

 XRHealth		XRBehavior VRFR-930 "First Resort" – Instructions For Use	
Document No.: EFA-010		Rev.: 01	Page 1 of 24
Product Name: XRBehavior VRFR-930 "First Resort"			UDI: 7290016986181



XRBehavior™ VRFR-930 "First Resort"

Instructions for use

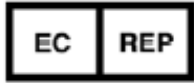
Rx Only

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

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Software Version: XRBehavior VRFR-930 ("First Resort")

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1. Abbreviations and Symbols

VR	Virtual Reality
VRH	Virtual Reality Approved Hardware (list available, appendix A)
HHS	Hand-Held Sensors (part of the VR system, monitoring and enabling interacting with the VR by using hands/fingers)
ROM	Range of Motion
DOF	Degrees of Freedom
VRFR-930	XRBehavior VRFR-930 ("First Resort")
Latest Version	Version
LHP	Licensed Healthcare Provider (Mental Health Professional, Social worker, Physicians, Psychologists, Caregivers, Geriatricians etc.)

2. General Information

2.1. Intended use

The VRFR-930 First Resort is a prescription only software application that provides virtual-reality–based measurements and exercises designed to support the self-management of stress, anxiety, and physical discomfort. The system is used with commercially available head-mounted displays.

VRFR-930 offers guided behavioral and cognitive-behavioral therapy (CBT) training scenarios that help users practice coping strategies and relaxation skills. VRFR-930 does not diagnose, treat, or prevent any medical or psychiatric condition and does not provide a report that analyzes the measurements, makes medical diagnoses, or recommends treatment.

2.2. Intended user populations

VRFR-930 software is intended to be used by the following populations:

- Software operators:
Licensed Healthcare Providers (LHP) and/or patients that utilize exposure therapy as part of their treatment.
- End users:
 - VRFR-930 is intended to assist individuals that will benefit from using XRBehavior series as support for relaxation and cognitive behavioral strategies that may support users experiencing social challenge situations
 - The LHP must confirm their patients' eligibility for VR sessions through an evaluation session and verify that there are no contraindications to carrying out a VR session (carefully read the relevant sections: Cautions, Warnings and Precautions).

2.3. Intended use environment

First Resort software is intended to be used only in the following environments or areas:

- Home environment.
- Healthcare facilities (hospitals, clinics).

3. Contraindications

Before using the First Resort software, the user must be sure that they do not suffer from one or more of the following conditions or disorders :

1. Tumors or other Space Occupying Lesion of cervical region;
2. Undiagnosed neurological symptoms/signs;
3. Acute fracture of the cervical spine (especially fracture of Odontoid Process (Dens));
4. Post MVA (Motor Vehicle Accident) with no previous physician screening, where spinal structures may be compromised.
5. Pathological fractures of spine;
6. Contagious or infectious conditions (while multiple users use same headset);
7. Facial lesions or superficial lesions that may have contact with the VR headset;
8. Any condition where it is otherwise contraindicated to move cervical region actively or passively;
9. Epileptic seizures;

4. Additional Precautions

1. Neck movement may adversely affect users with cervical spine abnormalities, pain or other acute condition; If user feels any discomfort, they should terminate session immediately.
2. The age limit for use is not determined by the software and is subject to the VR headset hardware manufacturer's specified age restrictions.
3. Some users with existing Vertigo or Nausea may experience exacerbation of the symptoms in VR environment; If user feels any discomfort, they should terminate session immediately.
4. Vision disorders – users requiring glasses that does not fit under the VR headset or have other major vision problem that does not allow clear viewing of the VR environment may not be able to use the software appropriately.
5. Acute neck pain – users suffering from acute neck pain may experience difficulties carrying the weight of the VR headset.
6. Consult with your physician before using the software if you have pre-existing vision abnormalities, psychiatric disorders, suffer from a heart condition or other serious medical condition.
7. VR hardware (including headsets, controllers, and other devices) may contain magnets or components that emit radio waves. The frequencies of these radio waves may interfere with pacemakers, hearing aids, defibrillators, or other implanted electrical devices. If you have a pacemaker or other implanted medical device, do not use the VR Hardware without first consulting your doctor or the manufacturer of your medical device. You must maintain a safe distance between the VR hardware and your medical devices, and stop using the VR hardware if there is persistent interference with your medical device.
8. Although the XRBehavior Software is based on techniques and imagery that most users find relaxing, there is a chance that some of the imagery users encounter may evoke unintended anxious feelings based on personal

associations. Also, at times the guided relaxation exercises will ask users to notice and be with their feelings, which can sometimes evoke distress in some users. Please consult with your LHP before using the software if you have pre-existing mental health diagnoses, such as dissociative disorders, psychotic disorders, or severe depressive, trauma or anxiety disorders.

5. Warnings and General Limitations

1. Warning and general limitations related to the safe use of the Virtual Reality Hardware console (recommended for use with XRBehavior software series) are applicable when used with XRBehavior VRFR-930 software.
2. Prior the usage of the commercial Rx only Virtual Reality Hardware, it is required from the user to carefully read all instructions, limitations, and precautions in the Health, Safety, and Warranty Guide attached to the hardware.
3. The LHP must confirm their patients' eligibility for VR sessions through an in-person trial session and clearly guide them on how to safely experience the environment delivered. If the LHP notices any anomalous events or features in the simulated environment being delivered to the patient, they should remove the patient from the environment immediately.
4. XRHealth R&D LTD is not responsible for any malfunctions, defects, or user errors related to the purchase, installation, and use of the above-mentioned hardware.
5. Each VR training session using XRBehavior series software shall not last longer than the continuous duration recommended by the hardware manufacturer.
6. If user is experiencing symptoms associated with: tiredness; dizziness, visual abnormalities (blurred vision, double vision, etc.), disorientation, impaired balance being under the influence of alcohol or drugs; digestive problems; emotional stress or anxiety, suffering from cold, flu or headaches, migraines or earaches the training session must be terminated immediately.
7. If you are, or might be, pregnant, or if you suffer from physical, mental, visual or heart problems, and/or neurological conditions that might make you prone to seizures you should speak with your LHP.

8. XRHealth Mobile app is not for emergency use. Please instruct patients to dial the national emergency response service or go to the nearest emergency room in the event of a medical emergency.
9. In order to create a safe environment:
 - The objects that are seen in the virtual environment do not exist in the real environment, so do not sit or stand on them or use them for support.
 - Remove any tripping hazards from the area before using the hardware.
 - Do not handle sharp or otherwise dangerous objects while using the headset.
 - Make sure the headset is level and secured comfortably on the patient's head, and that they see a single, clear image.
 - Ease into the use of the hardware to allow patients to adjust to it; use for only a few minutes at a time at first, and only increase the amount of time using it gradually as each patient grows accustomed to virtual reality.
 - Take at least a 10 to 15 minute break every 30 minutes. Each person is different, so take more frequent and longer breaks if a patient feels discomfort. The LHP should decide what works best for each patient.
 - Do not use the headset with the sound at a high volume so that patients can maintain awareness of their surroundings and reduce the risk of hearing damage.
10. VRFR-930 is used with commercially available head-mounted displays. The age limit for use is not determined by the software and is subject to the VR headset hardware manufacturer's specified age restrictions
11. XRBehavior environments are designed to be experienced while sitting or, if indicated by the LHP or if the patient prefers it, standing, without walking around while wearing the VR headset to avoid accidents.
12. If delivered incorrectly, exposing patients to challenging simulated environments may have a negative effect on their mental state and well-

being. The LHP should carefully select and/or modulate the simulated environments used according to their patients' needs and capabilities.

13. XRBehavior uses consumer-grade devices (VR headset, smartphone, tablet) that might be used according to their safety information and instructions for use. To reduce the risk of personal injury, discomfort, or property damage, the LHP and the patients (if needed) should read these warnings carefully before use.
14. Special consideration is required when the patient has a history of traumatic episodes or is considered by the clinician to be susceptible to experiencing a triggered traumatic episode. For this consideration, the exposure tools software should only be used when the patient and clinician are physically together in-person (i.e., non-remote/non-virtual setting).

6. VRFR-930 Overview

Software description

1. First Resort is a VR program based on Cognitive Behavioral Therapy (CBT), designed to support patients' emotional well-being over the course of 8 weeks. It guides them through reflecting on values, setting goals, and exploring how thoughts influence feelings and actions — with practices that build awareness, emotional resilience, and a sense of control.
2. XRBehavior is not intended to have any diagnostic function.
3. At the end of each session, training results are presented on the data portal. The data shown only represents actual training results and is not considered a professional recommendation nor intended to be used for diagnostic purposes. Health Care Providers are always responsible for exercising their independent medical judgment in making any and all treatment decisions.
4. VRFR-930 consists of 8 weeks of content, with some required and some optional components. The patient will be introduced to the program and all the core Mechanisms of Action (MoAs) by completing required training and initial sessions of Mindfulness, Cognitive Reframing, and Exposure Therapy.
5. After the program introduction, additional social challenge situations (exposure therapy) will be introduced. The program will prevent the patient from moving any faster than 3 new social challenges each week; however, the patient can always return to any social challenge situation that they have already completed to conduct additional practices of these scenarios. After completion of the 3 new social challenges, continued mindfulness and cognitive reframing practice is encouraged, but not required.

7. Hardware and Software requirements

1. The usage of the XRBehavior software requires a pre-purchase of a high-end off-the-shelf VR platform:
 - The compatible VR platforms for the use of VRFR-930 software, are listed in appendix A: [Approved VRH List](#).
 - A stable internet connection with an upload speed of at least 3Mb/sec and upload speed of at least 0.5MB/sec is mandatory.

8. Software installation and updates (Mobile Device Management - MDM)

1. The VR device must be added to your device list on the Clinician Platform and assigned to a patient in order to function properly.
2. Without an assigned patient, session data will not be stored or linked to any user.
3. Assigning a new patient to the device will restart the program from the beginning.
4. Clinicians can monitor patient activity and progress through reports generated in the Reports tab of the Clinician Platform
5. XRHealth R&D software will be installed, updated and managed by a selected MDM solution for remote headset management.
6. This solution enables XRHealth R&D to fully manage the software version and update status in each device.

9. Instructions for use check list

1. The following instructions shall serve as a check-list for operating the VRFR-930 software:
 - Carefully read the instructions for use by the VRH manufacturer (list of compatible hardware for VRFR-930 available in [Appendix A](#), below).
 - Carefully read the Health and Safety Warning of the VRH manufacturer (list of compatible hardware for VRFR-930 available in [Appendix A](#), below)
 - Assess the medical condition of the user and confirm that it is suitable for using a VR device. In any case that the VR device suitability is unclear, please consult with a physician.
 - Read the [contraindications for use](#) and [additional precautions](#) for the use of VRFR-930 software to ensure safety.
 - Make sure the environment in the location designated for training is free from obstacles; It is advisable to clear the surrounding area from any hazardous furniture or other objects. Follow VRH manufacturer's instructions concerning prior usage environment preparations/precautions.
 - Prior to use, suit the VR Headset and adjust it to your head, as described in the VRH manufacturer's manual.
 - If applicable, safely secure the HHS (VR remotes) to the wrists, as instructed by the VRH manufacturer.
 - If you are wearing glasses, you can choose whether to take them off (most users can see clearly even while not wearing any glasses) or wear the headset over them (some frame types do not fit under the VR Headset, in

such cases the use of contact lens or using alternative glasses is required to use the VR Headset).

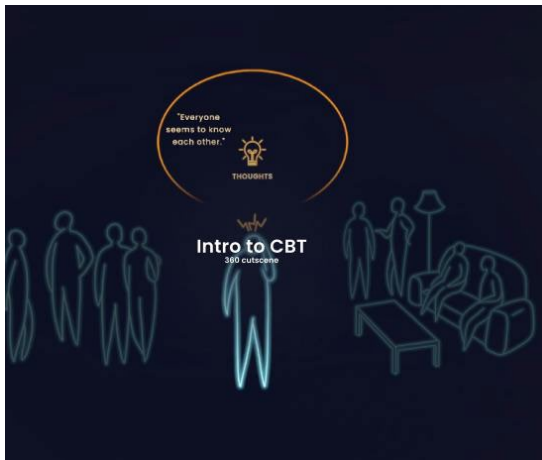
- Immediately terminate the VR session and discontinue using the VR headset in any case of pain, discomfort, dizziness or nausea resulting from the usage of the VRFR-930 software or the attached VRH. Some users may have a transient mild negative sensation associated with the VR environment. In any case that you experience symptoms which are not transient, contact your physician.
- 2. The duration of each VR session shall not last longer than the VRH recommended continuous minutes per patient (see Appendix A: Approved VRH List).
- 3. If you suspect at any time that the performance and/or session instructions do not fit the training plan defined by your physician, immediately stop the training.
- 4. If you suspect that the trouble is related to hardware malfunction/calibration, you can reset the VRH and restart the training session.
- 5. In case that the VR environment is not calibrated/centered, press and hold the calibration button to reset your orientation.
- 6. If you suspect that there is a problem with the VRFR-930 software, immediately contact XRHealth R&D LTD. (or the relevant distributor in your country). Meanwhile, stop using the device.
- 7. If you experience symptoms associated with: tiredness; being under the influence of alcohol or drugs; digestive problems; emotional stress or anxiety, suffering from cold, flu or headaches, migraines or earaches you are required to terminate the training session immediately and discontinue using the VR headset.

10. How to use First Resort

- 10.1. Select First Resort from the XR Portal Library. You will find the app under Behavioral Space.



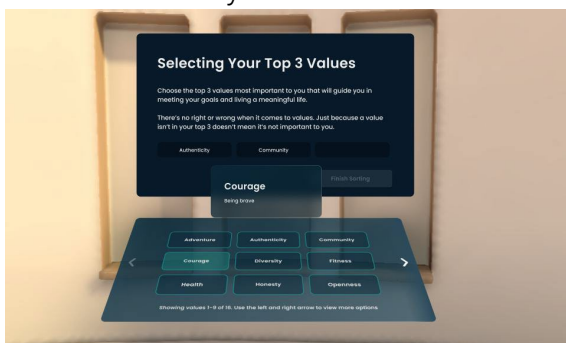
10.2. Watch the first time tutorial. You can watch the tutorial in the app.



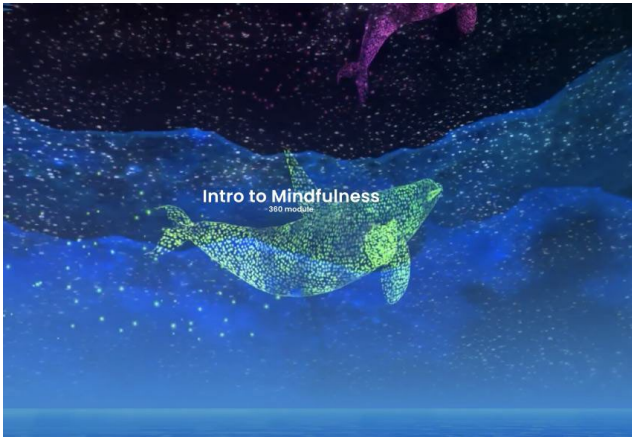
10.3. Complete the short assessments - help the app get to know you and track your mood.



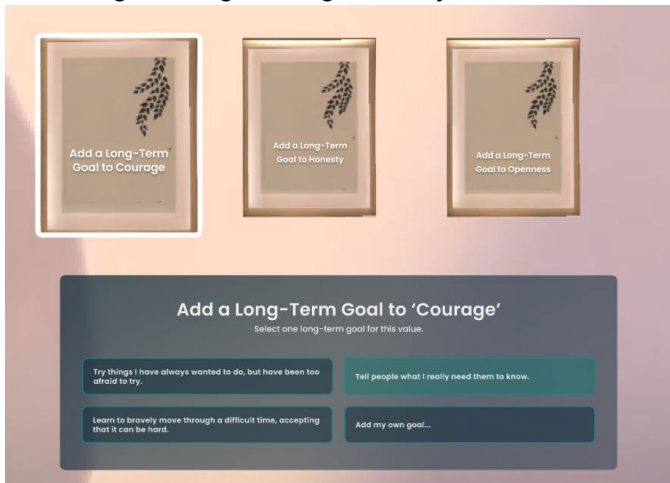
10.4. Set your values - watch a short video about values, then choose the ones that matter most to you.



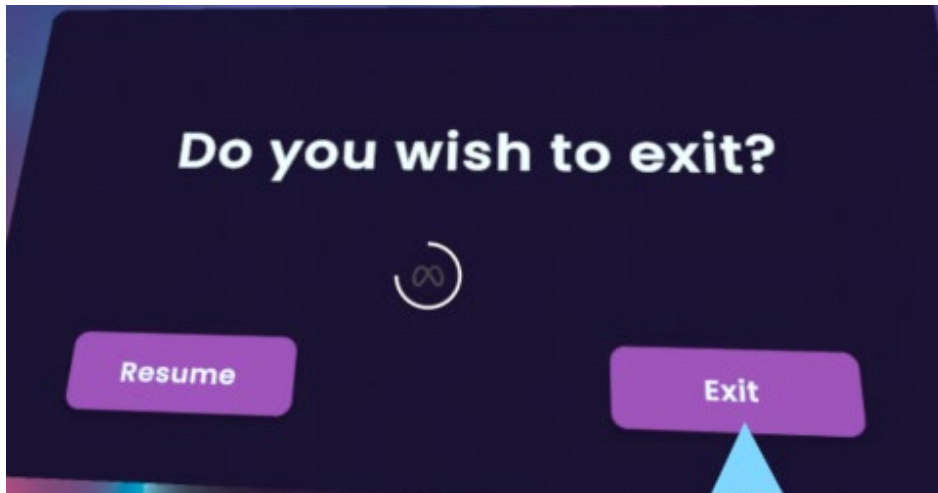
- 10.5. Practice mindfulness - watch an introduction to mindfulness, then follow a guided practice in a calming VR environment.



- 10.6. Set your long-term goals - watch a video on goal setting, then define a meaningful long-term goal for yourself.

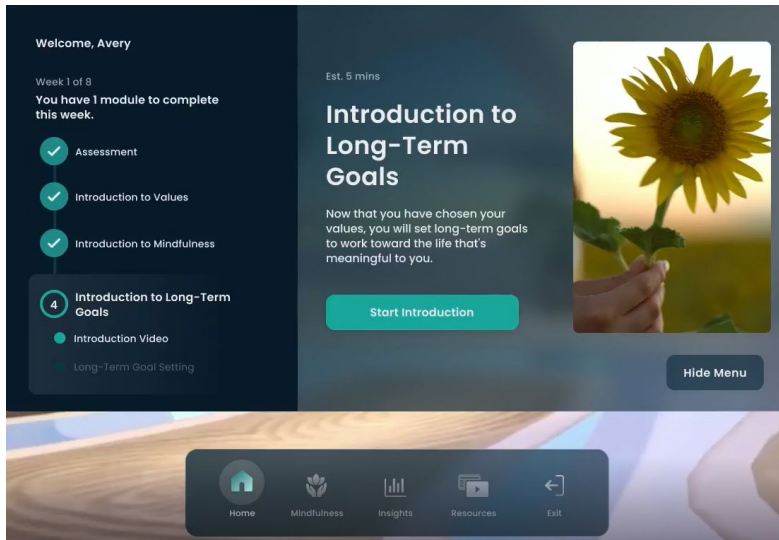


- 10.7. After completing this steps you will get to the the Home screen, where you can explore, revisit content, or continue at your own pace.
- 10.8. To exit the application, press the Menu button on your left controller and select "Exit."



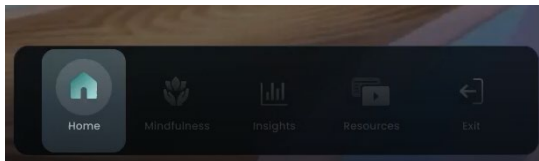
- 10.9. Each time you start the program, you will see the home screen. In the middle panel, you can see which practice you are currently on and a brief description of it. Sometimes there will be informative videos to watch before starting a new module. You c



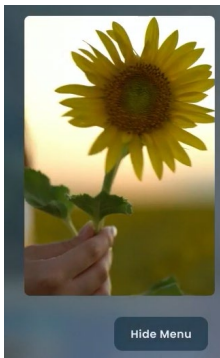


10.10. You can track your progress using the panel on the left-hand side. It shows the requirements for each week and which practices you still need to complete.

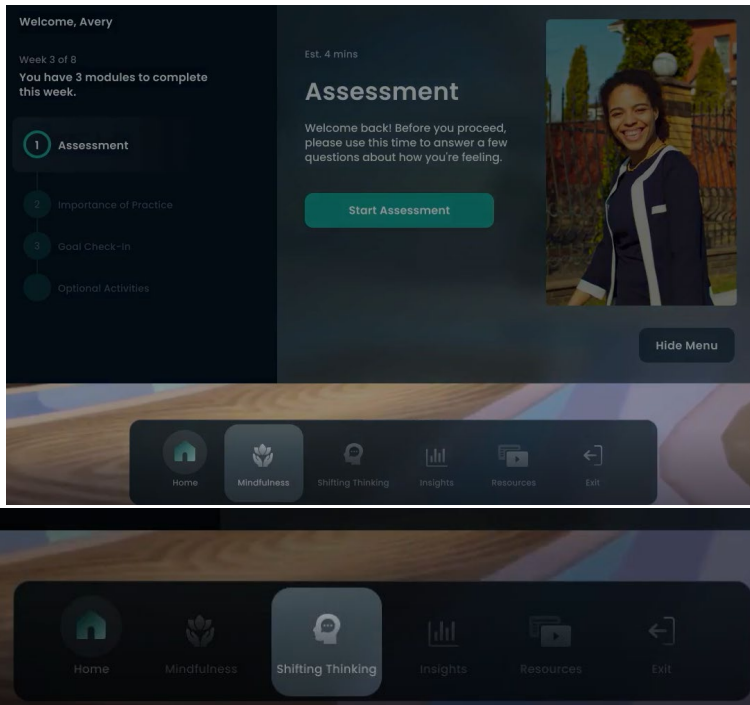
10.11. The home button on the left side of the bottom menu takes you back to the home screen.



10.12. You can hide the lower menu by clicking "hide menu".



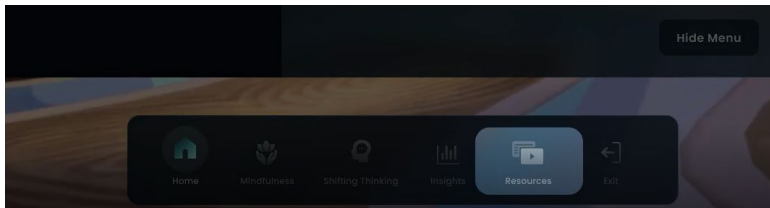
10.13. Once you have completed your first introduction video and practice session, you can revisit mindfulness and "shifting your thinking"



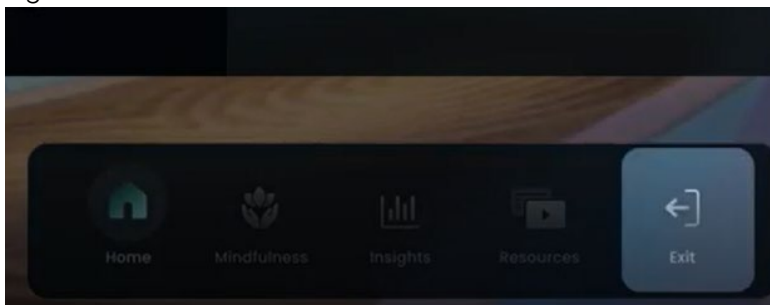
10.14. To revisit your values and goals you can go to your home environment and use the trigger on your controller and click on your plex on your home wall.



10.15. By clicking the “resources” button, you can always come back to any instructional video.



10.16. You can also leave the app by clicking the save and exit button on the bottom right.



10.17. The 8 week program will be as follows:

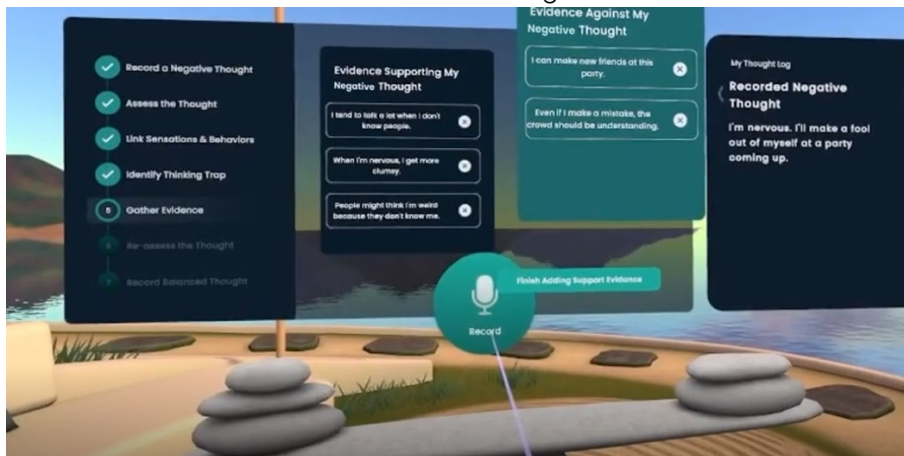
Week 1	Week 2	Week 3	Week 4-7	Week 8
Introduction to CBT + How to Get Around	Progress Assessment	Progress Assessment	Progress Assessment	Goal Check-In
First Assessment	Short-Term Goal Setting	Importance of Practice	Goal Check-In	Final Assessment
Introduction to Values + Values Setting	The Power of Your Thoughts Video	Goal Check-In	Optional: Practice Shifting Thinking / Mindfulness	Graduation and Maintenance
Mindfulness: Introduction + Practice	Shifting Your Thinking Video + Practice			Optional: Practice Shifting Thinking / Mindfulness
Long-Term Goal Setting				

10.18. Each week will unlock a new session. Each session lasts about 20 min, and includes:

- Cognitive behavioral education – Short, engaging videos introduce foundational CBT concepts such as thought patterns, emotional regulation, and behavior change Strategies.

- Values & goal setting – Users are guided to identify meaningful values, establish long term goals, and define short-term, actionable steps that align with those values.
- Mindfulness Practice – Calming, guided mindfulness experiences are included throughout the program to support emotional self-regulation and stress reduction.
- Reflection & reinforcement – Each week includes opportunities to revisit previous content and reinforce key skills through interactive practices and goal check-ins.

10.19. After weeks 1 and 2 there will be no set number of mindfulness sessions or “shifting your thinking” exercises you need to do. Instead, you can return to “shifting your thinking” whenever you have stressful, uncomfortable or worrisome thought.



10.15. Each week, a new mindfulness experience will open, with a new lesson, set in a new place. It is recommended to try this each week.

Notes:

- Each week begins with a short mental health assessment (PHQ-2, GAD-2, PSS-4 on weeks 1, 4, 8).
- You can always revisit previous content, and the app will suggest practices to repeat.
- Most users find the first two weeks the most content-heavy - it is recommended to split them into 2–3 shorter sessions.
- From weeks 3-8 you will need to check in on your short term goals each week.

- It is recommended to use First resort at least 3 times each week.
- To exit the application, press the Menu button on your left controller and select "Exit."

Appendix A: Recommended VRH List

For a list of recommended devices please refer to XRHealth Release Notes available at <https://www.xr.health/us/regulatory-information/>

Appendix B: Common Software Troubleshooting

- ❖ **Cannot Login –**
 - ❖ Make sure you have the correct XRHealth credentials received with onboarding e-mail. If you don't have credentials – contact support@xr.health.
 - ❖ Make sure your headset is connected to local Wi-Fi network.
- ❖ **Application is stuck –** Close the application using the home button and re-open it.
- ❖ **Software doesn't load (Stuck in loading animation) –** If closing and re-opening the app doesn't help – Re-install the application:
 - ❖ Go to library, and on the bottom right of the App icon, select Uninstall.
 - ❖ After uninstalling – reinstall application
- ❖ **Miscellaneous –**
 - ❖ Restart application
 - ❖ If that does not help – Reboot headset
 - ❖ Last option – Uninstall and Re-install application

**These Instructions for Use (IFU) is also available as a hard copy. If you are interested in printed copy of this IFU, please send a request to the customer support and it will be printed and delivered within 30 days.