Rx device are adjustable. You can extend them by pressing the grey button and pulling the arms. The dots and numbers on the inside of the arms indicate the size, with each dot representing half-size.

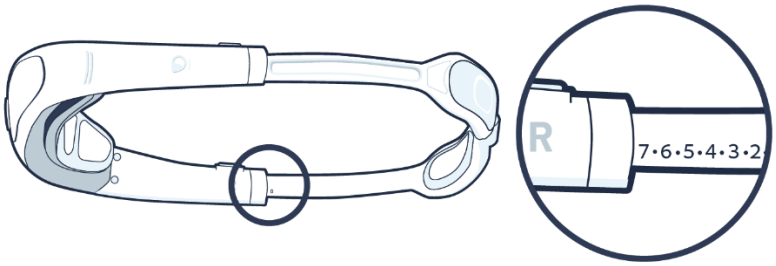


Figure 6: Arms size, Proliv™Rx device

Finding your size is a one-time process. Once you've got the right size, you're ready for all future sessions.

1 To find your size, you need to first extend your Proliv™Rx device before putting it on your head and tightening it. Men should start by setting the device to the largest size with the arms fully open. Women can start from size seven.

2 To optimize the effectiveness of your treatment, it's important to position your Proliv™Rx device correctly. Here are a few key points to keep in mind:

- The device should be **centered with your nose.**
- The front should **touch your eyebrows.**
- The device arms should rest **above your ears, not touching them**.
- The magnetic clasp at the back of the device must rest **above the bony bump** at the back of your head. You can find this bone by running your index finger straight up along your spine and then up along the back of your head until you reach the most prominent bump. Make sure your Proliv™Rx device is **right above, not below, the bump**.

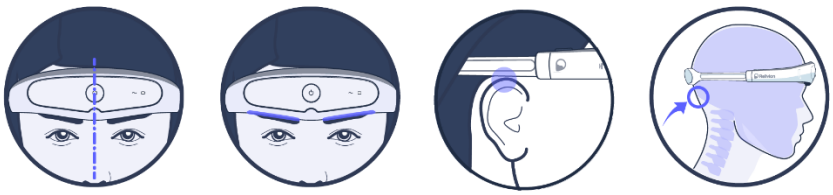


Figure 7: Correct position of Proliv™Rx device

If you have long hair, this is another vital point to remember:

- **Minimize the amount of hair** between the electrode pads and your scalp. Hair can disrupt the skin-electrode interface, impacting the stimulation. Use the magnet ends to penetrate your hair while placing your device. Keep the ends close to your scalp while you slide them through your hair, creating a parting all the way back.

3 Ensure your Proliv™Rx device is upright: Examine the inside of each arm to check if it is the left or right side and understand the correct orientation.

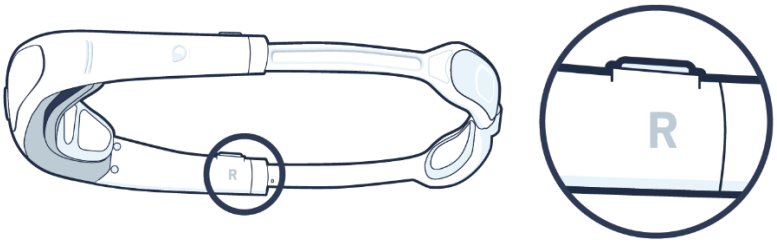


Figure 8: Right arm side, Proliv™Rx device

4 Open the magnetic clasp, position your index fingers on the back electrode covers, place the arm tips above your ears, and slide them all the way back while keeping them parallel. **Make sure the arms penetrate your hair while staying close to the scalp**. The magnet ends should connect at the back.

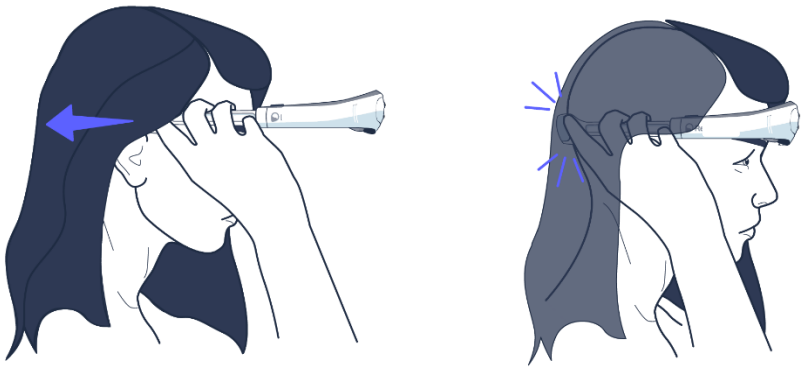


Figure 9: Placing the Proliv™Rx device on the head

5 To tighten your Proliv™Rx device to fit your head, place your index fingers on the grip lines toward the front of the device and your thumbs on the grip dots toward the back. Gradually tighten the device, keeping it symmetrical and making sure the magnet ends are still connected.

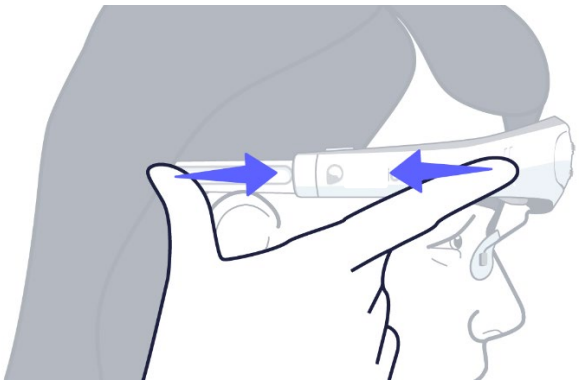


Figure 10: Tightening the arms of the Proliv™Rx device

After tightening the arms of the Proliv™Rx device, remember to check it's still positioned correctly, as shown on Figure 7 above. Check that:

- The device is **centered with your nose**.
- **The front touches your eyebrows.**
- The arms are **above your ears**.
- The device **rests right above the bony bump** at the back of your head.

The Proliv™Rx device should be placed on your head, ensuring a tight fit. However, you should still be able to move your neck, head, and face comfortably without disconnecting the magnet ends.

NOTE

After removing your device, you may notice a pressure mark. This will gradually fade and is not a cause for concern.

6 Take the device off your head and check the arms are symmetrical. The arms of your Proliv™Rx device should either be the same size or have up to a one-unit difference between them. For instance, if one arm is size seven while the other is size five, adjust both arms to size six, with size six becoming your designated size.

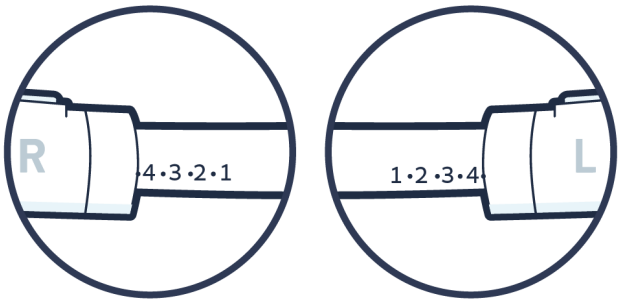


Figure 11: The Proliv™Rx device arms are symmetrical

NOTE

Remember to note down your size for future treatment sessions.

3 Using the Proliv™Rx

This chapter describes how to perform a treatment session with Proliv™Rx system.

2.3 PREPARING FOR A TREATMENT SESSION

1 Begin preparing for a treatment day by opening a packet of electrode pads. Insert the four small electrode pads at the front of your Proliv™Rx device and the two larger ones at the back.

NOTE Contact your supplier when you need additional electrode pads.

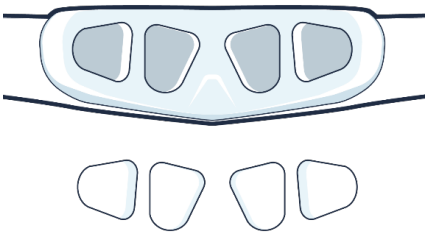


Figure 12: Front electrode pads

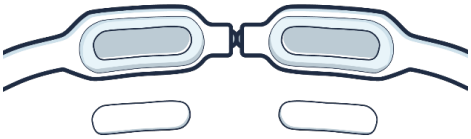


Figure 13: Back electrode pads

2 Before each session, clean your forehead with a wipe or wash it with soap and water to improve electrode-skin contact.

3 Before every session, wet the electrode pads with tap water using the provided spray bottle from the Proliv™Rx kit. Hold the nozzle against the pad (which is inserted into the electrode pad socket) and press down fully. The pad absorbs water faster when the nozzle is held against it. Spray each front electrode pad five times, and each back electrode pad ten times. **The wetter the pads, the better**. Ensure the electrode pads are wet enough by pressing on each pad. You should feel and see droplets of water coming out.

WARNING! Do not wet the electrode pads by rinsing the device under running tap water!

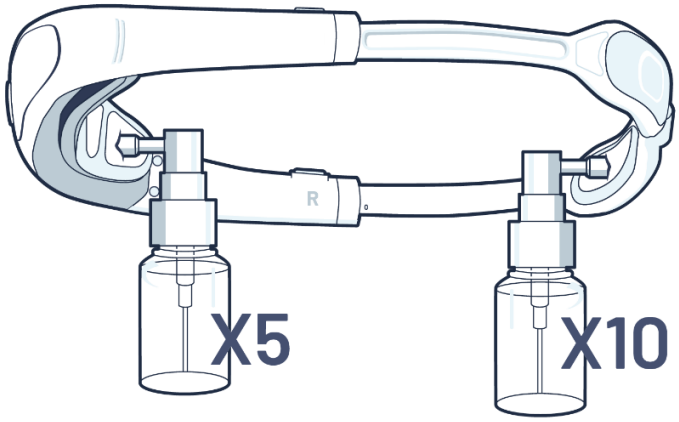


Figure 14: Wetting the electrode pads

4 Next, let down your hair and remove any hair accessories. If you have an eyebrow ring, you'll need to take it out before your session as it can interfere with the electrodes contact. If feels comfortable for you, you can wear your glasses while using your Proliv™Rx device.

5 Place the device on your head, ensuring that it **penetrates beneath your hair** and stays close to your skin. Keep in mind the positioning rules:

- The device is **centered with your nose**.
- **The front touches your eyebrows.**
- The arms are **above your ears**.
- The device **rests right above the bony bump** at the back of your head.

6 Finally, press on the **back electrode covers** until you feel moisture on your scalp. This enables the stimulation to pass through any hair between the pads and your scalp.

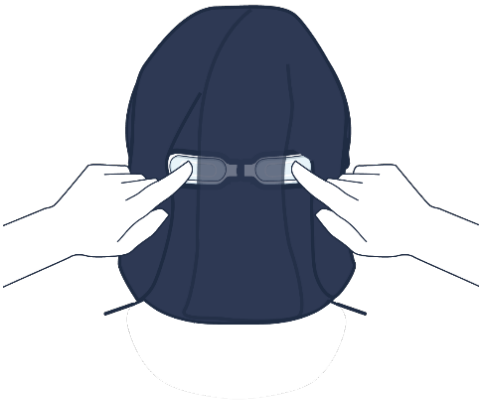


Figure 15: Pressing the back electrode covers to release moisture

2.4 CONDUCTING A TREATMENT SESSION

NOTE Remember to press the back electrode covers before every treatment session.

1 Turn the Proliv™Rx device ON by pressing the device's "Main" button.

2 Open the Proliv™Rx App and make sure the device is connected. The status bar should indicate "Ready for use".

3 Look for new messages or tasks on the "Today" page (the homepage) before starting a treatment session.

4 To start, tap the "Start session" button.

5 Device placement reminders will appear on the screen. Once you feel ready, tap "Continue". You can skip this step in future sessions by tapping the "Don't show again" checkbox.

6 The Proliv™Rx system runs a contact check before each treatment session. Once all electrodes have established good contact, the treatment session begins automatically. Follow the in-app troubleshooting guide to fix any contact issues. The app also notifies you if the device is worn upside down.

7 At the beginning of the session, the intensity will gradually and automatically increase up to a predefined level. As the intensity increases, you will feel a tingling sensation around the electrodes. If it feels uncomfortable during the automatic intensity increase, you can stop it at any point.

8 Gradually increase the intensity level until you reach the highest level that is still comfortable for you. You may decrease the intensity level at any time during the session. As you increase the intensity you may feel a tingling, stinging and/or itching sensation, and as the session continues you may experience scalp numbness. These are normal sensations for this type of treatment. The most effective treatment will be a treatment whose intensity level is as high as possible for you **but is still comfortable**.

NOTE Although the optimal intensity is 25 and above, stimulation must stay comfortable, it may take time to adjust to the stimulation. The app will guide you through the gradual adjustment process.

9 To pause the session, tap the ||(pause) button. The stimulation will immediately stop, and the session timer will pause as well. You may now decide whether to resume or end the session. If paused for 20 minutes, the session will end automatically.

NOTE When resuming a session, the system will run the contact check process again. The intensity level is automatically increased to a predefined level. Continue raising the intensity level manually to the highest comfortable level.

NOTE If you decide to end a session before its completion, you will not be able to return to the session and complete it later.

10 The treatment session will automatically end when the time is up. You may now remove your Proliv™Rx device from your head by detaching the magnet ends.

11 Turn off your Proliv™Rx device by pressing the Main button on the device. If it is not turned off, it will switch off automatically after 20 minutes.

12 At the end of the session, a session summary will be displayed on the app's screen.

13 Remove the electrode pads and discard them at the end of each day of use.

TIP 	It is highly recommended to increase the intensity level gradually. In each level increase, give yourself a few moments to check how it feels before moving up to the next level. As the treatment continues and you get used to how the stimulation feels, try increasing the intensity level while making sure it's still comfortable for you.

NOTE 	It is recommended to split the daily treatment sessions into morning and evening sessions to give your skin some rest between sessions.

4 Additional App Information

2.5 TODAY (HOMEPAGE)

From “Today”, the app’s homepage, you can initiate a treatment session and view your daily and weekly conducted and scheduled sessions.

2.6 QUESTIONNAIRE

While using the Proliv™Rx system, you will be asked to complete a mandatory biweekly digital depression self-report questionnaire to help you and your physician/psychiatrist track your depression status. Prior to your first Proliv™Rx treatment session and when it’s time to complete a follow up questionnaire, a message will appear on the app’s screen to allow you to fill in the questionnaire. To initiate your next treatment session you are required to complete the questionnaire.

NOTE

To save your treatment and self-report questionnaire data to the cloud, your smartphone must be connected to the internet.

2.7 REPORTS

The “Reports” page provides you with statistical information regarding your treatment progress. An option to export report in a PDF format, in order to send it to your health care provider, is also available from this page.

The “Reports” page includes the following data presented by graphs:

1. Biweekly questionnaires: Displays the total scores of the biweekly self-report questionnaires, over time. The baseline score is defined as your score prior to Proliv™Rx treatment initiation.
2. Treatment consistency: The score represents your treatment compliance in terms of number of treatments, by displaying the percentage of performed treatment sessions out of the planned sessions for a calendar week. Current week’s score will be presented only at the end of the week.
3. Average (Avg.) intensity: The score represents your treatments compliance in terms of intensity, by displaying the average intensity level used in treatment sessions during a calendar week. Current week’s score will be presented only at the end of the week.
4. Average session time: The score represents your treatments compliance in terms of length of treatment sessions, by displaying the average session time for treatment sessions performed during a calendar week. Current week’s score will be presented only at the end of the week.

2.8 MORE

The “More” page provides access to some of the technical aspects of the product:

1. Profile: User account details and device details.
2. Tutorials & Manuals: Links to the video tutorials and to the product’s manuals (online PDFs), contraindications, warnings and precautions.
3. About: Privacy policy, user agreement and information regarding the Proliv™Rx App.

5 Troubleshooting and Maintenance

2.9 TROUBLESHOOTING

This section offers troubleshooting for various issues with the Proliv™Rx system.

If a technical problem is not covered below or cannot be resolved by the suggested solutions, please contact Proliv™Rx Customer Care.

Problem/Symptom	Troubleshooting steps
The Proliv™Rx App is unable to connect to my Proliv™Rx device	• Make sure the device is charged. • Make sure the device is turned on. • Make sure Bluetooth is enabled on your smartphone. • Make sure the smartphone and the device are within close enough proximity to each other (five meters or less). • Make sure you correctly entered the last three digits of your device's Serial Number. The S/N label is located on the bottom front side of the device. If the problem persists, contact Proliv™Rx Customer Care.
Three beeps sounded during the treatment and the session was paused.	When poor electrode contact occurs, the status indicator light flashes red, the device beeps, and the treatment session is paused. To resolve the problem, tap “Resume treatment” to initiate the contact check process. The app will indicate which electrodes have poor contact and provide instructions to improve the contact. Optional solutions: • Press on the back electrode covers to release moisture. • Ensure the magnet ends are closed. • Make sure your device is secured tightly enough on your head. • Ensure the electrode pads are completely soaked. • Make sure you are using fresh electrode pads.

Problem/Symptom	Troubleshooting steps
The Proliv™Rx device does not turn ON.	• The battery is depleted. Charge your device, as described in the Getting Ready • PRELIMINARY STEPS section (). • The device is connected to a charger. Disconnect from the charger and turn the device on.
The status indicator light ( ) is steady red.	Indicates a device malfunction. Contact Proliv™Rx Customer Care.
Not all content is displayed properly on screen	The display size setting on your mobile phone might not be supported. • Go to the Display Size settings on your phone and change it to a smaller size.
The following error is displayed when starting a treatment session: *Error while sending [contact check] command to the device*.	• Log out from the app by going to Menu□Account□Log out • Now, re-log in to the app, pair the device and start a treatment session.

Table 5: Proliv™Rx product troubleshooting

2.10 CLEANING AND MAINTENANCE

- There are no parts that need regular service or technical maintenance.
- Clean the device with a wet cloth periodically, as visibly required.
- Do not use solvents of any kind (acetone, petrolatum, etc.) on the device
- Dispose of the electrode pads at the end of a treatment day.
- When the device is not in use, make sure the arms are not connected to each other by the magnets.

NOTE Leaving wet electrode pads in the device overnight may degrade the electrode conductivity.

NOTE Store the Proliv™Rx device in its case when not in use.

2.11 DISPOSAL

- Discard used electrode pads in regular trash receptacles after each daily use.
- Follow national, state, and local regulations for the proper disposal of the device, as it contains a Lithium-Ion battery.

6 Cybersecurity

Recognizing the concern of our customers and rapidly growing cybersecurity threats, Neurolief is committed to the deployment of a comprehensive security strategy that assures the safety of our product, business, and personal data.

Neurolief uses industry-standard instructions to protect the Proliv™Rx system, including its device, mobile app, system servers hosted on Amazon Web Services, and the data on those servers.

All data transmitted from the mobile app to the device, or the system servers is encrypted using industry-standard **Data Encryption** protocols. We **Authenticate** our users via SMS verification code, **Control Access** to the device by allowing a single connection to a mobile device. We ensure **Confidentiality** by not holding any Personally Identifiable Information on the Proliv™Rx Device and mobile app. We **Backup** our servers regularly to minimize the risk of data loss. Neurolief also provides **Regular Updates** to the mobile app and servers to address new security vulnerabilities and potential threats. All integration, backup and restore actions are performed only by the company's technicians, following validation protocols which include security configuration and backup functions.



Figure 16: Implemented Cybersecurity controls in Proliv™Rx

We also implement **Hardware Protection** circuits that limit the voltage and delivered charge, to ensure your safety. These circuits cannot be controlled by any external source, providing a reliable safeguard against manipulation.

The Proliv™Rx app is installed on a personal phone. The user is responsible for the mobile phone's security. We provide you with best practices and recommendations to increase the cybersecurity of your mobile phone and the Proliv™Rx mobile app and device.

- **Authorized Device Use:** Ensure that the device is not left unsecured when not in use, to prevent unauthorized personnel use.
- **Password Management**: Use strong, unique passwords on your mobile phone and change them regularly.
- **Software Updates**: Keep the mobile operating system on your mobile phone up to date. Ensure that the Proliv™Rx software is always up to date by enabling automatic updates or visit the official mobile app store regularly to check for updates. Download the Proliv™Rx app only from the official app stores.
- **Network Security**: Connect the mobile device only to secure, trusted networks. Avoid using public Wi-Fi when operating the device.
- **Incident Reporting**: Immediately report any suspicious activity or security incidents to Proliv™Rx Customer Service team (see contact details below).

The company maintains architectural diagrams and a bill of materials (SBOM) of its software. This information may be available for certain customers per request. For more information, contact our Customer Service team, per details provided below.

Incident Response

In the event of a cybersecurity incident, follow these steps:

1. **Disconnect**: Immediately turn off the device manually and disconnect the mobile device from the network to prevent further unauthorized access.
2. **Report**: Notify the Proliv™Rx Customer Service team and provide detailed information about the incident.
3. **Follow Instructions**: Follow the instructions provided by the Customer Service team to mitigate the impact and restore device functionality.

The company will inform the relevant users when a vulnerability fix is ready and available for installation by publishing an advisory in the company's website, In the event of a critical update, registered users will also be directly notified via email or phone. The following information will be disclosed:

- Overview of the identified vulnerability, its nature, potential impact, affected devices and software versions.
- Actions taken to mitigate the vulnerability, including details on software updates, or other remediation measures.
- Information on the risk assessment of the vulnerability, outlining the potential risk to patient safety, data integrity, and overall device functionality if any.

Contact Information

For any cybersecurity-related concerns or questions, please contact our Customer Service team at support@prolivrx.com or call our hotline at +1-888-473-5484.

End of Service

Upon reaching the **End of Service (EOS)** date for the Proliv™Rx system, the following measures will take effect:

1. **User Notification and Access Termination**

- You will receive prior notification before service discontinuation.
- On the EOS date, access to the Proliv™Rx system, including the device, mobile app, and cloud services, will be permanently disabled.

2 **Data Handling**

- **Device:** The Proliv™Rx device does not store personal data, eliminating any risk of data exposure.
- **Mobile App:** Treatment data is temporarily stored and deleted after syncing with the cloud. Upon service termination, the app will no longer be accessible.
- **Cloud Storage:** Medical data will be securely retained by Neurolief per legal and regulatory requirements. After the mandatory retention period, all stored data will be permanently destroyed.

3 **Termination of Support and Updates**

- No further software updates, security patches, or technical support will be provided.
- Neurolief's Customer Service team will no longer be available for troubleshooting or assistance.

For further inquiries regarding the end-of-service process, please contact our Customer Service team before the EOS date.

7 Technical Specifications

This chapter describes the technical specifications of the Proliv™Rx system.

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)
Constant Current	Yes
Waveform	Symmetrical rectangular biphasic pulse, 100% compensated
Maximum Current – Trigeminal	3.95 mA (per channel)
Maximum Current – Occipital	10.66 mA
Maximum Phase Duration	Front electrodes: 300 µsec Back electrodes: 200 µsec
Maximum Frequency	80 Hz
Maximal Voltage	• @500ohms – 1.9V front electrodes/5.3V back electrodes • @2,000ohms – 7.9V front electrodes/21.3V back electrodes • @10,000ohms – 39.5V front electrodes/100V back electrodes
Maximum Charge per Phase	1.19 µC front electrodes /2.12 µC back electrodes
Maximum Current Density (mA/cm^2, peak)	0.64 front electrodes / 1.14 back electrodes
Maximum Current Density (mA/cm^2, r.m.s.) @500 ohms	0.031 front electrodes / 0.036 back electrodes
Maximum Average Power Density (W/cm^2)	0.000003 front electrodes/0.000006 back electrodes
Maximum Rise Time	≤5 µsec

Timer	Up to 40 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
Device	
Number of Electrodes	6 (4 forehead electrodes and 2 occiput electrodes).
Replaceable Electrode Pads	One packed unit includes 6 pads. Contact your supplier to order more.
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	
3 years	
Software application (app)	
iOS version 15 or above, Android version 12 or above	
Encrypted communication channels	• BLE- communication between app and device • REST over HTTPS- communication between app and cloud services

Table 6: Technical specifications

8 Electromagnetic Compatibility

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

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group1 Class B	The Proliv™Rx uses Radio Frequency (RF) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class B	The Proliv™Rx 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 7: Manufacturer's declaration – Electromagnetic emissions

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	• 0% UT – 0.5 cycle at 0°, 45°, 90°,	Evaluated during AC/DC	Mains power quality should be that of a typical domestic establishment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
on power supply input lines IEC 61000-4-11	135°,180°, 225°, 270° and 315° • 0% UT – 1 cycle • 70% UT – 25/30 cycles • Single phase at 0° 0% UT – 250/300 cycles	adapter approval	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Power frequency magnetic field IEC 61000-4-8	50/60 Hz, 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.
			Portable and mobile RF communications equipment should be used no closer to any part of the Proliv™Rx, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms 150kHz to 80MHz	$d=1.17\sqrt{p}$ 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
Radiated RF IEC 61000-4-3	10 V/m from 80 MHz to 2.7 GHz	10 V/m from 80 MHz to 2.7 GHz	Where *P* is the maximum output power rating of the transmitter, in watts (W), according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol – 

Table 8: Manufacturer's declaration – Electromagnetic immunity

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

Table 9: Recommended separation distances between portable and mobile RF communications equipment and the Proliv™Rx

Electromagnetic Compatibility Warnings

The Proliv™Rx 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 Proliv™Rx essential performance, and incorrect output that exceeds the device's specifications may occur.
- Exposure to electromagnetic interference may result in temporary disruption of communication between the device and the mobile app; during such events, stimulation is designed to continue without interruption. Communication is expected to be restored automatically once the electromagnetic interference is resolved. If discomfort occurs during treatment and app control is not available, the treatment can be stopped by pressing the device's Main button.
- 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 properly.
- 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) and Wireless Power Transfer (WPT) equipment should be used no closer than 30 cm (12 inches) to any part of the Proliv™Rx device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The Device should not be used around strong magnetic fields, e.g. near an MRI machine.

9 FCC Compliance

This Proliv™Rx device complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following conditions –

1 This device may not cause harmful interference.

2 This device must accept any interference received, including interference that may cause undesired operation.

FCC ID: 2AO9M-01

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

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

FCC Compliance Statement

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in residential installations. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, it 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.

10 Summary of Clinical Data

Proliv™Rx as an adjunctive treatment for Major Depressive Disorder (MDD) was studied in two clinical trials.

Feasibility Study

The first trial, a feasibility study, was a prospective open label study which included 29 enrolled participants aged 21 to 65, diagnosed with depression, who had failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. Of the 29 participants, 24 completed the study.

The primary efficacy outcome of the trial was the change in depression symptoms from study baseline (initial score before treatment) to the end of 6 weeks of daily Proliv™Rx treatment. This change was assessed by each participant's physician using the Hamilton Depression Rating Scale (HDRS21). Participants experienced improvement in symptoms, with an average HDRS21 reduction of 10 points, representing a 40% average improvement in depression scores. In total, 67% (16/24) of the participants improved by 40% or more, and 42% (10/24) of the participants improved by 50% or more. Regarding safety, there were no serious adverse events reported during the study, and all adverse events were mild to moderate, suggesting a favorable safety profile for the studied therapy.

The feasibility trial was used to mainly assess safety and could not be used to determine treatment effectiveness due to the lack of control group.

MOOD Study

The second trial, the pivotal trial, was a prospective, randomized, parallel-group, sham-controlled study with an open label phase - the MOOD trial. The primary outcome was assessed from the start of the study through the first 8 weeks, when the two-group structure and blinding were maintained.

MOOD Study Analysis Populations

As is common in most studies, the MOOD study results were analyzed in different analysis populations (different ways of grouping participants for analysis).

The Intent-to-Treat (ITT) population (n=124): Included all participants who were randomized and attempted any use of the investigational device, regardless of significant protocol deviations or lack of follow-up data.

The Modified Intent to Treat (mITT) population (n=97): This was the primary analysis population that was pre-specified by the protocol for assessing effectiveness (main way the study judged if the treatment worked). It included all participants from the ITT population who used the device for at least 40 minutes per day, 5 days per week, over 8 weeks (a total of at least 1,680 minutes).

MOOD Study Demographics and Baseline Data

The study included, in the main analysis population (mITT), 97 participants with major depressive disorder (MDD) (72 females and 25 males) who did not achieve satisfactory improvement from previous antidepressant medications in the current episode. All the participants in the mITT population exhibited compliance (following the treatment instructions as prescribed) with the prescribed treatment regimen. The participants were enrolled at 13 sites in the US and Israel.

Baseline demographics were consistent with an MDD population in terms of age, gender, race, body mass index (BMI), education, employment status and head circumference. 74% (72/97) of the participants were female. The mean (average) age was 47.9 years (SD = 12.96 [SD means standard deviation, which shows how spread out the ages were]). The mean age in which the first depression episode occurred was 25.9 (SD = 13.6) years and ranged from 8 to 67 years. The number of antidepressant medications with no or insufficient response (that did not provide enough improvement) in the current episode was 1.8 (SD =0.89) and the mean current depression episode duration (the length of time the person has been experiencing their current depression episode) was 14 months (SD = 7.81). 62.9% (61/97) of the participants received psychotherapy treatment (talk therapy with a mental health professional) and all subjects were using antidepressant medications prior to and throughout the trial.

Assessment of blinding, which indicates whether the research participants knew whether they had the active or sham device, was performed after the first use of the device.

Effectiveness Outcomes

The primary outcome was the change in depressive symptoms from baseline to week-8 post Proliv™Rx treatment initiation as measured by HDRS17 total score in the modified intent to treat (mITT) analysis group (n=97).

The active group (participants who received the real Proliv™Rx treatment) showed an 8.62-point reduction from the baseline following the 8-week-long treatment period while the sham group showed a corresponding reduction of 6.01 points. The group difference translates to a statistically significant 2.61-point therapeutic gain (p-value=0.0196). Therefore, the study was deemed successful.

ITT (n=124):
All randomized participants

mITT (n=97):
Participants with no enrollment criteria violations who completed the minimal treatment time

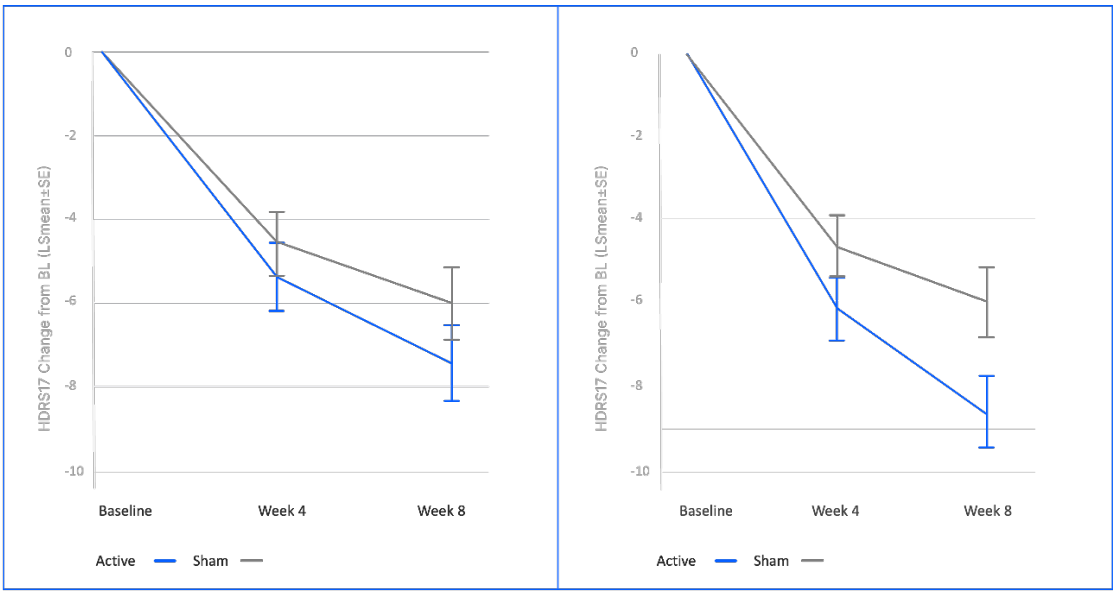


Figure 17: Change from Baseline in HDRS17 Regression Model Results – ITT and mITT analysis set

The active arm was also compared to the sham arm across the following secondary endpoints; no statistically significant differences were detected under the prespecified Benjamini-Hochberg procedure.

- Remission rate - the percent of participants with HDRS17 score ≤7 at 8 weeks post treatment initiation. The observed remission rate was higher in the active arm in comparison with the sham arm, 21.3% (10/47) versus 6% (3/50) respectively.
- Responder rate - the percent of participants achieving at least 50% reduction from baseline in their HDRS17 total score, 8 weeks post treatment initiation. The observed response rate was greater in the active treatment group (31.9%, 15/47) than in the sham control group (18.0%, 9/50).
- Mean change in MADRS total score from baseline to week 8 post treatment initiation – The observed mean (SD) changes in MADRS total score were -10.3 (8.07) and -8.3 (8.03) for the active treatment and sham control groups, respectively.

In addition, favorable trends were observed for the following tertiary endpoints:

- HDRS17 clinically substantial improvement – defined as a reduction of at least 7 points. This level of improvement was attained in 61.7% (29/47)of the active treatment group compared with 32.0% (16/50) of the sham control group.
- HDRS17 category shift to lower depression severity. While none of the participants were considered Mild or in Remission at baseline, after 8 weeks of treatment 51% (24/47) of the participants in the active group were considered Mild or in Remission, compared to only 26% (13/50) in the sham group.

Open Label Phase

Participants who continued from the active group to the open label phase of the study, for a total of 16 active treatment weeks, showed continued improvement and benefits with increasing rates of response and remission up to the end of the study. Furthermore, participants who transitioned from the sham group to the active group after completing the double-blind phase improved significantly over the eight weeks treatment of the open-label phase. Although these results are difficult to interpret due to the absence of sham control for placebo effects in this extension of the study, the open-label phase provides additional information regarding the effectiveness of the active Proliv™Rx treatment.

Clinical Study Conclusions

Proliv™Rx demonstrated effectiveness in reducing depressive symptoms in adults with an inadequate response to prior antidepressant medications.

Reporting adverse events

MedWatch is the FDA's program for reporting serious side effects, product quality issues, treatment failures, and use errors involving medical products, including medicines, biologics, medical devices, dietary supplements, infant formula, and cosmetics.
If you experience a serious reaction, you can submit the online reporting form.
The FDA will confirm receipt of your report and contact you if additional information is needed.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

- Report Online at : www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.homm

- Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at : www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

- Call FDA at 1-800-FDA-1088 to report by telephone.

- Reporting Form FDA 3500 is commonly used by health professionals. The form is available at www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

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