

# **Roga 1 User Manual**

## **Cranial Electrotherapy Stimulator for the treatment of anxiety and insomnia**

Welcome to the Roga family! This user manual contains all the information you need to know about using your new Roga device.

Roga 1 is a non-invasive and non-pharmacological cranial electrotherapy stimulator (CES) FDA cleared to treat anxiety and/or insomnia. Along with your purchase of Roga 1, you are also supplied with access to the Roga app to enhance your relaxation experience while using your Roga 1 device.













This manual contains instructions that will help you to use the Roga 1 device correctly. Please read this manual carefully to ensure proper device use. Roga Life Inc. will not be held responsible for any harm, injury, or personal damages to self or property incurred by incorrect use of the device.

**Caution:** U.S. federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Cranial electrotherapy stimulators are available without prescription in other countries worldwide; however, it is recommended that you consult with your licensed healthcare provider if you use this device in conjunction with prescribed medications or other therapeutic interventions. Seek medical assistance immediately if your health issue persists or you experience any side effects.

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# Symbols

Symbol	Description
	Before using the device, read the instructions for use thoroughly
	Consult Instructions for Use and Symbols Glossary on this website: <a href="http://www.rogalife.com/pages/user">www.rogalife.com/pages/user</a>
	Store Roga 1 electrodes between 41-80°F
	Check Roga electrode expiry date located on the electrode bag label
	Type BF Equipment
	Keep the device dry
	This product must be properly recycled. Do not throw in the trash with ordinary household waste. Dispose in accordance with local recycling instructions.
	The user manual contains warnings and precautions related to safety. Read the instructions carefully and use the device as instructed.
	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	1730 E Holly Ave, Suite # 819 El Segundo, CA, 90245, US
	Roga 1 is a medical device
	Roga Life Inc. is ISO 13485/EN ISO 13485 certified

<table border="1"><tr><td style="padding: 5px;">EC</td><td style="padding: 5px;">REP</td></tr></table>	EC	REP	Emergo Prinsessegracht 20 2514 AP The Hague Netherlands
EC	REP		

## Introduction

This is the user manual for Roga 1: a wearable medical device for the non-invasive and non-pharmacological treatment of anxiety and/or insomnia in the home healthcare setting. The Roga 1 package contains two components: (1) the Roga 1 cranial electrotherapy stimulator (CES) and (2) access to the Roga app (available in Google Play and the Apple Store).

1. The Roga 1 hardware device comes with five components: two power adaptors (android and iphone), one Roga 1 CES stimulator, one leadwire with earhooks, and one bag of adhesive simulation patches (electrodes). The Roga 1 device is powered by your smartphone (android or iphone). The Roga 1 device delivers a low level electrical pulse to the brain to reduce symptoms of anxiety and/or insomnia.
2. The Roga app is available to download onto your phone through Google Play or the Apple Store. Enjoy listening to 20-min audio tracks designed to provide Roga soundscapes and video content to enhance your relaxation experience during your treatment.

Note: This manual contains all of the information required for safe and correct use of the Roga 1 medical device.

Roga 1 is indicated for the treatment of anxiety and/or insomnia, and is regulated by the FDA as a class II and in Europe as a class IIa medical device. The device is an effective stand alone treatment for the symptoms of anxiety and/or insomnia; however, it can also be used in conjunction with other treatment modalities. There are no known contraindications associated with pairing CES with other anxiety or insomnia treatments. Please be aware that not all persons will receive the same benefits from using Roga 1: device efficacy will vary from person to person, and depends upon the health of the individual and the type and severity of condition being treated. The device should be used for up to six consecutive weeks to fully assess its effectiveness to reduce anxiety or insomnia symptoms.

## Intended Use

Roga 1 is a cranial electrotherapy stimulation (CES) device intended for the treatment of anxiety and/or insomnia.

# Roga 1 Features

- Stimulation intensity control between 100-500 microamperes ( $\mu\text{A}$ )
- 0.5 Hz (pulse frequency)
- Mastoid process electrodes
- Blue indicator light specifying when the device is turned on
- Small, discrete, concealable device. Small enough to fit into your pocket
- Automatic shut-off at 60 minutes
- Earhooks to secure the device in place during treatment
- Powered by a smartphone (android or iphone)
- Access to the Roga app
- One year limited warranty

## Indications

Roga 1 is a cranial electrotherapy stimulation (CES) device intended for the treatment of anxiety and/or insomnia.

## Contraindications

Currently, there are no known contraindications associated with cranial electrotherapy stimulation. However, clinical research is ongoing, and precautions should be considered. Roga 1 should not be used in conjunction with any implanted device such as a pacemaker or defibrillator. The device should not be used if metal implants are present in the neck or head, and patients with epilepsy should be supervised by a licensed healthcare practitioner when using a CES device. Consult your licensed healthcare provider before using Roga 1.

## Warnings and Precautions:

1. For external use only.
2. Before use, consult your primary healthcare provider if you have the following:
  - a. Pacemaker or defibrillator
  - b. Epilepsy
  - c. Metal implants in the neck or head
3. Do not allow children to use the device.
4. The effects of CES during pregnancy are unknown.
5. Do not operate machinery or a vehicle during treatment or for many hours after using the device.
6. Do not place the stimulation pads over areas of the skin that are irritated, scraped, bruised, or cut.
7. Remember to remove hearing aids before treatment.
8. Only use the stimulation pads (electrodes) that come with the device. Refills are

- available for purchase at [www.rogalife.com](http://www.rogalife.com).
9. Only use the power adaptor and leadwire that come with the device.
  10. Device servicing is not available. Opening the device case will void the warranty. If you require assistance with your device, please contact customer service.
  11. Do not get the device wet. The Roga 1 device is not water resistant.
  12. While using the device, patients should be monitored by their physician for signs of worsening.
  13. Prior to use, do a quick visual inspection of all the parts before starting treatment.
  14. Plug the device into only an android or iOS phone.
  15. Patient data and published clinical trials report the following adverse events: dizziness, skin irritation/burn, headaches, and nausea. Sleep difficulties or increases in anxiety rarely occur. If you experience any adverse event or if your symptoms of anxiety do not reduce within 6-weeks of using the device, consult your physician.
  16. To mitigate the risk of headaches, do not use the device more than the daily recommended treatment duration and maintain a stimulus intensity level that is comfortable to you. If a headache occurs during treatment, stop using the device. If the headache is severe, consult your licensed healthcare practitioner.
  17. To mitigate the risk of dizziness, do not use the device more than the daily recommended treatment duration and maintain a stimulus intensity level that is comfortable to you. If mild dizziness occurs during treatment, in most patients it does not last long — proceed with treatment. If dizziness is severe, stop using the device and consult your licensed healthcare practitioner.
  18. Do not place the electrodes on other parts of the body other than behind the ears.
  19. Do not have the device in direct contact with the skin other than the electrodes, earhooks, and lead wire.
  20. Use the device for a maximum of 1 hour per day.
  21. Do not use the device if any part is broken.
  22. Keep your cellphone charged, fully, before using the device.
  23. The CES device cable can snag on objects if the user is walking around while wearing the device. Please exercise caution.
  24. Discontinue use if any device component is damaged.
  25. The device is not designed for use in an oxygen rich environment.
  26. U.S. federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
  27. Do not use high frequency surgical equipment at the same time; it may result in burns at the site of the electrodes and possible damage to the Roga 1 device.
  28. Do not use Roga 1 in close proximity (e.g. 1 m) to a shortwave or microwave therapy device; it may produce instability in the Roga 1 output.
  29. Do not place electrodes near the chest (thorax); it may increase the risk of cardiac fibrillation.
  30. Do not place electrodes directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus) or on the chest, upper back, or crossing over the heart.

## Adverse Events / Side Effects

Adverse events tend to be rare, mild, and resolve quickly. Patient data and published clinical trials report the following adverse events: dizziness, skin irritation/burn, headaches, and nausea that can last hours to days. Sleep difficulties or increases in anxiety rarely occur. Consult your licensed healthcare practitioner if you experience any adverse event or if your symptoms of anxiety do not reduce within 6-weeks of using the device.

## In the Box

The Roga 1 box contains two components:

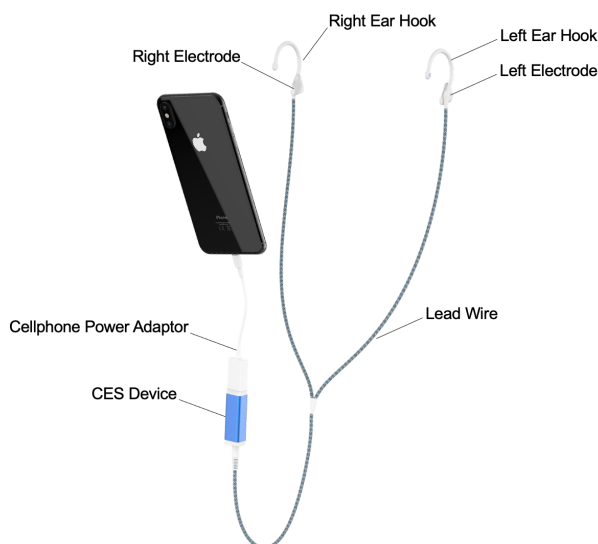
- A. The Roga 1 device
- B. Four pairs of electrodes. (Please refer to the electrode packaging for electrode expiry date.)

The Roga 1 device is powered by a smartphone. As soon as you plug the device into an android or iphone, the device turns on automatically, and will remain on for up to 60 mins. Please read the detailed set-up Instructions to learn how to set-up a treatment session using the device.

## Device Parts:

The Roga 1 device comes with four (5) parts:

	Part Description	Part Number
1	Android/iphone power adaptor x 1	PN 0102, PN 0103
2	Roga 1 CES device in aluminum case x 1	CAT 0126
3	Leadwire with earhooks x 1	PN 0094
4	Simulation patches/electrodes x 4 pairs	CAT 0140



## Directions for Use

You can use the device while seated or lying down. For best results, it is recommended to be as relaxed as possible; however, you can use the device while watching television, working on a computer, or reading. Do not operate machinery or a vehicle during treatment or for many hours after using the device.

### Directions for Use:

1. Important: do not plug the device into your cellphone until you complete steps 2-11.
2. Gently clean the skin at the back of your ears with water and soap on a washcloth. Pat the skin dry.
3. Retrieve two stimulation pads (electrodes) from the electrode package.
4. Snap one stimulation pad to each earhook.
5. Remove the right earhook with its corresponding stimulation patch from the plastic shield.
6. Hook the right earhook into the top of the right ear and gently adhere the stimulation patch behind the right ear (Make sure the patch is on the bone behind the ear and no hair is in between the electrode and your skin).
7. Repeat step #4 for the left earhook.
8. Plug in the leadwire into the Roga 1 device.
9. Plug in the power adaptor (android or iphone) to the Roga 1 device.
10. Ensure that the intensity slider is set to the lowest stimulation intensity before plugging the device into your cellphone.
11. Do not use concurrently with other devices.
12. When you are ready to start your treatment session, plug the device into your cellphone by way of its power adaptor. Roga 1 will turn on automatically as soon as you plug the device



in, and a blue indicator light will turn on indicating that the device is on.

13. Increase the intensity of stimulation by pushing the intensity slider upward. You may feel a slight tingling sensation on the skin or mild dizziness as you increase the intensity. Many people, however, do not feel anything during the treatment.

\*\* Please note that you do not have to feel the stimulation on your skin in order for the device to be effective. The Roga device is working as long as the blue indicator light is on. Place the intensity at a comfortable level for you. If you feel dizzy, reduce the intensity. Dizziness typically does not last long.

14. Use the device for a minimum of 20 minutes and for a maximum of 60 minutes. The device will automatically turn off after 60 minutes. Do not exceed 60 minutes.

15. When you are finished using your Roga 1 device, simply

- a. Unplug it from your cellphone
- b. Remove the earhooks with electrodes from the skin and place the electrodes back on their plastic shield for storage. Store electrodes in their ziplock bag.

16. Store the device in its carrying case out of reach of children.

#### Important Notes:

- Do not use any other brand of stimulation patches (electrodes). Only use the Roga 1 electrodes. Refills are available for purchase at [www.rogalife.com](http://www.rogalife.com)
- If you require more information regarding the set up of the Roga 1 device, please consult your licensed healthcare provider.

## Turning the Device On/Off

Turn on the device by plugging the device into your smartphone. Once plugged in, the device turns on automatically. There is a 60 minute auto shut-off. A blue indicator light turns on when the device turns on. The device comes with a power adaptor for an android phone or iphone.

Before turning the device on, make sure that the intensity slider is set to the lowest setting and the device is fully set-up with both stimulation patches (electrodes) placed behind each ear. Read the directions for use for more information.

## Attaching the Stimulation Patches/Electrodes:

1. Retrieve two stimulation pads (electrodes) from the electrode package.
2. Snap one stimulation pad to each earhook.
3. Remove the right earhook with its corresponding stimulation patch from the plastic shield.
4. Hook the right earhook into the top of the right ear and gently adhere the stimulation patch behind the right ear (Make sure the patch is on the bone behind the ear and no hair is in between the electrode and your skin).
5. Repeat steps 3-4 for the left earhook.

## Replacing the Stimulation Patches/Electrodes

An initial purchase of the Roga 1 device provides four pairs of stimulation patches/electrodes. Refills are available for purchase at [www.rogalife.com](http://www.rogalife.com)

## App Download

The Roga 1 device comes with free access to the Roga app. The app does not control the Roga 1 device and does not contribute to the CES treatment. The app contains guided meditations and soundscapes to help enhance the relaxation experience during your Roga treatment. Each session is 20-60 minutes long. It is best to use earbuds to listen to Roga app content while using your Roga device.

## Treatment Recommendations

- For initial treatment: use Roga 1 every day, 20-60 minutes for 4-6 weeks. Do not exceed 60 minutes.
- Select a stimulus intensity that is comfortable for you. The device provides stimulus intensity between 100-500  $\mu$ A. Use the intensity slider on the front of the device to raise or lower the intensity.
- Once desired anxiety reduction is achieved, and to maintain results, use Roga 1 2-3 times per week for 20-60 minutes.
- Some people require longer treatment sessions to reduce their anxiety level. Rest assured that the Roga 1 device can be used safely for longer durations (up to 1 hour each day).
- The beneficial effects of CES are observed over time. Being consistent and using the device regularly gives the best results.

## Technical Specifications

Parameter	Description
Power supply	Device is powered by a smartphone (android or iphone). Power adaptors are supplied with the device
Timer / Auto shut off	The device will automatically shut-off after 60 minutes. To turn the device off sooner, simply unplug the device from the cellphone
Waveform	Square wave, biphasic

Frequency	0.5 Hz (pulse frequency)
Output mode / current: stimulus intensity range (based on 8,000 ohm resistance) +/- 20%	100 $\mu$ A - 500 $\mu$ A (microamps)
Pulse duration	400 ms(milliseconds)
Burst duration	800 ms(milliseconds)
Cycle duration	10 s
Max charge per pulse	200 $\mu$ C (microcoulombs)
Max energy per pulse	800 $\mu$ J (microjoules)
Size	Length: 64.2mm Width: 17.6mm Height: 16.6mm
Weight	10g

## Detailed Summary of Clinical Testing

Research spanning many decades demonstrates that cranial electrotherapy stimulation (CES) administered at a frequency of 0.5 Hz to a maximum current intensity of 500  $\mu$ A plays a clinically significant and safe role in treating anxiety and/or insomnia, and for that reason, Roga 1 was designed to deliver 0.5 Hz stimulation to a maximum intensity level of 500  $\mu$ A.

### Anxiety Studies:

There are 16 clinical trials published demonstrating significant reduction in anxiety induced by CES with the above stimulation characteristics. Of the 16 clinical trials, 5 are randomized double-blind sham controlled studies, 2 are randomized single-blind sham controlled studies, and 9 are open label studies. Across all trials, 494 subjects were included and anxiety reduction was measured by validated assessment scales like the Hamilton Rating Scale for Anxiety (HAM-A) or the General Anxiety Disorder-7 questionnaire (GAD-7). Quality of life was measured using the EQ-5D-5L. On average, 60 minutes of CES stimulation daily for 6-weeks was shown to reduce anxiety symptoms between 32-50% in addition to a significant improvement in quality of life in clinically diagnosed patients.

In terms of adverse events, CES stimulation set to 0.5 Hz with an intensity maximum of 500  $\mu$ A imposes side effects that are rare, mild, and self-limiting. When considering all of the adverse events reported throughout the 16 clinical trials or databases like the FDA MAUDE, side effects rarely occur and include: mild dizziness, nausea, headache, and local skin irritation.

Table 1: Occurrence of Adverse Events Associated with CES	
Number of Adverse Events Reported	Incidence Rate
494 subjects in clinical trials: 8 reported mild headache 2 reported mild nausea 1 reported mild dizziness Local skin irritation	Headache = 1.6% Nausea = 0.4% Dizziness - 0.2% Local skin irritation - not reported in literature
From 2012-1019, 3 FDA MAUDE reports for CES adverse events.	Rare

## What Kind of Anxiety can Roga Help?

There are a number of clinical trials reporting the beneficial effects of CES to treat the following anxiety types:

- Generalized anxiety
- Acute anxiety
- Treatment resistant anxiety
- PTSD

## Servicing, Device Repair or Modification

Other than the removable stimulation patches (electrodes), there are no serviceable parts inside the device. If you require assistance with your device, please contact Roga customer service. Changes or modifications to the device are not approved by Roga Life Inc. and could void the warranty and user's authority to operate the device.

## Cleaning, Storage and Disposal Instructions

Gently clean the components of the Roga device with 70% isopropyl alcohol (rubbing alcohol) using a cotton pad or cotton cloth. Do not use spray cleaners, bleach, or abrasive chemicals on any component of the device. Do not submerge any component of the device in water.

When not in use, store the stimulation patches/electrodes on the plastic shield provided with the electrodes. This will prevent the electrodes from drying out. The electrodes cannot be cleaned. Do not submerge them in water or apply any type of cleaning solution. This product must be

properly recycled. Do not throw in the trash with ordinary household waste. Dispose in accordance with local recycling instructions.

Use the Roga 1 case to store and transport the device to prevent device damage. If device damage or injury occurs, contact Roga Life Inc. (+1 510-817-2218) to report the device incident or injury.

## Shelf Life

The electrodes have a shelf life. Please refer to the electrode packaging for expiration date.

## Troubleshooting

1. When the device is plugged into a smartphone, the blue indicator light does not turn on.
  - a. Contact customer service
2. Electrodes are not sticking to the skin.
  - a. The electrodes can be used up to 5 times. The length of time that the electrodes remain sticky depends upon the amount of oil, dirt, and debris the electrode is exposed to during treatment. Remember to clean the skin with mild soap and water on a washcloth before using the electrodes. Refills are available for purchase at [www.rogalife.com](http://www.rogalife.com)
3. I'm having difficulty unsnapping the electrodes from the earhooks.
  - a. Place your thumb near the attachment site on the earhook and push the electrode out of the earhook instead of attempting to pinch the electrode to pull it out.
4. I don't feel the stimulation on my skin.
  - a. Not everyone feels the stimulation on their skin. The highest intensity (500  $\mu$ A) is quite low, and many people do not feel any sensation. That does not mean the device is not working. You do not have to feel the electric stimulation to receive the full benefits from the device. Cleaning the skin with mild soap and water and a washcloth before adhering the electrodes to the skin will enhance stimulation.
5. My anxiety level is not reducing.
  - a. If you are not observing any results, try increasing the frequency and duration that you are treating; some people require up to 4-6 weeks before they observe any significant changes. Consult your licensed healthcare practitioner if your symptoms persist or worsen.

# Roga Life Inc. Limited One Year Warranty

**Roga Life's One Year Hardware Warranty for Roga Products.** Roga Life warrants that, for a period of 12 months, after the delivery date, the Roga Product purchased (not including consumable or disposable components or accessories) will be free of defects in materials and workmanship and will function in substantial conformity with Roga Life's specifications. This warranty is expressly limited solely to the original purchaser and does not extend to any transferee, assignee or subsequent purchaser or user of the Roga Product. This warranty shall not apply to (and Roga Life shall have no obligation with respect to) any alleged defect to the extent of: (i) any alteration, addition, attachment to, or modification of the Equipment not authorized in advance in writing by Roga Life that interferes with normal and satisfactory operation or maintenance; (ii) noncompliance with instructions for use or environmental specifications for the Equipment; (iii) use of any accessories to the Equipment not supplied by Roga Life; (iv) repair or maintenance of the Equipment by any party not authorized in advance in writing by Roga Life; (v) neglect, misuse, accidents, failure of electrical power, air conditioning, humidity control, or other acts or conditions not within the reasonable control of Roga Life; (vi) any defect in connection with which Customer fails to notify Roga Life. During the warranty period, products will be replaced at Roga Life's sole option. Such replacement shall be Roga Life's sole obligation and Customer's sole remedy. Products replaced under this warranty shall be warranted for the remaining unexpired period of warranty only.

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