



VRReliever™ MD-710 "Relax8"

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 MD-710 ("Relax8") V1.2.6

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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
MD-710	VRReliever MD-710 (“Relax8”)
Latest Version	Version 1.2.6

2. General Information

Intended use

The MD-710 ("Relax8") 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 MD-710 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 MD-710 provides VR exercises and takes measurements which enables the patient and/or clinician to monitor changes over time. MD-710 does not provide a report that analyzes the measurements, makes medical diagnoses, or recommends treatment.

Intended user populations

MD-710 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

Relax8 software is intended to be used only in the following environments or areas:

- Home environment;
- Healthcare facilities;

3. Contraindications

Before using the Relax8 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;
10. For breathing module only – do not use if you suffer from Active Asthma, Chronic Obstructive Pulmonary Disease (COPD) or Congestive Heart Failure.

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 MD-710 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. MD-710 Overview

Software description

1. The MD-710 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 MD-710 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 MD-710 includes a single game: “Relax8”.
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. MD-710 software guides patients in the performance of relaxation techniques, according to a customized session play defined by setting:
 - Session environment;
 - The total duration of the training session;
 - Number of guided breathes per minute;
 - Vocal guidance during session;
6. MD-710 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 a summary screen. 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 MD-710 software requires a pre-purchase of a high-end off-the-shelf VR platform:
 - The compatible VR platforms for the use of MD-710 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

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

- 13.1. Any other software can be installed, updated and managed by a selected MDM solution for remote headset management.
- 13.2. This solution enables XRHealth 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 MD-710 software:

- Carefully read the instructions for use by the VRH manufacturer (list of compatible hardware for MD-710 available in [Appendix A](#), below).
- Carefully read the Health and Safety Warning of the VRH manufacturer (list of compatible hardware for MD-710 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 MD-710 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 MD-710 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 you 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 MD-710 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. MD-710 Training Experience

Relax8

The game is comprised of two main modules: "Meditation" and "Breathing".

In the Meditation module the user can select different environments and enjoy guided meditation sessions.



The Breathing module is based on "lazy eight" breathing technique which combines paced breathing with tracing an 8-figure track in a 3D environment.

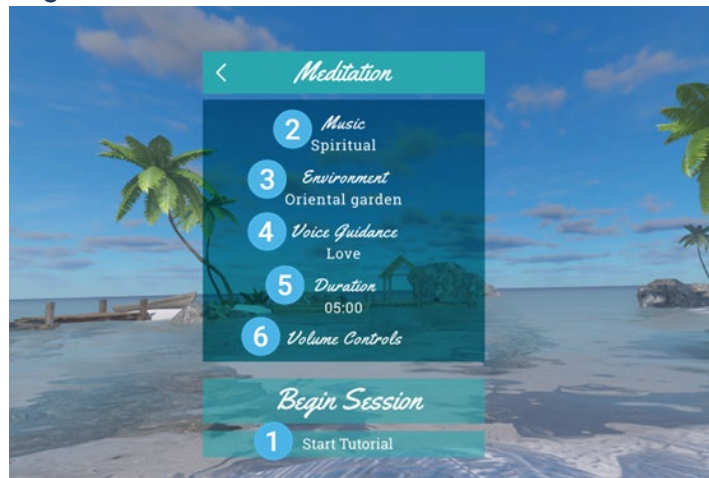
It is recommended to use the application while sitting down.

Meditation

Game Flow

Meditation – Listen to a session of guided meditation while in natural VR environments.

Meditation Settings screen

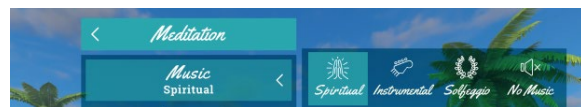


1. Start Tutorial:

Play the meditation tutorial. Tutorial will run automatically while using the application for the first time.

2. Music:

Choose the session background music out of 3 options: Spiritual, Instrumental, Solfeggio, or choose not to play music during the session.



3.Environment:

Choose the scenery in which the session will take place in. Choose from an oriental garden, a beach or a forest.

4.Voice Guidance

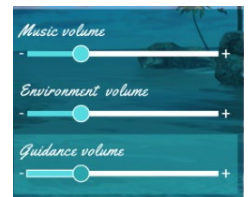
Choose the type of voice guidance you would like to listen to while practicing meditation out of 3 options: Love, Relaxation, Healing or choose not to play voice guidance during the session.

5.Duration

Choose the session duration: 5 or 10 minutes. Pausing and stopping the session is available at any time during the session through the Pause menu.

6.Volume Control

Control the volume of the different sound features: background music, environment background sound and voice guidance.



Pause Menu

Pressing the Pause button on the controller will pause the session and open the Pause menu. You can change the type of music, environment and control the volume. In addition, you can start over by pressing the "Restart" button. You can choose whether to finish the session or resume. Furthermore, you can quit the game and go back to the XRHealth Portal.



Summary screen

The summary screen presents the duration of the last meditation session, as well as the session's properties – Session type and Guidance type.

To start a new session – Meditation or Breathing, press the "New Session" button. You can choose to stay in the environment without starting a new session by pressing "Stay in Environment".



Breathing

Game Flow

Follow the butterfly and point at it with the controller as it flies along the lazy-eight track. While pointing on the target, an aura will surround it.

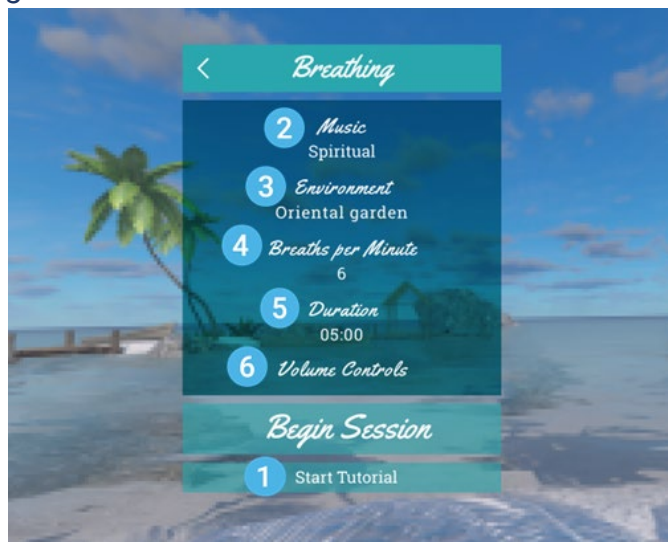


When the target is on the left side of the 8-figure, breathe in. When it reaches the right side, breathe out.

Increase or decrease the target's speed by swiping/pressing up/down on the track pad or pressing up/down on the Thumb-sticks (depending on VRH).

For *6DOF VRH* it is possible to use either right hand or left hand (default is right hand). The selection is available on the settings screen.

Breathing Settings screen



1. Start Tutorial:

Play the Breathing tutorial. Tutorial will run automatically while using the application for the first time.

2. Music:

Same as in Meditation, choose the session background music out of 3 options: Spiritual, Instrumental, Solfeggio, or choose not to play music during the session.

3.Environment:

Same as in Meditation, choose the scenery in which the session will take place in. Choose from an oriental garden, a beach or a forest.

4.Breaths Per Minute

Choose the rate of breaths you would like to practice from a scale of 2-11 breaths per minute.



This parameter sets the initial speed of the butterfly.

5.Duration

Choose the session duration from a scale of 1-10 minutes. Pausing and stopping the session is available at any time during the session through the Pause menu.

6.Volume Control

Same as in Meditation, control the volume of the different sound features: background music, environment background sound and voice guidance.

Pause Menu

As in Meditation, pressing the Pause button on the controller pauses the session and opens the pause menu. You may change the type of music, environment and control the volume. In addition, you can start over by pressing the "Restart" button. You can choose whether to finish the session or resume. Furthermore, you can quit the game and go back to the XRHealth Portal.

Summary screen



The summary screen presents the session's properties as set at the beginning of the session: Session type and Breaths per minute.

The session's results are presented on the right side of the screen:

Duration, Average Breaths Per minute, and accuracy percentage of following the target.

To start a new session – Meditation or Breathing, press the "New Session" button.

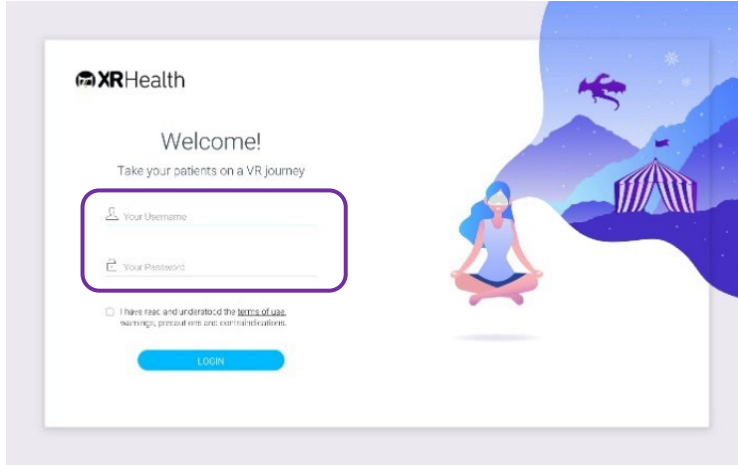
You can choose to stay in the environment without starting a new session by pressing "Stay in Environment".

9. External Control

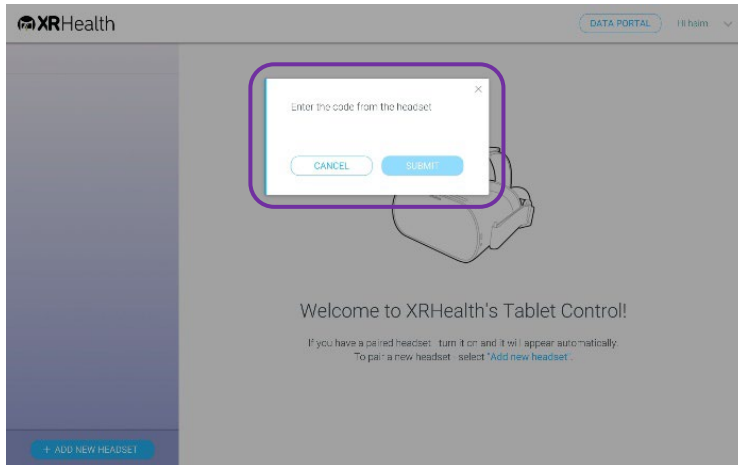
External control over the VR device is available via the XRHealth External Control app. To fully use all features of the External Control App – please fully read its User Manual.

Here is a short summary of how to operate Relax8 via the External Control:

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

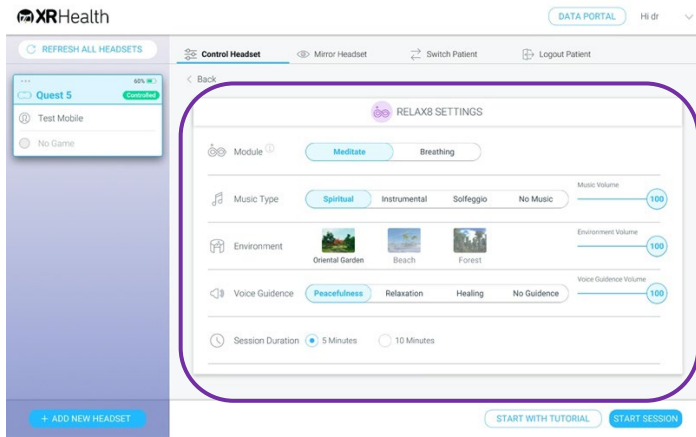


2. Pair a desired headset to external control device.

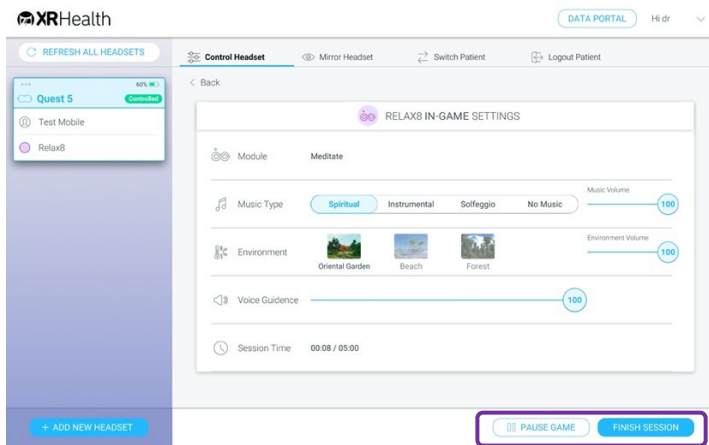


3. Select the patient with the VR device from the patient list.

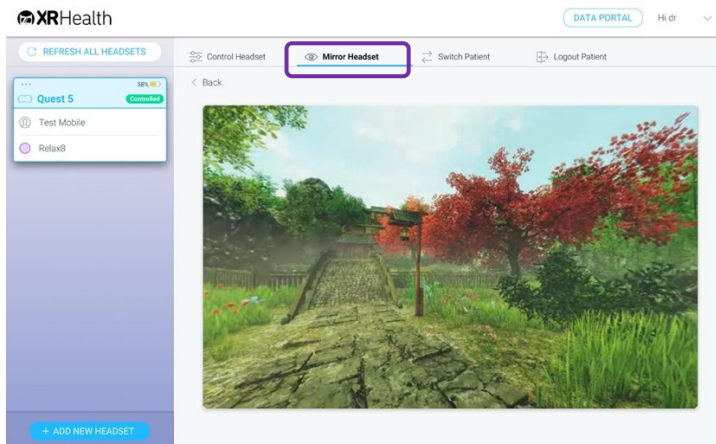
- Define the desired session settings (See settings screen description above) and select Start Session.



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



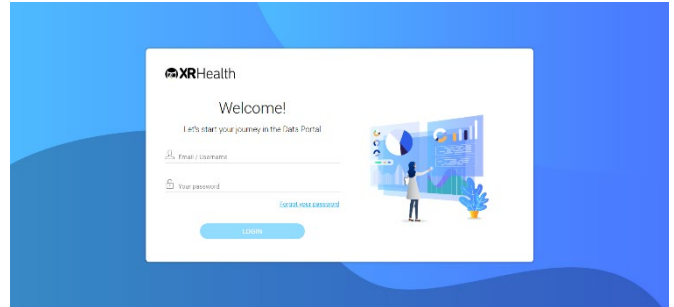
- Selecting the "Mirror" tab will show you the patient view within VR.



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

- 4.As a clinician you will need to go through an onboarding process in the web portal on your first login.
- 5.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.
- 6.Go to <https://portal.xr.health> and login with the supplied username and password to start the onboarding process.
- 7.In the onboarding process you will be required to set up your personal detail, email and new password.

Login

8. Login page is accessible on <https://portal.xr.health>
- 9.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.
10. For home users – the credentials for log in to the Data Portal are the same one used in the VR Portal.
11. Logout – once logged in – the option to logout is in the top right corner (press on the profile settings character)
12. Auto logout – for security reasons, the Data Portal will automatically logout after 15 minutes of inactivity.

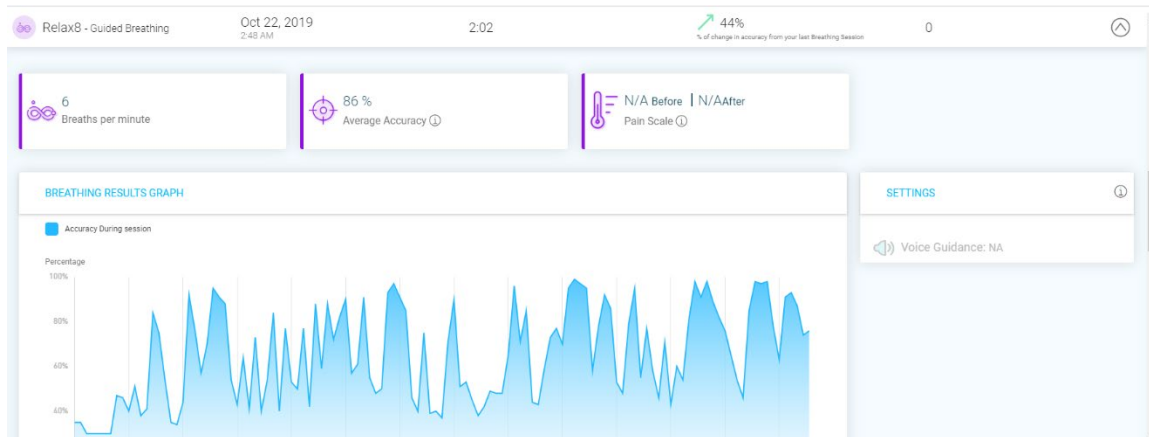
13. After login you will see XRHealth welcome page where you can navigate to activities page or one of the dashboards.

Activities

14. 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	Sweat Score
Relax8 - Visualization	Aug 12, 2019 11:41:04	0:43	6%	0
Rotate	Aug 18, 2019 11:30:44	1:27	49%	179
Reset	Aug 12, 2019 11:35:40	1:23	0%	2210
Luigi - Tennis	Aug 12, 2019 11:35:34	2:57	6%	0
Luigi - New Viewpager	Aug 18, 2019 11:30:44	0:43	6%	0
Balloon Blast	Aug 12, 2019 1:52:10	1:24	0%	2240
Balloon Blast	Aug 12, 2019 1:42:10	1:21	0%	6600
Balloon Blast	Aug 12, 2019 1:42:10	1:04	6%	7510
Rotate	Aug 12, 2019 0:22:10	0:33	29%	101
Rotate	Aug 12, 2019 0:34:10	1:4	0%	0
Rotate	Aug 12, 2019 0:33:10	0:55	200%	508

15. The Relax8 activity page will enable you to see your results for session:

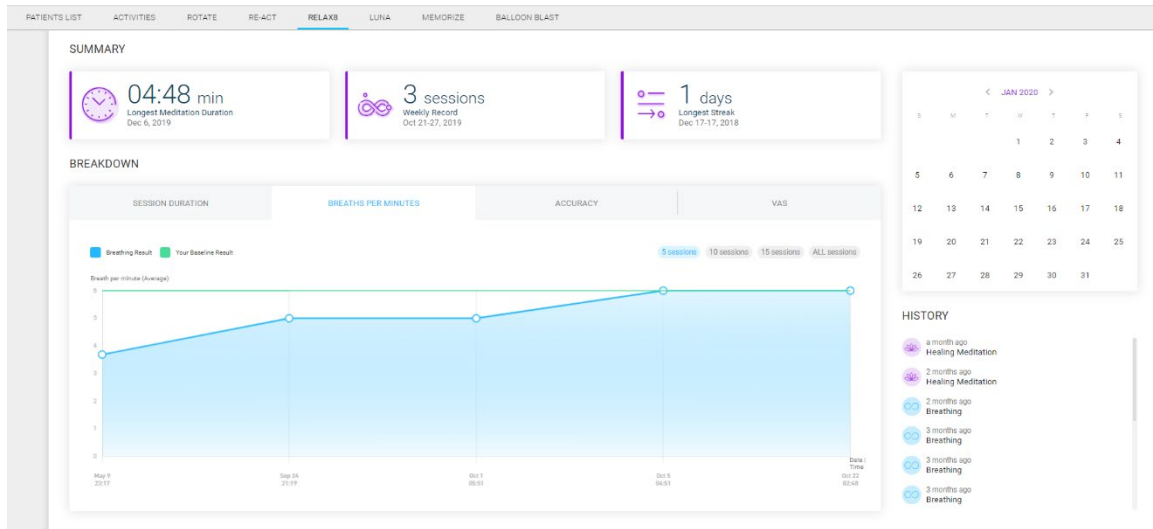


- Breathes per minute – the required breathes per minute defined during the session.
- Average accuracy – This index shows how well the user accurately followed the game objects, representing overall ability to produce the controlled movement required by the game.
- Pain scale – presents the subjective choice of the user for determining the severity of the symptoms before, and after the session. On a scale of 1-10.

16. On the right side you can find the settings for that specific selected activity.
17. On the graph you may see a bar chart presents accuracy during the session, where 'X axis' is time in the session. 'Y axis' represents the accuracy.

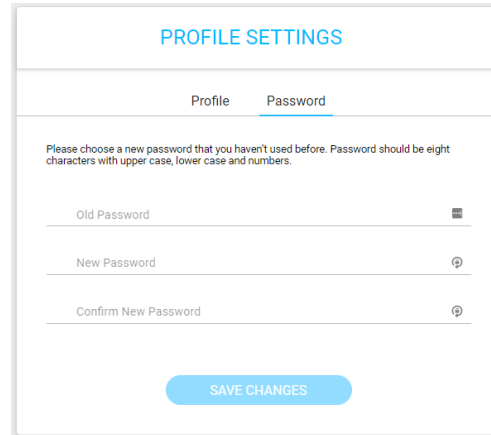
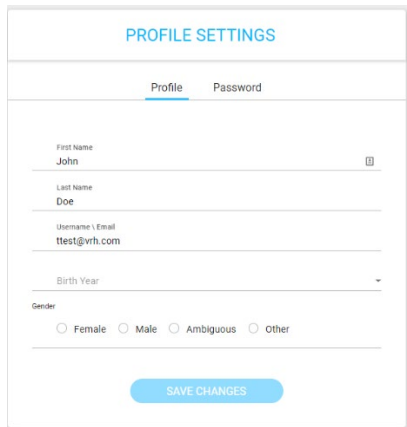
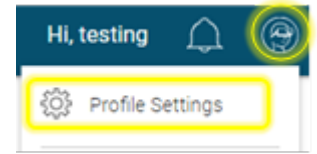
Dashboards

18. 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.
19. Navigate to the desired dashboard by clicking on the application name from the top bar.
20. Dashboards have 3 main sections:
 - **Summary:** The upper tiles of the dashboard show the user best score in the application for various metrics monitored over time.
 - **Breakdown:** The main graphs shows how the user metrics changes over time. You may view the following graphs:
 - Session duration between sessions
 - Breathes per minute between sessions
 - Accuracy between sessions
 - 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

- Both a patient user and a doctor user can access the user profile from the right side of the top bar.
- Managing your user profile enables the user to perform 2 things:
 - Change personal details: Name, Last Name, Email/username
 - Change password



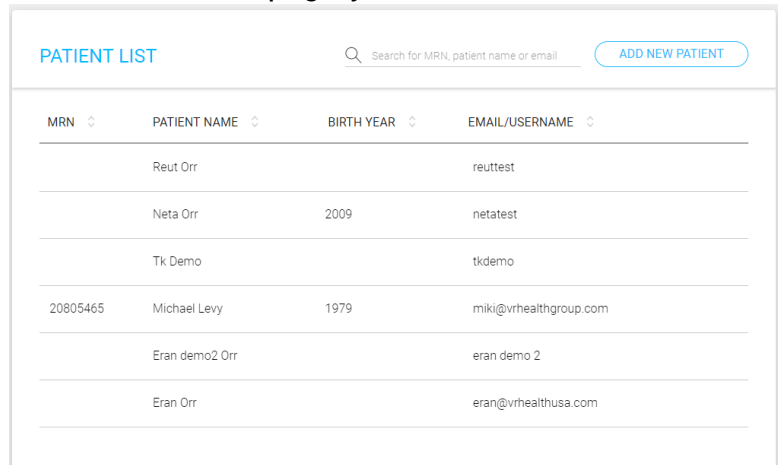
Patient List (For clinician user only)

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

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

- 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



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

- 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 X

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

Female Male Ambiguous Other

PATIENT DIAGNOSIS ^

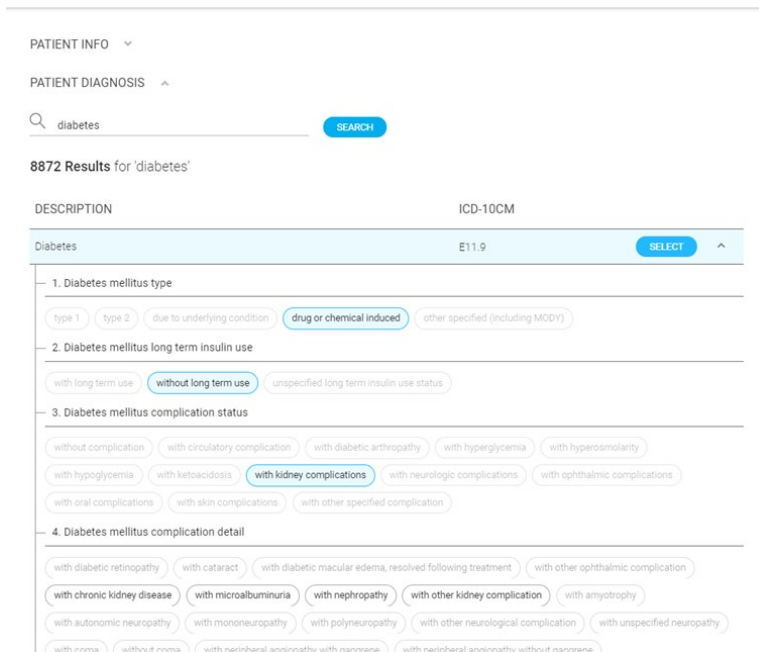
Powered by IMO® **SEARCH**

Additional Notes **SUBMIT**

CANCEL **CREATE**

27. XRHealth Data Portal enables a clinician to create / edit / delete patients.
28. 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.
29. 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

NEW PATIENT ×

PATIENT INFO ▾

PATIENT DIAGNOSIS ▲

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DESCRIPTION	ICD-10-CM	LAST UPDATED	
Diabetes 1.5, managed as type 1	E13.9	13 Aug 2019	🗑️

🗨️ Here is some more information SUBMIT

ADDITIONAL NOTES	LAST UPDATED	
This is an additional patient information	13 Aug 2019	✎️ 🗑️

CANCEL
CREATE

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

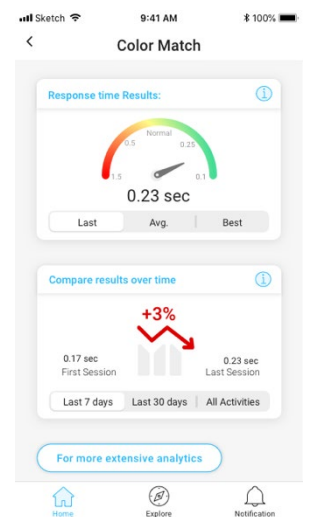
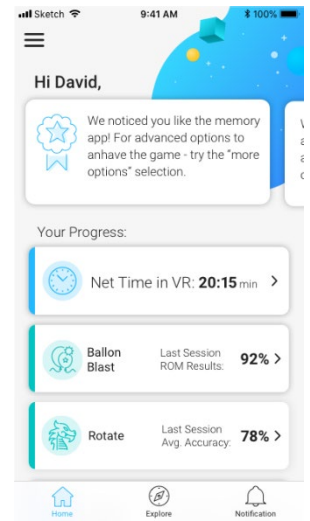
30. In order to edit a patient, hover on the patient row and hit the edit patient symbol on the right

MRN ▾	PATIENT NAME ▾	BIRTH YEAR ▾	EMAIL/USERNAME ▾
Reut Orr			reuttest ✎️ 🗑️

11. Mobile App

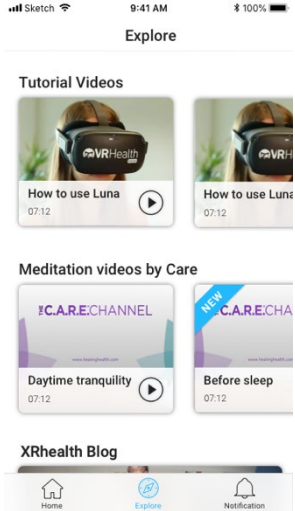
General

- 31. 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
- 32. The Mobile app is available for both iOS and Android devices.
- 33. 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



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- 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



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>

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 Wifi 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 doesn't 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.