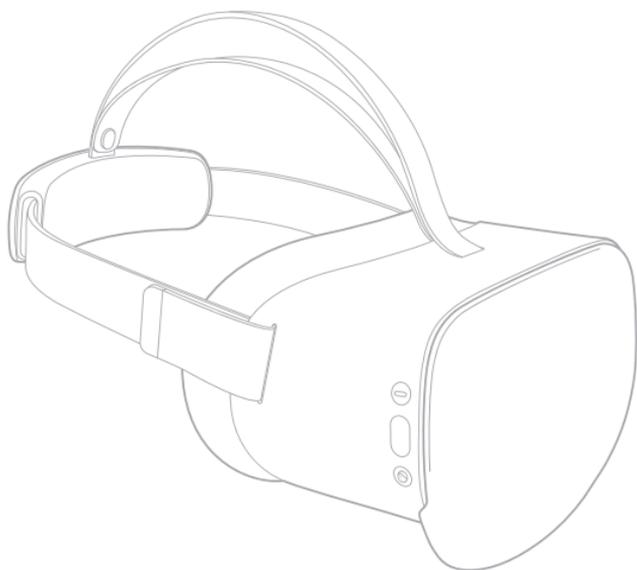


RelieVR_x[™]



User Manual

Therapeutic VR_x Platform



Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare professional.

Symbol Glossary Definitions

	Manufacturer
	Date of Manufacture
	Catalog number
	Serial number
	Refer to instruction manual/booklet
	Temperature limitation
	Humidity limitation
	Atmospheric Pressure limitation
R_x Only	Prescription Only
	Bluetooth
	Emitting waves
	Do not dispose
	Class II ME Equipment
	Type BF Applied part

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● **Welcome**

The RelieVRx™ program, from AppliedVR, enables people to change the way they process pain and develop new, positive habits and coping skills that improve quality of life. The RelieVRx system is a skills-based program that can easily be self-administered in the comfort of the home, at any time – advancing remote care as well as quality and efficiency in chronic lower back pain management.

● **Device Description**

The RelieVRx program is a prescription-use medical device with preloaded software content on a proprietary hardware platform that delivers automated cognitive behavioral therapy and other behavioral methods to patients diagnosed with chronic lower back pain. It is an immersive virtual reality (VR) system that delivers VR content while incorporating biopsychosocial pain education, diaphragmatic breathing training, mindfulness exercises, relaxation exercises, and executive functioning games. The medical device integrates an all-in-one head-mounted display with a Software Application and a Breathing Amplifier™ to enable the diaphragmatic breathing exercises. The device is intended to be self-administered, unsupervised in the patient's home while the patient is in a seated position. The device is powered by a rechargeable lithium battery. Each device is intended for a single patient. The medical device is meant for repeated use, does not include non-medical software, and is only effective when treating chronic lower back pain.

● **Indication for Use**

The RelieVRx program is a prescription-use immersive virtual reality system intended to provide adjunctive treatment based on cognitive behavioral therapy skills and other evidence-based behavioral methods for patients (age 18 and older) with a diagnosis of chronic lower back pain (defined as moderate to severe pain lasting longer than three months). The device is intended for in-home use for the reduction of pain and pain interference associated with chronic lower back pain.

● **Contraindications**

There are no known contraindications.

● **Warnings**

- Safety and effectiveness have not been demonstrated in patients with moderate to severe depression.
- If a user experiences motion sickness, dizziness,

headache, or eye strain when using the device, stop use of the device and resume therapy per your doctor's advice.

- Use only in a safe environment. This product creates an immersive virtual reality experience that blocks your view of your actual surroundings. Please move to an indoor safe and comfortable area and take note of your surroundings. Do not get close to dangerous areas like stairs, windows, heat sources or other hazardous areas. Sit down before wearing the headset and stay seated during use of the headset.
- If you are using a pacemaker or other implanted medical device, do not use the RelieVRx device until you consult a doctor or medical device manufacturer.
- Do not wind cables around the neck. Tangled cables can cause strangulation.
- The RelieVRx device must be turned off and power supply must be disconnected from AC outlet before performing any repair and maintenance procedure. Failure to do so may result in electric shock.
- If you suffer from the following, please consult your doctor before use:
 - Hearing or visual impairment
 - Hypersensitivity to flashing light or motion
 - Injury to eyes, face, or neck that prevents comfortable use of VR
 - Have a history of epilepsy, suffer from physical, mental or heart disease
 - Have any serious medical condition

● **Precautions**

- Keep this device away from the heat of fireplaces and radiant warmers.
- Avoid water spillage and keep this device away from moisture from a nebulizer, steam kettle, humidifier, or other moisture-emanating devices.
- Keep the unit clean and protect it from lint, dust and sunlight.
- Do not operate the RelieVRx device outside of the environmental conditions provided in the technical specification. Operating the RelieVRx device beyond the specified environmental conditions may lead to a hazard.
- Care must be taken when operating this device around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to the RelieVRx device or to the other equipment. Try to minimize this interference by not using other equipment

in conjunction with this device.

- Use of parts and cables other than those specified or provided by the manufacturer of the headset could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and may result in improper operation.
- Use of the RelieVRx device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Do not alter the device.
- This Medical Equipment is designed to comply with IEC 60601-1-2: 2014. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:
 - Reorient or relocate the receiving device
 - Increase the separation between the equipment
 - Connect the equipment to an outlet on a different circuit from that to which the other device(s) are connected

Consult your authorized dealer for help.

- Consult with your doctor if you are pregnant, elderly, or have any condition of concern.
- Keep the device and parts out of the reach of children, pets and pests to avoid any hazards.

● Notes

Read all instructions before using the RelieVRx device.

- There are no known skin irritations due to prolonged exposure to the RelieVRx device.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RelieVRx device, including cables specified by the manufacturer.

- The RelieVRx device contains no user serviceable parts inside, and servicing (other than that explicitly defined elsewhere in this manual) must be performed by the manufacturer or its authorized agent.
- The RelieVRx device should be intact upon receipt. Devices should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to AppliedVR.
- Please contact AppliedVR immediately if you observe any changes in the performance of the device.

Latex Information

All components of the RelieVRx device are latex-free and not made with natural rubber latex and may be placed directly against the skin.

NOTE

If you experience seizures, loss of consciousness, convulsions, claustrophobia, involuntary movements, vertigo, nausea, dizziness, drowsiness, visual abnormalities (hallucinations, ambiguity, or diplopia), itching, swelling or other discomfort stop use of the device and follow up with your doctor/physician.

● Product Care

Avoid Damaging the Screen

CAUTION: To avoid damaging the screen:
DO NOT expose the headset to direct sunlight.

Extra care should be taken when the headset is placed outdoors, on a balcony, windowsill or in the car. Exposure to direct sunlight for less than 1 minute may cause permanent yellow spots on the screen and damage the optics and display. The headset will not be usable if damaged.

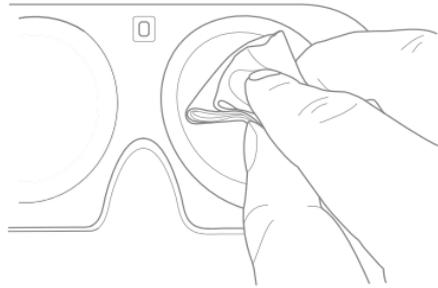
- There are no user-serviceable parts inside.



● Lens Care

Protect the optical lenses during use and storage to prevent sharp objects from scratching the lenses.

Using a dry nonabrasive lens wipe, wipe the lens from the center to the outer edge.



Do not clean the lenses with any harsh cleaning products such as bleach.

Using abrasive cleaning solutions may lead to damage to the lenses.

To prevent damage to the device, store the headset in its provided protective case when not in use

● Care & Cleaning Recommendations

1. Headset:

We recommend cleaning the headset routinely. Wipe all non-porous surfaces, including the top straps, the back head-pad, face cushion and the headset enclosure with a hydrogen peroxide-based disinfectant wipe (AHP®)¹.

Allow surfaces to remain wet for the duration specified on the packaging of the wipes.

Let the surface dry completely before use.

2. Face Cushion and Care:

- a. Wipe the non-porous parts of the face cushion with a hydrogen peroxide-based disinfectant wipe, and allow it to remain wet for the duration specified on the packaging of the wipes.
- b. DO NOT use the hydrogen peroxide-based disinfectant or other chemical wipes on the lens
- c. Store the headset in the provided case.

¹ <https://www.solutionsdesignedforhealthcare.com/product/disinfectants/oxivir-1-wipes/>
AHP® is a registered trademark of Diversey, Inc.

● What's Inside

- Pico G2 4K headset, with Breathing Amplifier™
- USB-C Charging Cord and Wall Charger
- User Manual and Quick Guide
- Protective Case



Headset with Breathing Amplifier



Headset Face View



USB-C Charging Cord and Wall Charger



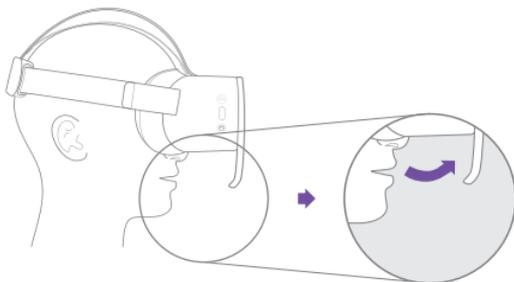
User Manual



Quick Guide

Printed materials are examples only, actual materials may differ

The **Breathing Amplifier¹** is a custom attachment, designed to help amplify the sound of your breath. When you exhale through your mouth, the Breathing Amplifier¹ directs your breath toward the microphone. Certain modules are responsive to these sounds and allow you to visualize your breath in the RelieVRx program.



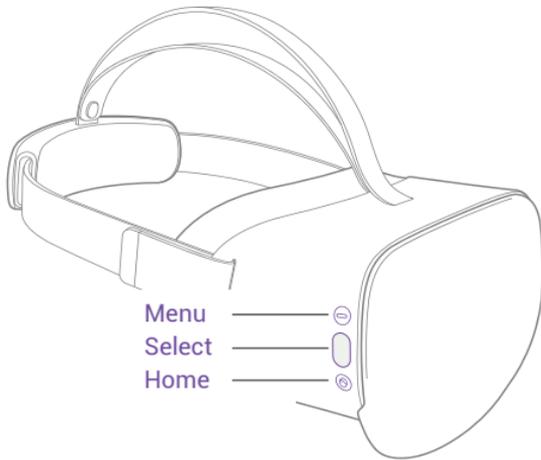
Do not remove the Breathing Amplifier from the device. If the Breathing Amplifier detaches from the headset, please contact customer service for assistance.

¹Lympouridis, Vangelis, Derek Nielsen, and Josh Sackman. Headset Respiration Faceplate. US D902,205 S, United States Patent and Trademark Office, 17 November, 2020

● Get to Know Your System

Headset

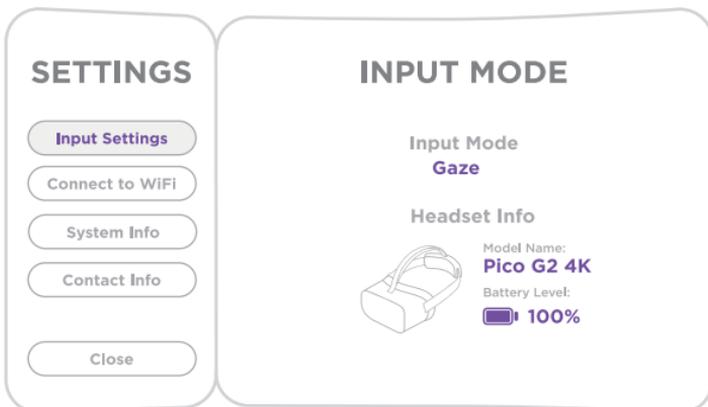
-  **MENU** button brings up the In-App Menu if it is pressed while in an experience
-  **SELECT** button can be used to make a selection
-  **HOME** button returns to Home Menu with a Short Press; the home button will also recenter the headset user interface with a Long Press



● Battery Levels

Check Battery Levels

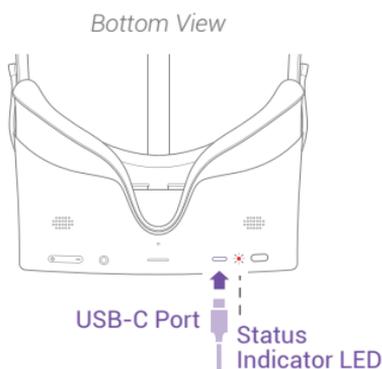
You can check the battery level of your headset in the INPUT SETTINGS screen within the main menu. It can be accessed by selecting the  SETTINGS icon in the bottom center of your screen.



● Charging the Headset

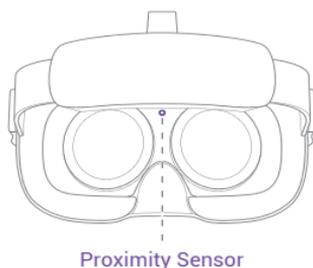
The headset battery will last approximately 2.5 hours when playing content. Use the adapter and cable provided in your case to charge the headset. The charging port is located on the bottom of the headset.

Please plug the USB-C cable into the device, connect the other end of the cable into the power adapter, and plug your power adapter into a power outlet. The Status Indicator LED flashes a **RED** light when the battery is low.



NOTE

The headset only charges when you are not wearing it. Ensure that the proximity sensor in the headset is not covered, otherwise the headset will not charge.



● Status indicator LED lights

Battery Levels:

- **BLUE** - Halfway Charged
- **SOLID RED** - Low
- **BLINKING RED** - Extremely Low

When Charging the Device:

- **YELLOW** - Charging
- **GREEN** - Charging Complete

NOTE

The battery is not user replaceable or serviceable.

Do not attempt to open your headset to access the battery.

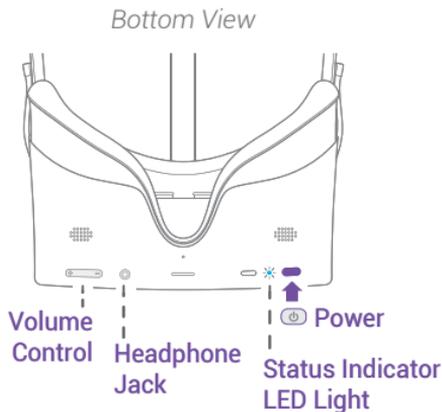
TIP

For best results, we recommend leaving your device plugged in after each use. This ensures it will be ready to go whenever you need to use it.

● Power: On/Off

Powering On

Long press the  POWER button on the bottom of the headset and wait for the **BLUE** LED light to turn on. The blue loading screen will appear in the headset followed by the Home Menu.

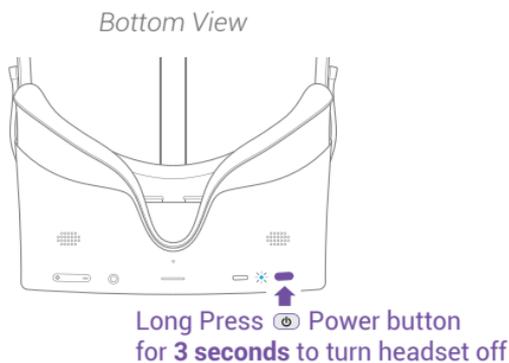


Powering Off

When you take off your headset, it will go to sleep after not being used. To wake it back up, put your headset back on. If the device is in sleep mode and not plugged in for an extended time, you will be required to plug in the headset and recharge the battery before your next use.

To turn the headset off completely

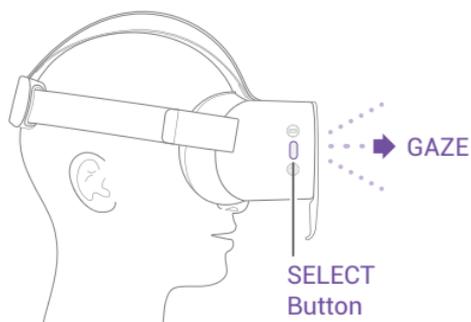
Long press the  POWER button for a full **3 seconds** until the screen goes black.



CARE: Store the headset in its protective case when not in use to prevent damage.

● Use Your Gaze to Make Selections

We developed GAZE-BASED controls to keep you from being tethered to a controller, and to make our system more accessible to those with limited mobility.



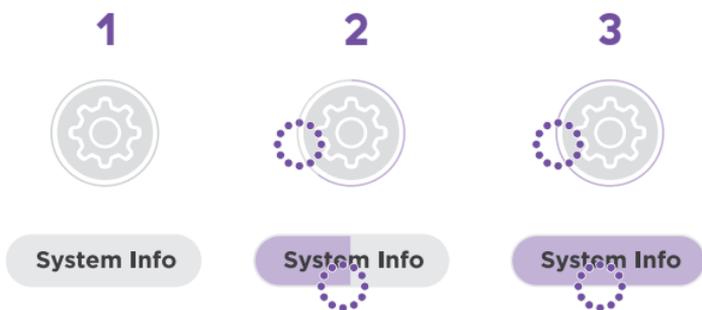
How does it work?

The  CURSOR follows the motion of your head. Simply look around to move the cursor until it lands on the button you want to activate.

How do I make selections?

Move the  CURSOR so that it hovers over the icon you'd like to activate. When the icon fills up (in about 2 seconds), your selection will activate.

To make selections move the  GAZE Cursor on top of the icon you would like to activate:



NOTE

You can also press the  SELECT button on the right side of the headset.

● Getting Started

Before you start, please make sure you are seated in a safe environment in an area free of obstructions.

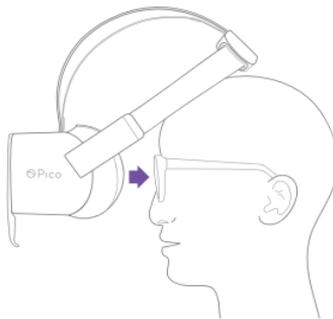
1. Power On

Remove the VR headset from its case. Long press the  POWER button on the bottom of the headset and wait for the Status Indicator LED to turn on a **BLUE** light.



2. Put on the headset

Using one hand, hold the VR headset over your eyes in a comfortable position. If you wear glasses, you can wear them underneath the VR headset. The headset fits most standard glasses with a frame width of less than 160 mm.



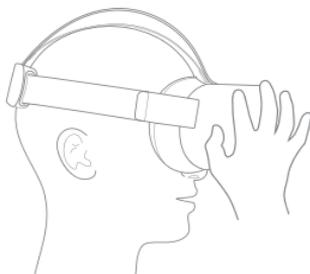
3. Welcome to the RelieVRx program

Once you power up your headset for the first time, a series of onboarding screens will help guide you through: how to fit your headset properly, how to use our GAZE-BASED cursor, and how to connect to your WiFi. This onboarding includes a RelieVRx program overview and information on the first session in the program.

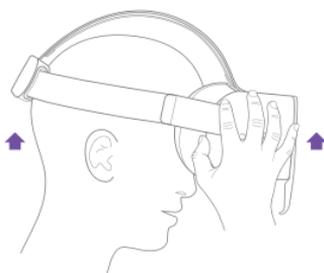
4. Focus your view

You can adjust the precise position of the VR headset on your face in order to see a clear image. This is done by moving the VR headset slightly up and down your face. The home screen will display an image of a person wearing the RelieVRx device.

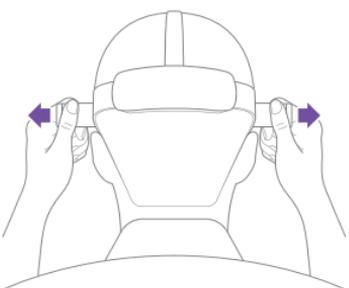
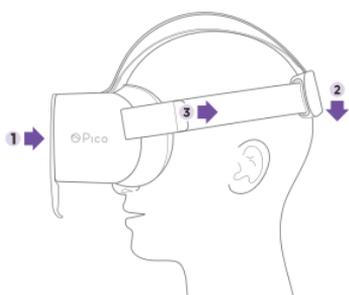
Look directly at the text and imagery so that it is centered in your field of vision. Move the VR headset slightly up and down your face until you find a position where the image and text on the screen is clear and visible. If necessary, tighten the head straps again to keep the VR headset in that position.



Text Should Be Clear and Visible



Up & Down



5. Ensure a comfortable fit

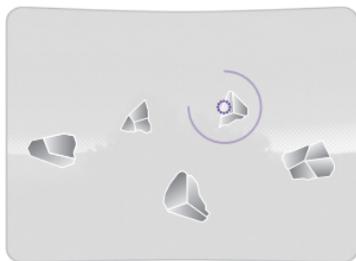
Using your other hand, hold the battery pack at the back of the VR headset's head strap. Now pull the strap down over the back of your head. If the head strap is too tight, loosen it by detaching the Velcro at the sides of the head strap. Then pull the head strap until it is loose enough to fit around your head before reattaching the Velcro.

Tighten the Velcro straps

Once the head strap is around your head, tighten the strap by detaching the Velcro at the sides of it. Pull the ends of the head strap until it is sufficiently tight before reattaching the Velcro. The VR headset should feel snug but not uncomfortably tight.

6. Using the GAZE control

You will now be introduced to the GAZE-BASED controls where you can learn what  GAZE is and how to use the  GAZE cursor. Hold your  GAZE cursor on each piece of the crystal to rebuild it.



7. Setting Up WiFi

Next, you'll be walked through setting up your device with WiFi. If you wish to set up WiFi or check WiFi status at a later period, you may do so in the Settings Menu. Please refer to the "Connect to WiFi" section of this user manual for more details.

NOTE

WiFi is optional but recommended. By turning on the WiFi, AppliedVR will collect the information outlined in our privacy policy, which is available here: www.appliedvr.io/privacy-policy.

8. Ready to Start

Now you will be introduced to the RelieVRx program, including what to expect during the next 8 weeks.



Daily VRx Sessions

Once you complete the VRx session, the next experience will automatically appear on the home screen. It is recommended that only one session is completed per day.

9. Powering Down

At the end of the session, remove the headset, and long press the power button for a full 3 seconds until the screen goes black. To ensure the headset is charged and ready for your next use, make sure you plug the headset back into the USB-C charger.



This is a general example, your specific Virtual Reality experience may differ slightly.

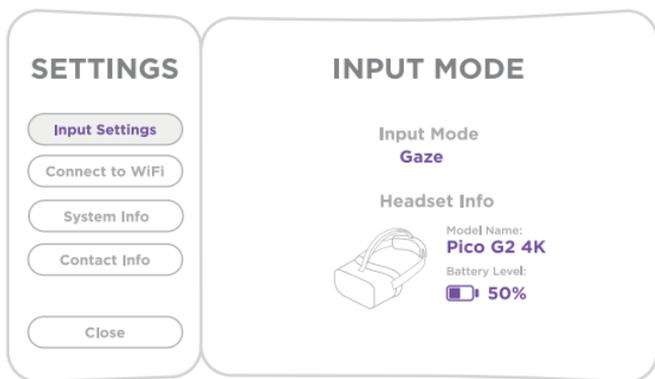
NOTE: Store the headset in its protective case when not in use to prevent damage.

● Navigation - Settings Menu

The Settings Menu can be accessed by selecting the  SETTINGS icon in the bottom center of your screen. In the Settings Menu, you can check the battery level, connect to WiFi, check system information, find your device ID, and find the AppliedVR support team's contact info.

● Input Settings

In the Input Settings screen, you can check your battery levels of the headset.



● Connect to WiFi

NOTE

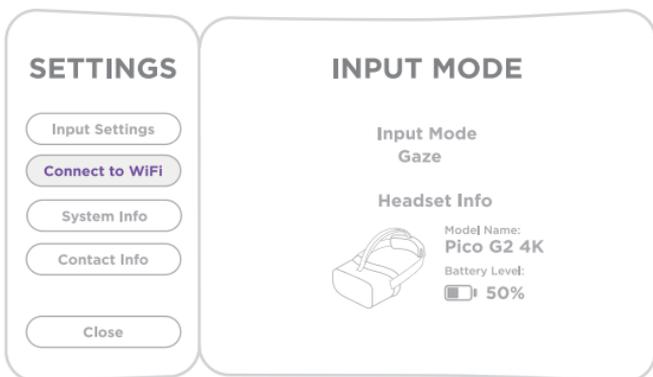
WiFi is not required to use RelieVRx's therapeutic program. However, WiFi may be required to provide technical support and to ensure your software is up to date.

Before Connecting to WiFi:

1. Have your WiFi network name and WiFi password on hand.
2. If possible, have a friend or family member read you the steps and your password, so you can focus on what's going on in your headset.

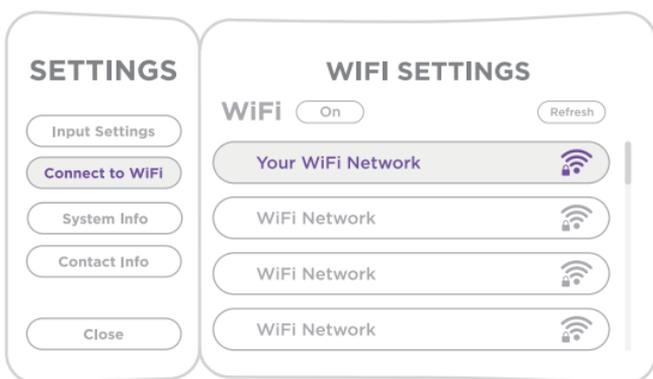
To connect to WiFi:

1. Use  GAZE to focus and activate the  SETTINGS icon at the lower center of the Home Menu.
2. Use  GAZE to focus and activate the CONNECT TO WiFi button on the left panel of the menu.



3. A list of WiFi networks will appear on the right panel of the menu. If you don't see your network, make sure to scroll down by using  GAZE to focus on the arrows to the right.

Once your network is identified, use  GAZE to focus on your network name to start the connection process.



NOTE

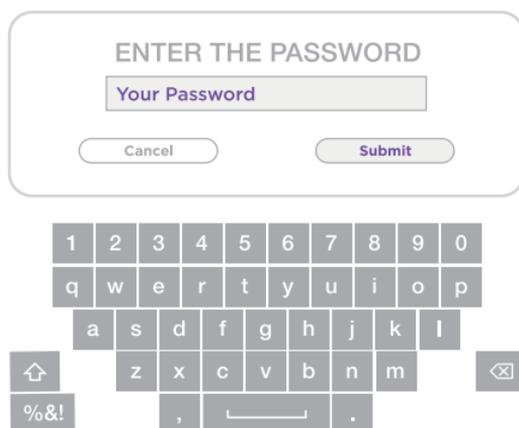
If you select the wrong network, you can  GAZE at the “Return” arrow to go back to the list of WiFi networks.

4. Enter password and connect.
 - a. Enter password. Enter one character at a time by gazing at each character. Hold your  GAZE to confirm each character of your password.

You will see the character added to the password bar right above the keyboard. To delete a character, simply  GAZE at

the back arrow. If you need a special character, select that on the lower left of the keyboard.

- b.** Use  GAZE to focus on the SUBMIT button directly below your password to start the connection process.



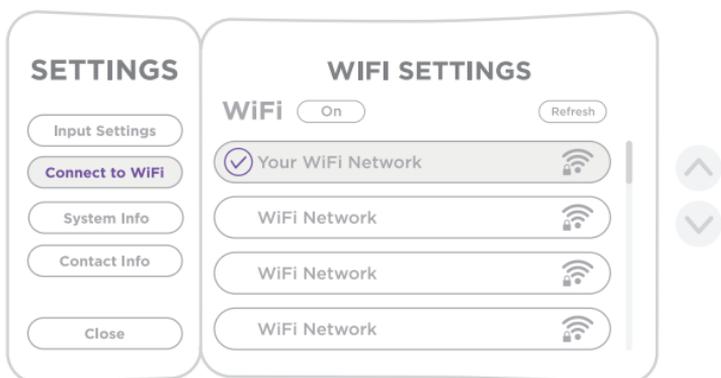
5. Connecting to WiFi

- a.** As your WiFi connects, you can see the process on your screen along with any additional information necessary to completing WiFi setup.



- b.** Once you have successfully connected, you will be automatically returned back to the home menu.

6. If there is a need to check your WiFi connection after initial setup, you can go to **CONNECT TO WIFI** in the settings menu. A connected network will have a “check mark” to the left of the WiFi network name.



NOTE

WiFi is optional but recommended. By turning on the WiFi, AppliedVR will collect the information outlined in our privacy policy, which is available here: www.appliedvr.io/privacy-policy.

● System Info

Select the **SYSTEM INFO** icon to find out what version software your headset is running.

● Contact Info

Select the **CONTACT INFO** icon to find your Device ID and the support team's contact information. Your Device ID and contact information can be helpful if you contact customer support for troubleshooting assistance.



● Navigating through VRx Sessions

Do you need to adjust the volume, skip a session or return home once you are in a module? Access those functions through the In-App Menu.

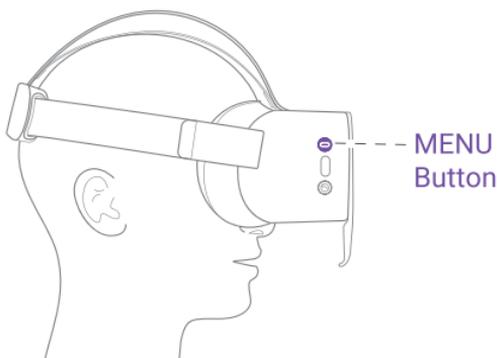
In-App Menu

1. To prompt the In-App Menu to appear, you can do this two ways:
 - a. Look for the  ANCHOR icon which can be found in the lower center of your screen to launch the menu.

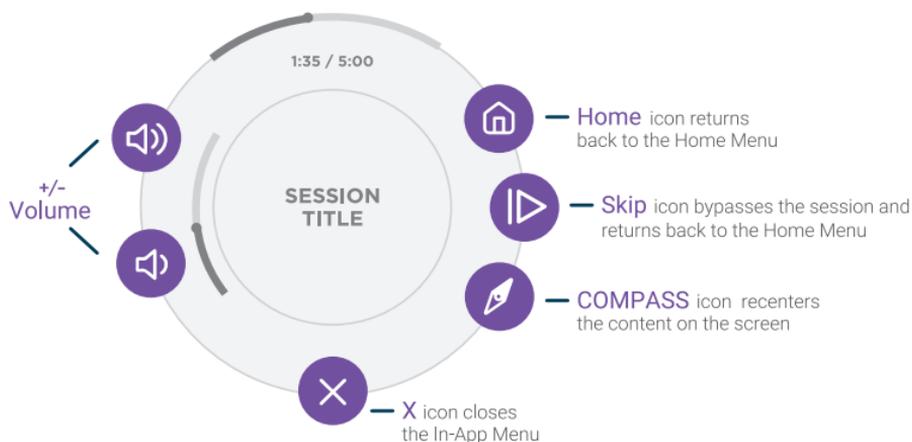


This is a general example, your specific Virtual Reality experience may differ slightly.

- b. You can also press the  MENU button on the headset to access this. (The Menu button is the top button on the exterior right side of the headset.)

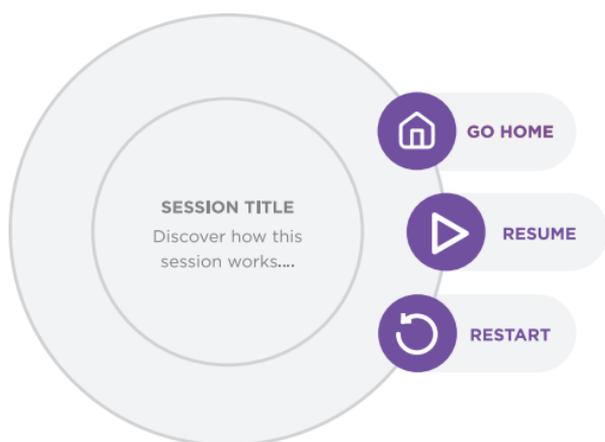


2. Once you're in the In-App Menu, you can learn more about the module you're in, adjust the volume, skip an experience, reorient your view, or return home by selecting the icon for each.



● Pause Menu

Need to take off your headset in the middle of a session? The Pause Menu will appear once you put your headset back on. In the Pause Menu, you can go to the Home Menu, resume the experience, restart the experience, and read more about the experience you're in.



● VR Headset/Software Glossary

Headset

-  **MENU** button brings up the In-App Menu if it is pressed while in an experience
-  **SELECT** button can be used to make a selection
-  **HOME** button returns to Home Menu with a Short Press; the HOME button will also recenter the headset user interface with a Long Press

Software

-  **GAZE** cursor is a dotted circle, and represents the cursor of the VR Interface
-  **SETTINGS** icon launches Settings Menu
-  **COMPASS** icon reorients the interface screen
-  **ANCHOR** icon opens the In-App Menu
-  **HOME** icon returns to the Home Menu
-  **X** icon closes the In-App Menu
-  **PLAY/RESUME PLAY** icon resumes the experience (if experience is paused)
-  **SKIP** icon bypasses the current experience and returns you back to the Home Menu
-  **RESTART** icon restarts the current experience from the beginning
-  **VOLUME** icon adjusts volume
-  **BATTERY** icon shows the battery life of the headset

System

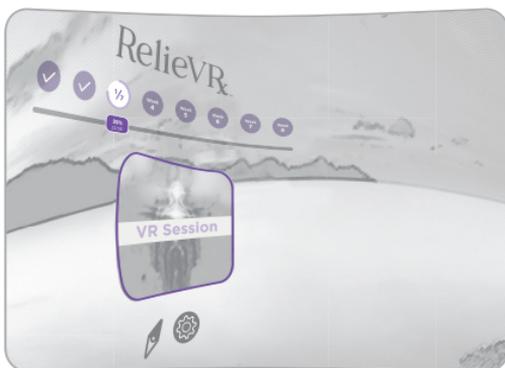
MODULE - Session Experience Tile

HOME MENU - The Home Screen of RelieVRx, where you start your daily sessions

SETTINGS MENU - The control panel where you can access system information

● Screen Reorientation

Recenter the screen to your view with the  COMPASS icon. Should your screen be facing the wrong way, you can use this option to bring it back to center.



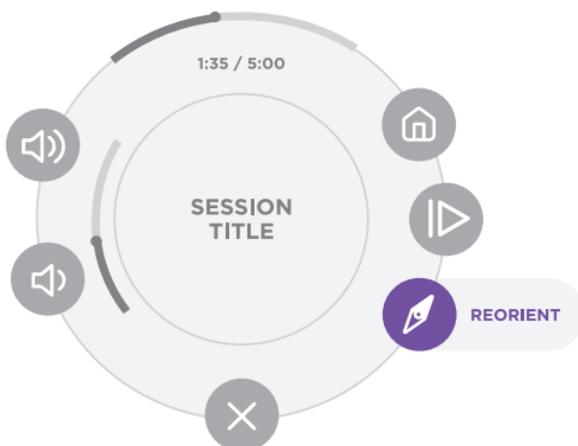
NOTE

If you prefer to use VRx while reclined, we recommend remaining upright rather than laying fully flat.

● Reorient and Recenter Your Screen

There are a number of ways to reorient:

- In the Home Menu, Select the  COMPASS icon on the lower center of the screen.
- When in a session, select the  ANCHOR icon at the lower center of the screen. The In-App Menu will appear. Select the  COMPASS icon on the lower right of the In-App Menu.



A window will pop up and ask you to relax and look forward. Adjust to a more comfortable position and level your gaze.

RELAX AND LOOK FORWARD

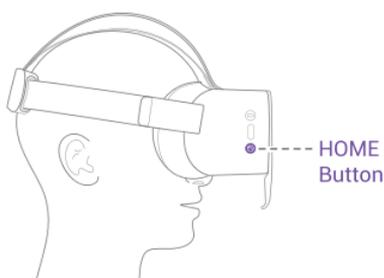
Reorienting in:

5

The interface will automatically adjust the screen after 5 seconds.

NOTE

You can also hold down the  HOME button on the headset to reorient. (The HOME button is the bottom button on the exterior right side of the headset.)



● **Troubleshooting**

Headset not powering on?

Make sure the headset is completely plugged in while charging. If the battery is completely drained, allow two hours to fully charge.

Fully charged, but nothing visible on screen?

If the headset is fully charged and not powering on, hold the power button for 15-20 seconds to force a reboot to the headset.

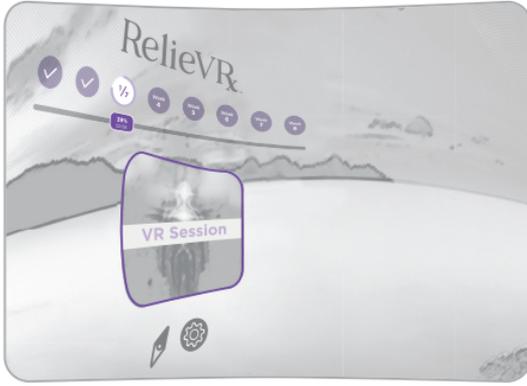
Blurry visuals?

If the view appears blurry, adjust the headset up and down the face until the view comes into focus. Adjust the straps if necessary.



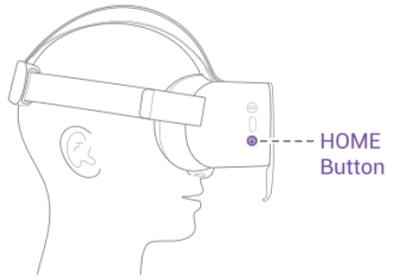
UP & DOWN

Menu pointing the wrong way?



There are 3 ways to correct reorientation:

1. Look forward and level your gaze. Long press the  HOME button on the headset to reorient the screen. *(The HOME button is the bottom button on the exterior right side of the headset.)*

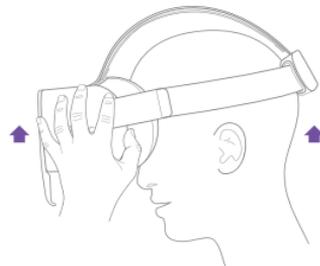


2. Select the  COMPASS icon in the menu.

Lower Center Of Home Menu



3. You can remove and put back on the headset and it will reorient itself.



UP & DOWN

● Therapeutic Program Instructions

The RelieVRx program is intended to be used daily for 8 weeks, covering all 56 sessions sequentially. As therapy progresses, new categories and principles are introduced to facilitate user's understanding and learning of pain management skills.

RelieVRx is a skills-based program that teaches the user how to recognize and adjust cognitive, emotional, and physical responses to chronic lower back pain.

Therapy Approach:

Evidence-based, behavioral medicine principles



Mindfulness



Cognitive Behavioral Therapy



Pain Neuroscience Education



Program Structure:

8-Week Sequential Structure **56** DAYS TOTAL

Weekly Multi-Modal Structure **5** VR EXPERIENCE CATEGORIES

Daily Therapeutic Structure **1** SESSIONS PER DAY FOR **6** MINUTES EACH (AVERAGE)

8-Week Sequential Structure:

Weekly Narrative for Users

Week 01		Week 02		Week 03		Week 04		Week 05		Week 06		Week 07		Week 08	
Breath & Pain		The Mind & Pain Relief		Attention & Distraction		Relaxation		Shaping the Nervous System Toward Relief		Notice The Body		Moving Forward		Journey To Wellness	
<p>Educational Content: Program rationale, Stress and Anxiety</p> <p>Interactive Experience: Receive breathing/relaxation training</p>		<p>Educational Content: Understand bodily sensations</p> <p>Interactive Experience: Activities to release tension and pain</p>		<p>Educational Content: Psychological Awareness</p> <p>Interactive Experience: Receive breathing/relaxation training to help cope with difficult experiences</p>		<p>Educational Content: Psychological Awareness</p> <p>Interactive Experience: Receive breathing/relaxation training to help cope with difficult experiences</p>		<p>Educational Content: Review of previous content</p> <p>◀ ◀ ◀ ◀</p> <p>Interactive Experience: Variety of experiences to reinforce pain relief skills</p>		<p>Educational Content: Sleep management and pain</p> <p>Interactive Experience: Activities to improve sleep and sleep related habits</p>		<p>Educational Content: Acceptance and mindfulness</p> <p>Interactive Experience: Reinforce previous skills as well as mindfulness</p>		<p>Educational Content: Information to transfer skills to daily lives</p> <p>Interactive Experience: Variety of concepts from previous weekly sessions</p>	

Table 1.1: Categories of Experiences in the RelieVRx program

Category	Title		Information or skills provided
I	Relaxation/ Interceptive		<p>Relaxing scenes that change from busy/active to calm reflecting a user's progressively enhanced state of relaxation. These sessions train users to understand and perceive what's going on inside the body as they engage in relaxation.</p>
II	Education		<p>Brief visual and voice-guided lessons about the central nervous system as it relates to pain and breathing. These experiences use anatomical animation to facilitate learning and establish a medical and scientific rationale for the program.</p>
III	Mindful Escapes		<p>Immersive 360° videos with therapeutic narration, guided breathing, music, and visual effects to reinforce mindfulness-based pain relief skills and increase engagement.</p>
IV	Pain Distraction		<p>Interactive games to train pain relief skills related to shifting attentional focus away from pain.</p>
V	Dynamic Breathing		<p>Breathing-based interactive environments to train pain relief skills and induce relaxation. These sessions become increasingly challenging as users increase their skill with diaphragmatic breathing and parasympathetic control.</p>

● **RelieVRx Study Design Overview**

AppliedVR conducted a study in community-based individuals to test the hypothesis that use of an “in-home” skills-based virtual reality (VR) chronic pain solution (RelieVRx), once a day for 8 weeks, would significantly reduce pain intensity and pain interference on activity, mood, sleep and stress in individuals with chronic lower back pain. To test this hypothesis we collected pain intensity and pain interference ratings from 94 participants before starting the RelieVRx program and immediately following the program, and compared those with a separate group of 94 participants who received a “sham” VR intervention, and were asked to give the same pain intensity and pain interference ratings pre- and post-intervention. Both patients and the data analyst were unaware of the device received by each participant. The study included English-fluent men and women aged 18-85 with access to WiFi, a diagnosis of low back pain without radicular symptoms, pain duration of at least six months, and average pain intensity of ≥ 4 on an 11-point scale) over the previous month. Individuals were excluded if any of the following held: An inability to understand the goals of the study due to cognitive difficulty. Current or prior diagnosis of epilepsy, seizure disorder, dementia, migraines, or other neurological diseases that may prevent the use of VR. Medical condition predisposing to nausea or dizziness. Hypersensitivity to flashing light or motion. No stereoscopic vision or severe hearing impairment. Injury to eyes, face, or neck that prevents comfortable use of VR. Cancer-related pain. Moderate to severe symptoms of depression. Previous use of the RelieVRx program for pain, or current participation in any interventional research study or completed participation in the past two months. Currently pregnant or planning to become pregnant during the study period. No access to WiFi. Currently works at or has an immediate family member who works for a digital health company or pharmaceutical company that provides treatments for acute or chronic pain.

Results Summary

Safety

No Unanticipated Adverse Device Effect (UADE) or Serious Adverse Event were observed or reported in our clinical study. In the study, patients were asked to report adverse events throughout the study. No participant reported any adverse events. In a survey administered 30 days after the treatment

was completed, to inform future product improvement opportunities, participants were asked to report any negative experiences that had occurred during any of the 8 weeks of treatment. In this retrospective survey, 20.8% of patients reported experiencing motion sickness or discomfort with the headset (usually around the weight of the headset).

Efficacy

Each of the five primary endpoints (pain intensity, and pain interference in activity, mood, sleep and stress) were measured on a 0 - 10 point scale with larger values representing greater pain intensity or pain interference. For each of these five primary endpoints, we computed the percentage reduction in pain intensity and pain interference from pre-treatment to the end of treatment. The table below (See Table 1.2) presents the average percent reduction in pain intensity and pain interference for the RelieVRx program group and the Sham VR group. Pain symptom reductions ranged from 42-57% for RelieVRx and 24 - 38% for Sham VR. We also computed a statistical test of the difference in pain symptom reductions between the two groups using a t-test. "P-values" less than .05 are considered small enough to confer efficacy on the RelieVRx program relative to Sham VR. The RelieVRx program showed a statistically significant reduction in pain intensity and pain interference relative to Sham VR for all five metrics. We also computed the "effect size" that measures the magnitude of the change from pre-treatment to end of treatment in the RelieVRx program group. For all five pain metrics the effect size for the RelieVRx program was large (defined as an effect size of .80 or greater).

Table 1.2

Average Percent Reduction in Pain Intensity and Pain Interference from Pre-Treatment to End-of-Treatment					
	Pain Intensity	Activity Interference	Sleep Interference	Mood Interference	Stress Interference
RelieVRx	42	49	52	56	57
Sham VR	24	32	38	37	37
RelieVRx vs Sham (p-value)*	<.001	.021	.021	.021	.021
RelieVRx effect size**	1.3	1.3	1.0	1.2	1.2

Notes:

* Primary analysis p-values for interaction, except sleep interference where p-value is for condition
 ** Standardized mean difference (Cohen's d)

Uncertainty

As with all clinical trials, there is some uncertainty associated with the benefits. However, by virtue of being randomized, with exceptionally high compliance (>95% of the ITT Analysis Set with primary endpoints), the effects of design choices such as self-reporting and lack of control of medication usage were minimized. While the results are generalizable to a broad population, the effectiveness of RelieVRx is unknown for prospective users who might have greater pre-treatment depressive symptoms.

Many other factors that might characterize and/or increase uncertainty were not present in the study:

- Confidence intervals are not excessively wide in either group
- The study was appropriately sized
- Missing data were minimal in both groups, and both groups maintained good treatment compliance
- Attrition was low in both groups
- There was a lack of major protocol deviations in both groups
- User experience is representative of what real-world patients can expect The chosen sham treatment is recognized as the best available option for the type of treatment

Therefore, we believe that the level of uncertainty associated with the study data is low.

- **Start-Up System for User**

For reference, you will see the home menu appear upon your start-up system.



This is a general example, your specific Virtual Reality experience may differ slightly.

- **VRx Sessions**



Quickly enter a virtual experience by choosing from the tile options in the Home menu.



This is a general example, your specific Virtual Reality experience may differ slightly.

Once you complete the VRx session, the next experience will automatically appear on the home screen. It is recommended that only one session is completed per day.

● **Returning the Device**

A prepaid return shipping label has been provided in the case. To return the RelieVRx device, package all contents back in the original packaging box. Adhere the shipping label to the box, and drop it off at your nearest FedEx location.

To find the nearest FedEx Location, you can visit:
www.fedex.com/locate/index.html

NOTE

If you do not have the original packaging box, please use another shipping box.

You may return your device for repair if directed to do so by an AppliedVR Customer Service agent.

● **Software Description**

The RelieVRx program runs on an Android operating system developed and configured by AppliedVR to support the RelieVRx's content delivery. RelieVRx software comes preloaded on the dedicated head mounted display (HMD) when provided to users.

● Technical Specifications

Hardware Model: Pico G2 4K

REF Number: RVX-2002

Rating: 5V DC, 2A

Manufacturer and Model of Headset:

GoerTek Technology Inc. Model: A7510

Screen: 4K LCD

Screen Resolution: 3840 x 2160

Number of Pixels Per Eye (horizontal / vertical): 1907 / 1964

Field of View Per Eye (horizontal / vertical): 98 / 101

Luminance:

Maximum and minimum luminance 0.06nit and 64.7nits

CPU: Qualcomm Snapdragon 835

Weight: 278g(w/o Band), 470g(total)

Frame-Rate: 72 fps

Minimum Frame-Rate Using the Software: 60 fps

Interpupillary Distance (IPD) and IPD Range:

Default 63mm, optical adaptive range is from 55~71mm

Range in Depths of the Virtual Content in the Software:

2m for optics; 3m for launcher software

Horizontal and Vertical Field of View Per Eye Horizontally:

98 horizontal, 101 vertical

Eye Relief for Prescription Lenses: 17mm

Storage: 32G

Content: AppliedVR's RelieVRx program

Tracking: x/y/z 360° - 3 Degrees of Freedom (3DoF)

Number of Discharge Cycles: 500

Expected Service Life of the ME Equipment: 3 year

External Camera: Not applicable

Type BF applied parts

Technical Specification of USB-C Charger:

I/P: 100-240Vac, 50/60Hz, 0.35A, Class II

O/P 5V DC, 2A

Frequency Range(BT): 2400-2483.5MHz

Max Output Power(BT): 5dBm

Frequency Range(WiFi): 2400-2483.5MHz, 5150-5350MHz

Indoor use only, 5470-5725MHz

Max Output Power(WiFi): 20dBm

- Type of protection against electric shock: Class II, internally powered.
- Degree of protection against electric shock:

- Type BF applied parts (Whole device is a Type BF applied parts)
- Degree of protection against harmful ingress of water or particulate matter: IP20
- Mode of operation: Continuous use
- Method of sterilization: Not intended to be sterilized/ disinfected
- Degree of safety of application in the presence of flammable anaesthetic mixture with Air or with oxygen or Nitrous oxide
- Suitability for use in an Oxygen rich environment:
- Not intended for use in an Oxygen Rich Environment

Device is not a mains-connected device.

The charger mains plug is used as a means of isolation/ disconnection. Do not position the device during charging so that it is difficult to access the mains plug during an unexpected error, which could lead to a hazardous situation.

Environmental conditions for transport and storage:

- An ambient temperature range of -25 °C to + 70 °C
- A relative humidity range of 15% to 95%, including condensation
- An atmospheric pressure range of 50.0 kPa to 106.0 kPa

Please use the following environmental conditions for operation:

- An ambient temperature range of 5°C to 40°C
- A relative humidity range of 15% to 90%, non-condensing
- An atmospheric pressure range of 70.0 kPa to 106.0 kPa

Maximum Altitude Use: 3000m

● Technical Information



Safety

Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste. It must be collected separately and must be disposed as per local regulations. Contact your authorized representative for information concerning the decommissioning of your equipment.

The headset contains a lithium ion battery. Recycle and dispose of the equipment properly according to local laws.

Keep the device away from excessive humidity and extreme temperatures and avoid direct sunlight or ultraviolet radiation.

Use the charging equipment supplied with the product. Do not attempt to replace the lithium ion battery yourself. Doing so may cause damage to the battery, overheating, fire, or personal injury. The battery may only be replaced by an authorized service provider. Batteries shall be replaced every 2 years.

Do not disassemble, replace or repair equipment on your own.

● **Electromagnetic Compatibility Declaration**

Guidance and Manufacturer's Declaration - Emissions

The RelieVRx device is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Table 1.3

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The RelieVRx device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The RelieVRx device 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.
Harmonics Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Immunity

The RelieVRx device is intended for use in the electromagnetic environment specified below. The customer or user of the RelieVRx device should assure that it is used in such an environment.

Table 1.4

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV & ± 8 kV for Contact Discharge ±2 kV, ±4 kV, ±8 kV and ± 15kV for Air Discharge	±2 kV, ±4 kV & ± 8 kV for Contact Discharge ±2 kV, ±4 kV, ±8 kV and ± 15kV for Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%
Electrical Fast Transient/ Burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	AC Mains Line to Ground ±0.5kV, ±1kV and ±2kV AC Mains Line to Line ±0.5kV and ±1kV	AC Mains Line to Ground ±0.5kV, ±1kV and ±2kV AC Mains Line to Line ±0.5kV and ±1kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<0% UT (100% dip in UT) for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225° and 315° 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles Single phase at 0° <0% UT (100% dip in UT) for 250/300 cycles	<0% UT (100% dip in UT) for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225° and 315° 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles Single phase at 0° <0% UT (100% dip in UT) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RelieVRx device requires continued operation during power mains interruptions, it is recommended that the RelieVRx device be powered from an uninterruptible power supply or a battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration -Immunity

The RelieVRx device is intended for use in the electromagnetic environment specified below. The customer or user of the RelieVRx device should ensure that it is used in such an environment.

Table 1.5

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	AC Mains 6Vrms 80% AM at 1 kHz 150 kHz – 80 MHz	AC Mains 6Vrms 80% AM at 1 kHz 150 kHz – 80 MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the RelieVRx device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> $d = \left\{ \frac{3.5}{F_1} \right\} \sqrt{P}$ $d = \left\{ \frac{3.5}{E_1} \right\} \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left\{ \frac{7}{F_1} \right\} \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p>
Radiated RF IEC 61000-4-3	10V/m, 80% AM at 1 kHz 80 MHz – 2700 MHz	(E1) = 10V/m	

1 r.m.s. At 80 MHz and 800 MHz, the higher frequency range applies.

2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the "RelieVRx" is used exceeds the applicable RF compliance level above, the "RelieVRx" should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the "RelieVRx".

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Guidance and Manufacturer's Declaration

Recommended separation distances between portable and mobile RF communications equipment and the RelieVRx device non life supporting ME Equipment.

The RelieVRx device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RelieVRx device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RelieVRx device as recommended below, according to the maximum output power of the communications equipment.

Table 1.6

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	800 MHz to 2,7 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration - Immunity to RF Wireless Communications Equipment

The RelieVRx device is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure that it is used in such an environment.

Table 1.7

Test Frequency	Band ¹	Service ¹	Modulation ²	Maximum Power	Distance	Immunity Test Level
MHz	MHz			W	Meters	(V/m)
385	380 - 390	TETRA 400	Pulse modulation ² 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ³ ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation ² 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ² 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ² 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ² 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11a/n	Pulse modulation ² 217 Hz	0.2	0.3	9

¹ For some services, only the uplink frequencies are included.

² The carrier shall be modulated using a 50 % duty cycle square wave signal.

³ As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst case.

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

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● **Customer Support**

For any other questions or for more support contact our support desk!

Thank you for choosing the RelieVRx program!

USER MANUAL FOR FOR THERAPEUTIC VR PLATFORMS: RelieVRx

NOTE

If you do not understand these instructions, or have any questions or concerns in setting up, using or maintaining RelieVRx and to report unexpected operation or events, contact:

support.avrpathway.com | support@avrpathway.com
+1 (844) PATH4VR | +1 (844) 728-4487

For questions or help with your AppliedVR device, please visit:
support.avrpathway.com or contact us:



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