



VRReliever™ PD-810 "Mindset"

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: VRReliever PD-810 ("Mindset") V 1.1.0

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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
PD-810	VRReliever PD-810 (“Mindset”)
Latest Version	Version 1.1.0

2) General Information

Intended use

The PD-810 ("Mindset") is intended to assist in relaxation and management of pain and physical discomfort through distraction and supporting meditation and relaxation exercises, performed in a virtual reality (VR) environment using commercially available VR headsets. The PD-810 is a prescription only device that can be used in clinical setting or at home, with or without the assistance of licensed health care provider. The PD-810 provides VR exercises and takes measurements which enables the patient and/or clinician to monitor changes over time. PD-810 does not provide a report that analyzes the measurements, makes medical diagnoses, or recommends treatment.

Intended user populations

PD-810 software is intended to be used by the following populations:

Software operators

Licensed Health Care Providers (i.e. Physical therapists, Physicians, Psychologists, Caregivers, Geriatricians etc.) and/or patients, that utilize physical activity as part of conventional treatment.

End users

Individuals that will benefit from using VRReliever series for relaxation and self-management of pain and physical discomfort.

Intended use environment

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

- Home environment;
- Healthcare facilities;

3) Contraindications

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

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. Pathological fractures of spine;
5. Post MVA (Motor Vehicle Accident) with no previous physician screening, where spinal structures may be compromised;
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. 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.
3. 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.
4. Acute neck pain – users suffering from acute neck pain may experience difficulties carrying the weight of the VR headset.
5. Consult with your physician before using the software if you have pre-existing vision abnormalities, neck pain or spine abnormalities, psychiatric disorders, suffer from a heart condition or other serious medical condition.
6. 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.
7. Although the VRReliever 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 physician or mental health clinician 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 VRReliever software series) are applicable when used with VRReliever PD-810 software.
2. Prior the usage of the commercial “off-the-shelf” 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. XRHealth IL LTD is not responsible for any malfunctions, defects, or user errors related to the purchase, installation, and use of the above-mentioned hardware.
4. Each VR training session using VRReliever series software shall not last longer than the continuous duration recommended by the hardware manufacturer.
5. 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.
6. 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.

6) PD-810 Overview

Software description

1. The PD-810 is a medical software that provides programmed exercises within a gamified three-dimensional VR environment to assist in relaxation and self-management of pain and physical discomfort through distraction and supporting meditation and relaxation exercises.
2. The PD-810 software is intended to be operated can be used in clinical setting or at home, with or without the assistance of clinician (see Intended use environment).
3. The current version of PD-810 includes a single game: “Mindset”.
4. The software offers a unique user experience throughout the whole training session, as well as data collection. Remote access to the training data allows the patient and the healthcare professional to monitor the patient’s progress.
5. PD-810 software guides patients in the performance of relaxation techniques, according to a selection of combined session play:
 - Volume control
 - Path of relaxation
 - Training Room level of choice
 - Video Selection
6. PD-810 software is not intended to be used for diagnosis or making treatment decisions.
7. 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.

Hardware and Software requirements

8. The usage of the PD-810 software requires a pre-purchase of a high-end off-the-shelf VR platform:
 - The compatible VR platforms for the use of PD-810 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.

Software installation and software updates via Oculus store

9. The software shall be downloaded and installed from the VRH store application and can be accessed by entering the applicable XRHealth IL software credentials (username and password).
10. The software comes with automatic update capabilities.
11. When the software is launched – it checks if the version being run is the latest version available. If not – the user receives a notice and can update the software to the latest version.
12. For safety reasons, XRHealth IL can define an update as mandatory for all users. If a mandatory update is necessary, the user will receive a notice that he and must download the update for safety reasons.
13. For regular updates, the user can select if to install the update, or not.

Software installation and software updates via MDM (mobile device management) solution

14. Any other software can be installed, updated and managed by a selected MDM solution for remote headset management.
15. This solution enables XRHealth IL to fully manage the software version and update status in each device.

7) Instructions for use

1. The following instructions shall serve as a check-list for operating the PD-810 software:

- Carefully read the instructions for use by the VRH manufacturer (list of compatible hardware for PD-810 available in [Appendix A](#), below).
- Carefully read the Health and Safety Warning of the VRH manufacturer (list of compatible hardware for PD-810 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 PD-810 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.
- 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 PD-810 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 game 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 PD-810 software, immediately contact XRHealth IL 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.

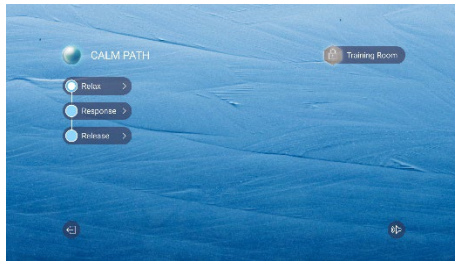
8) PD-810 Training Experience

Mindset Overview

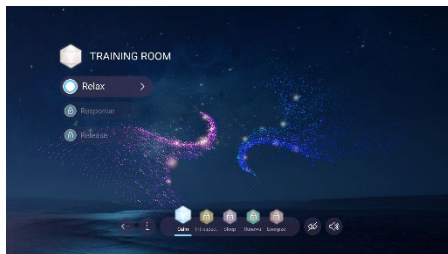
- The game is comprised of three main modules: "Paths", "Training Room" and "Explore"



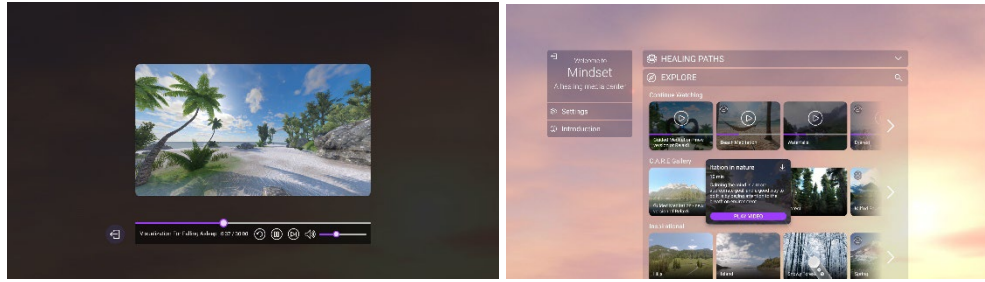
- In the **Path module** the user can select from different Paths. Each path is a learning path, where user is introduced to pain and stress management techniques, using voice guidance and guided imagery.



- In the **Training Room module**, the user can select from different Pain and Stress Management training levels, where they can interact with visuals to practice a previously learned Path. Training is achieved by an interactive game play as users activate visual elements by using their gaze.



- In the **Explore** module, the user can select from different videos, each offering different relaxation and meditation practices.



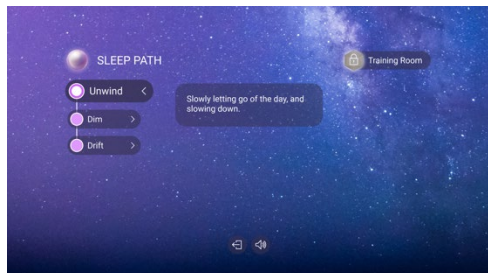
- **It is recommended to use the application while sitting down.**

Paths

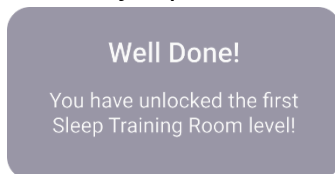
For first time users, Mindset will automatically launch an introduction tutorial, explaining about the app’s purpose and usage.

Paths Experience

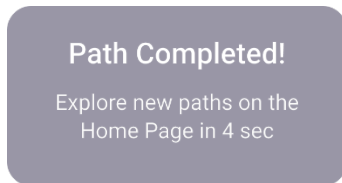
- When users enter a selected path, they will see the path menu UI. The menu will reveal the three steps of the current path, and when hovered, each step will present its description.
Volume control, quick access to training Room button and Exit Path are also available on the UI.



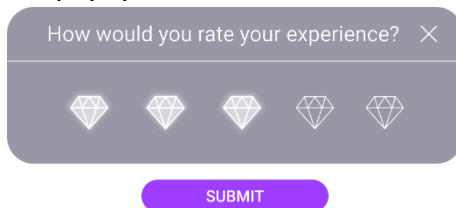
- When user first enter a path, they will hear an **introduction narration**.
- Path will begin and take the users through an **opening narration** with Pain and Stress management guidance, then a **video** will begin to play, followed by a **closing narration** with emphasis on key takeaways from the learned meditation technique.
- When a path step was completed, a Training Room level will unlock, allowing users to jump into the training room and practice the learnt technique.



- When users completed all three steps of the path, they will be notified on the completion of the path and offered a chance to explore more Paths. Users can opt out easily by exiting the path.



- Path Rating - Completing a path will prompt a satisfaction rating pop up, where users can rate the path on a scale of 1-5. Users can opt out of rating by closing the popup.

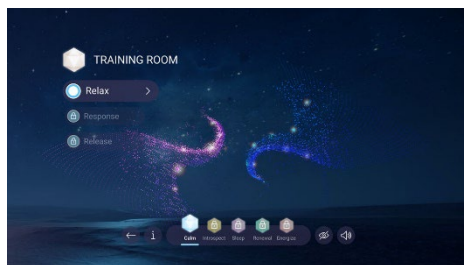


- Continue Path - Users that have exited a path in the path, and now wish to return to it, will be given the chance to continue from where they left



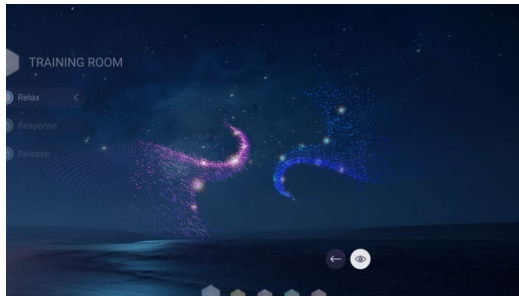
Training Room Experience

- When Users have unlocked at least one training room level, the Training Room Button will become available. Users entering the Training Room will be presented with a menu UI.
- Menu will consist of a bottom **Room Selector**, and a left **Level Selector**.
- Hovering on menu items will reveal a description of each of the levels, and the functionality of the various icons.
- Additional functionalities: Exit Training Room, Hide/Show menu, volume control.



Levels

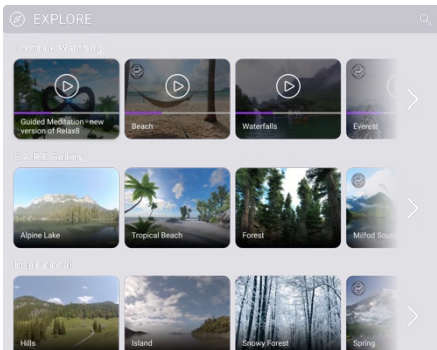
- Each level will present an interactive game, where users use their **gaze** to activate 3d object and particle effects. As a result of activating these elements, the environment will display visuals corresponding with the intent of the learned path. Eg: Calmer/relaxed starry skies.
- Users can train as long as they wish and exit at any given moment.
- **UI can be hidden** for a more immersive experience while training. When UI is hidden, the show for a more immersive experience while training. When UI is hidden, the show UI and Exit Training Room are still available.



Explore Experience

Users can browse through playlists of videos and select videos to view.

Each 360-video thumbnail includes an indication to let users know it is viewable in 360.

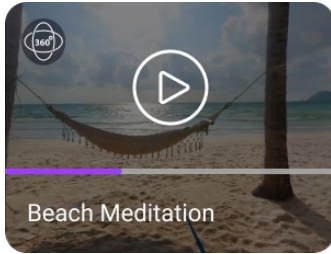


Continue Watching

Users can choose to continue watching a previously started video and watch from the same point they left. Previously watched videos will be marked with a

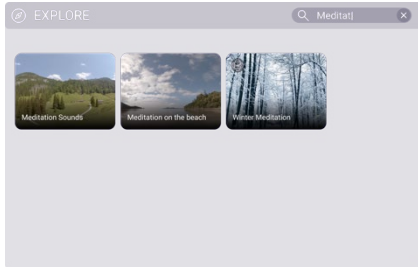
progress

bar.



Search for a specific Video

Users can opt to perform a search when looking for a specific video.



Download a Video for offline viewing

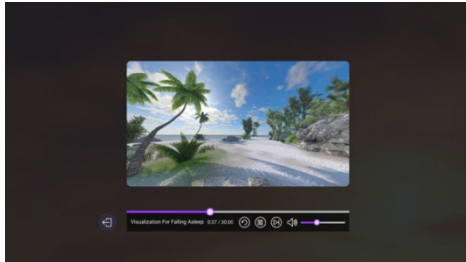
Users can download videos to their HMD, so that they can view when offline.



Watching Videos

Users will select and play any of the available videos in Explore.

While watching, users will be able to prompt the video controls, so that they can seek, pause, replay, or exit the video at any time.



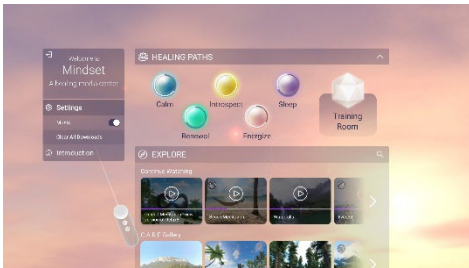
When watching a video, users will be offered to continue to the next video in the playlist. This option will present itself close to the current video end. Users will be offered the chance to exit if they do not wish to watch the next video.



General

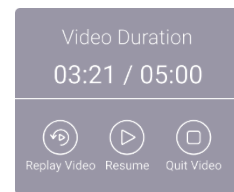
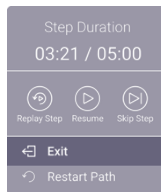
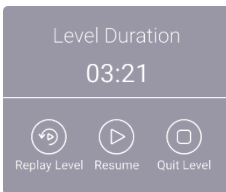
Music:

Music can be turned off completely during Mindset, and volume can be controlled on each module



Pause Menu

Pressing the Pause button on the controller will pause the session and open the Pause menu. Pause menu is available in the Home page as well as on each of the modules, offering users a chance to quit, resume, replay and module specific options.



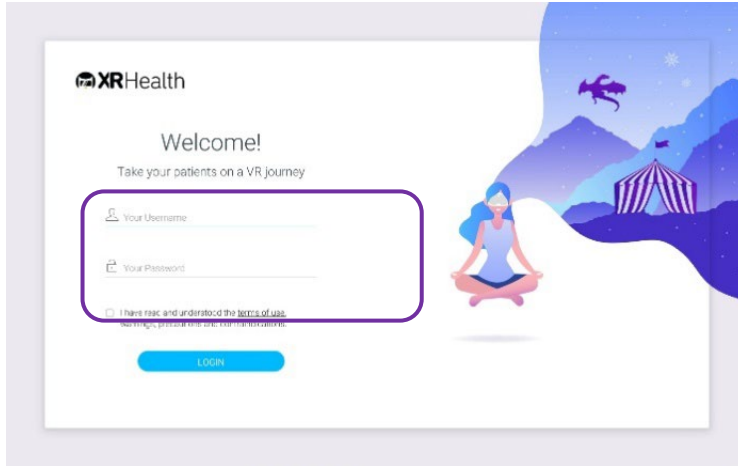
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9) External Control

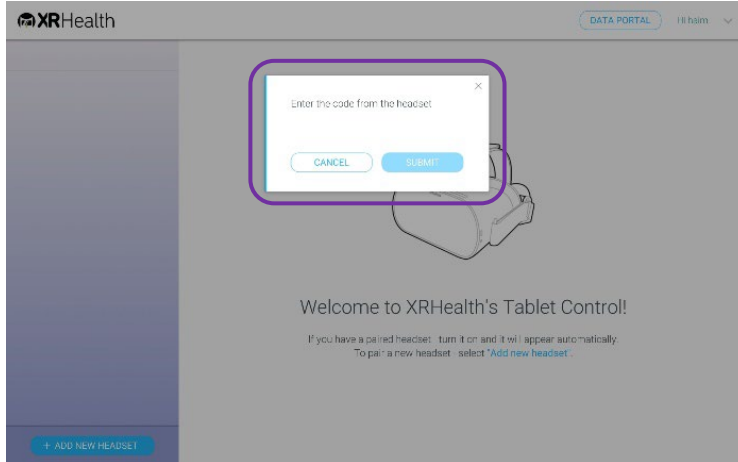
External control over the VR device is available via the XRHealth External Control app. To fully use all features of the External Control App – please fully read its User Manual.

Here is a short summary of how to operate Mindset via the External Control:

1. Login – Login to the External Control app using your Clinician credentials.

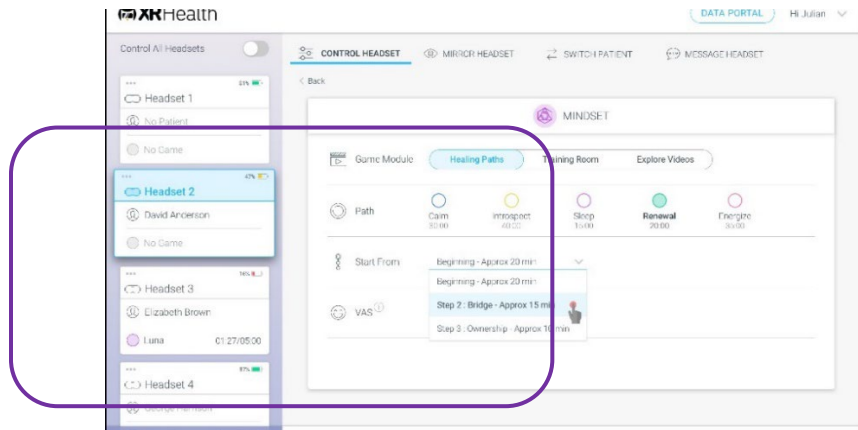


2. Pair a desired headset to external control device.

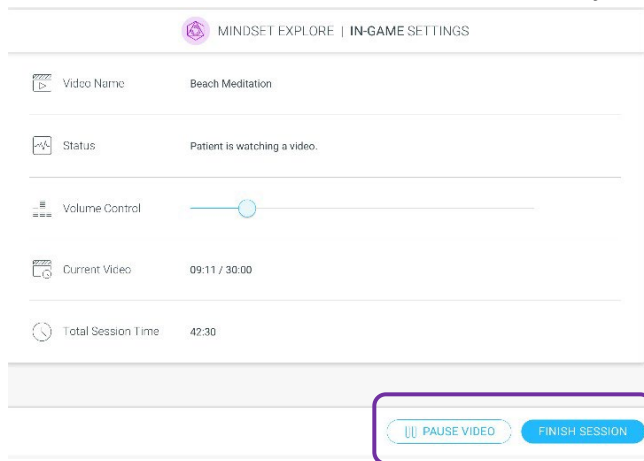


3. Select the patient with the VR device from the patient list.

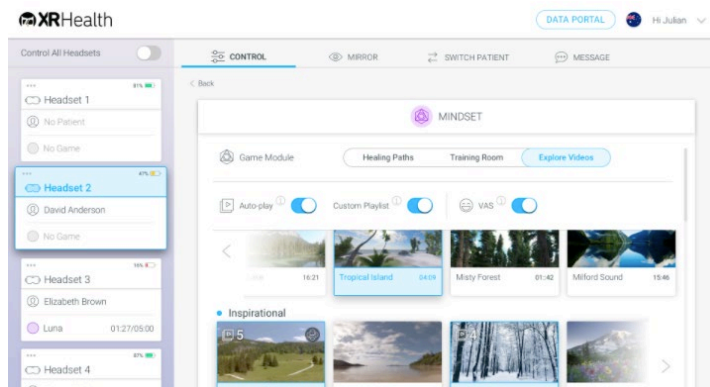
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7. You can Pause or Finish the session at any time.

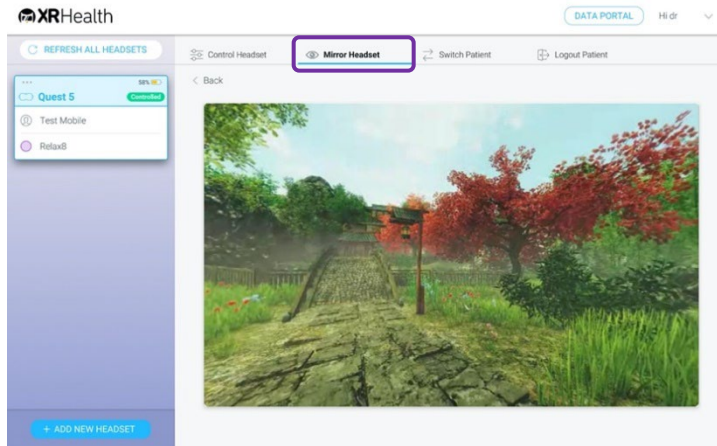


8. Only using the External control, you can define a “Custom playlist” in the Explore tab (and not use the pre-defined ones). To do so – go the explore tab, make sure to turn on “Auto Play” (which enables continuous watching) and then turn on the “Custom Playlist” toggle. When on – select the videos you desire on the playlist, one by one, and press “Save”.



This will save your playlist locally and have it set up for your next use. To run the playlist on the headset, just press “Start session”. To select a new playlist, press “Clear Playlist”.

9. Selecting the “Mirror” tab will show you the patient view within VR.



10) Data Portal

General

- 1) XRHealth Data Portal is a web interface, accessible from any device, that enables patients and clinicians to interact with user data and performance.
- 2) The Data Portal is the main interface for a clinician to create and manage his patients.
- 3) XRHealth Data Portal is accessible in the following URL:
<https://portal.xr.health>

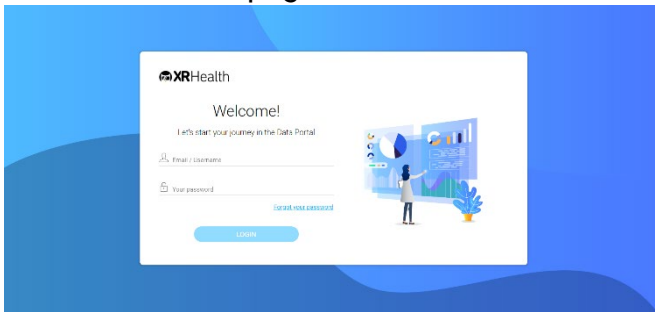
Clinician Onboarding process

1. As a clinician you will need to go through an onboarding process in the web portal on your first login.
2. Marketing team will supply you with an initial username and password. If you do not have your credentials, please contact support at support@xr.health.
3. Go to <https://portal.xr.health> and login with the supplied username and password to start the onboarding process.
4. In the onboarding process you will be required to set up your personal detail, email and new password.

Login

5. Login page is accessible on <https://portal.xr.health>
6. In order to login you will need your user credentials (patient or clinician). If you do not have your credentials, please contact support at support@xr.health.
7. For home users – the credentials for log in to the Data Portal are the same one used in the VR Portal.
8. Logout – once logged in – the option to logout is in the top right corner (press on the profile settings character)
9. Auto logout – for security reasons, the Data Portal will automatically logout after 15 minutes of inactivity.

10. After login you will see XRHealth welcome page where you can navigate to activities page or one of the dashboards.



Activities

On the activities page you can view a list of all your sessions sorted from the last session to the first. Each line represents a session you have completed.

Expand to see your data for a specific session by clicking a line.

App Name	Session Date	Session Duration	% of change from last activity
Re-Act	May 31, 2020 1:01 PM	17:49 min	14%
Mindset	May 30, 2020 12:17 PM	145:30 min	N/A

MEDIA TYPE	MEDIA NAME	DURATION	% COMPLETION
Explore	Visualization of falling a sleep	25:07 min	30%
Explore	Guided Meditation - new version of Relax8	30:05 min	10%
Training Room	Introspect	43:02 min	
Explore	The sounds of nature - relaxation and mindfulness	15:14 min	82%
Path	Renewal	07:34 min	44%
Path	Calm	03:56 min	25%

Luna - Breathing	Oct 5, 2018 6:05 PM	10:01 min	58%	1559
Re-Act	Oct 5, 2018 4:03 PM	06:14 min	3%	11873

The Mindset activity page will enable you to see your results for session:

- i. Pain scale – presents the subjective choice of the user for determining the severity of the symptoms before, and after the session. On a scale of 1-10.
- ii. Duration in Paths

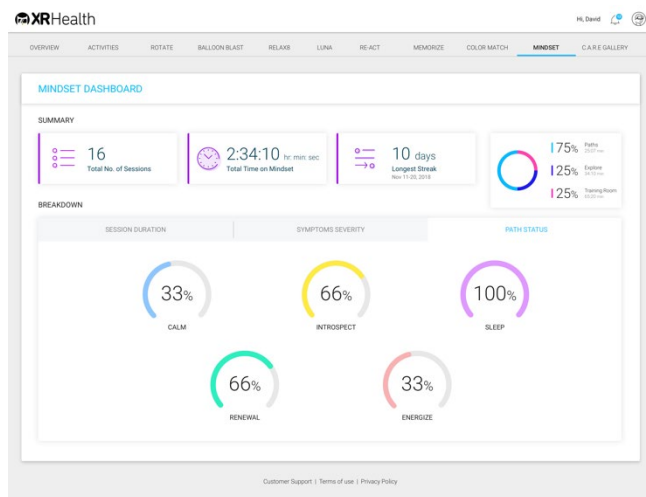
- iii. Duration in Explore
- iv. Duration in Training Room

Dashboards

- i. In the dashboard view you can see progress overtime and adherence to treatment. This is where you can compare results to others, see activity history and get meaningful insights from sessions.
- ii. Navigate to the desired dashboard by clicking on the application name from the top bar.
- iii. Dashboards have 3 main sections:
- iv. Summary: The upper tiles of the dashboard show the user best score in the application for various metrics monitored over time.
- v. Breakdown: The main graphs shows how the user metrics changes over time. You may view the following graphs:

- 1.1.. Session duration between sessions
- 2.2.. Breathes per minute between sessions
- 3.3.. Accuracy between sessions
- 4.4.. Pain scale (VAS) between sessions

You can select to see last 5/10/15 or all sessions performed. In the graph you can toggle between different metrics to see your results over time and compare them to others.



User Profile

11. Both a patient user and a doctor user can access the user profile from the right side of the top bar.

12. Managing your user profile enables the user to perform 2 things:

Change personal details: Name, Last Name, Email/username

Change password

The image displays two side-by-side screenshots of the 'PROFILE SETTINGS' interface. The left screenshot shows the 'Profile' tab selected, with fields for 'First Name' (John), 'Last Name' (Doe), 'Username \ Email' (ttest@vrh.com), 'Birth Year', and 'Gender' (radio buttons for Female, Male, Ambiguous, Other). A 'SAVE CHANGES' button is at the bottom. The right screenshot shows the 'Password' tab selected, with a note: 'Please choose a new password that you haven't used before. Password should be eight characters with upper case, lower case and numbers.' Below this are fields for 'Old Password', 'New Password', and 'Confirm New Password', each with a strength indicator icon. A 'SAVE CHANGES' button is also present at the bottom.

Patient List (For clinician user only)

1. When you are logged in as a clinician, the first page you will see is the patient list.

13. The patient list is a list of all your clinic patients.

14. Use the top search bar to search for a specific patient – you can search a patient by any of the patient fields:

MRN

Patient Name

Email / Username

PATIENT LIST			
MRN	PATIENT NAME	BIRTH YEAR	EMAIL/USERNAME
	Reut Orr		reuttest
	Neta Orr	2009	netatest
	Tk Demo		tkdemo
20805465	Michael Levy	1979	miki@vrhealthgroup.com
	Eran demo2 Orr		eran demo 2
	Eran Orr		eran@vrhealthusa.com

15. Pressing on a specific patient will take you to his activities page. From the activities page you can navigate to any of the dashboards by using the top navigation bar.

Patient Management (For clinician user only)

×
NEW PATIENT

PATIENT INFO ^

✉ Email / Username*

📧

* Use either email/username. Entering an email is necessary for home use. We will not use this email for any other purpose.

👤 First Name

👤 Middle Name

👤 Last Name

📄 MRN

📅 Birth Year

Gender

Male
 Female
 Ambiguous
 Other

PATIENT DIAGNOSIS ^

🔍 Powered by IMO®

SEARCH

💬 Additional Notes

SUBMIT

CANCEL

CREATE

1. XRHealth Data Portal enables a clinician to create / edit / delete patients.
16. We highly recommend filling up patient demographic and medical details in order to get the normative values for people in the relevant age group / diagnosis.
17. In order to create a new patient, press the “Add New Patient” button on the upper right side of the patient list.

Filling Email / Username field is mandatory

We recommend you fill Name / MRN in order to easily associate a specific user to a specific patient and track patient’s progress over time

Birth Year is important to create a relevant comparison to users in the same age group

Patient diagnosis field includes 2 fields:



- **Diagnosis field** – This field incorporates a smart search that goes through the ICD 10 codes and returns the different options to select from.
 - ❖ After the first search you might see an arrow facing down on the right side of a diagnosis – this arrow means this diagnosis has different categories to choose from
 - ❖ If you open that field using the arrow you will be presented with filters to select in order to narrow down the options.
 - ❖ Under the filter mechanism you can find the relevant list of diagnosis to choose from.

- ❖ At any stage – pressing the select button will add that diagnosis to your patient file.

- **Additional notes field** – This field is a free text field to enable you to add any additional notes on your patients

Both patient diagnosis fields save the time of update and enable you to add more diagnosis / edit / delete.

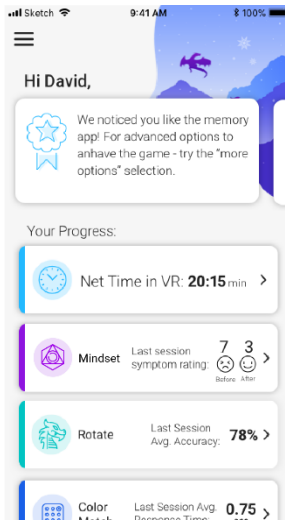
18. In order to edit a patient, hover on the patient row and hit the edit patient symbol on the right

MRN	PATIENT NAME	BIRTH YEAR	EMAIL/USERNAME	
	Reut Orr		reuttest	 

11) Mobile App

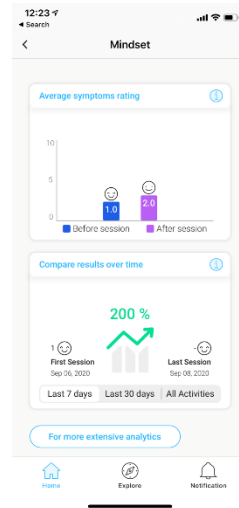
General

- 2. XRHealth Mobile app is the main patient interface that enables:
 - a. Tracking training performance in the different apps
 - b. Receiving notifications and updates about their training
 - c. Exploring a variety of videos, blog posts and health related information
- 3. The Mobile app is available for both iOS and Android devices.
- 4. The application flow includes:
 - a. Login (with the option of enabling FaceID or FingerID)
 - b. App Tutorial flow showing the different screens in the app
 - c. Home screen – displaying:
 - i. Recommendations and encouragements about the patients training
 - ii. Total net training time in VR
 - iii. Last session’s main performance indicator result (for each application used)

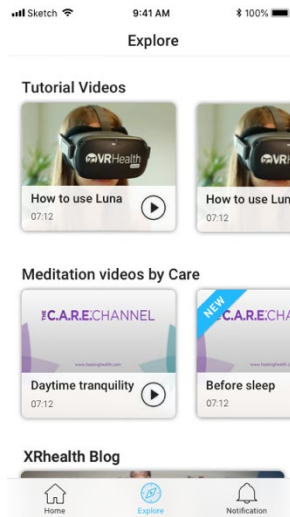


- d. In depth data screen (for a specific app) shows the following data:

- i. Last, Avg. and Best results compared to other users on the XRHealth platform
- ii. Change in average result over time:
 - 1. Last 7 days
 - 2. Last 30 days
 - 3. All activities



- e. Explore – a variety of videos, blog posts and health related info



- f. Notifications – notifications generated based on patient data giving insights and metrics about the patients results

12) Appendix A: Approved VRH List

The software is compatible with 3DOF and 6DOF standalone VR Headsets.

Recommended VRH List

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

13) 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.