XRHealth

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VRReliever™ CB-510 "Luna"

</div>

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™ CB-510 (*"Luna"*) V3.2.4

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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 VRH, monitoring and enabling interacting with the VR by using hands/fingers)

DOF   Degrees of Freedom

CB-510   VRReliever CB-510 software ("Luna")

Latest Version   Version 3.2.4

2.   General Information

Intended use

The CB-510 ("Luna") is intended to assist in the mitigation of pain, hot flashes and physical discomfort through distraction and supporting exercises, performed in a virtual reality (VR) environment using commercially available VR headsets. The CB-510 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 CB-510 provides VR exercises and takes measurements which enables the patient and/or clinician to monitor changes over time. CB-510 does not provide a report that analyzes the measurements, makes medical diagnoses, or recommends treatment.

Intended user populations:

CB-510 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 as support for pain mitigation, hot flashes and physical discomfort.

Intended use environment:

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

• Home environment;

• Healthcare facilities

3. Contraindications

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

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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.

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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 CB-510 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 VRRelieverTM 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. CB-510 Overview

Software description

1.1. The VRReliever CB-510 is a medical software that provides programmed exercises within a gamified three-dimensional VR environment to train a patient to respond differently to the physical sensation of pain or discomfort or to distract a patient from the physical sensation of pain or discomfort.

1.2. 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.

1.3. CB-510 software guides patients in the performance of physical and mental exercises, according to a customized session plan defined by setting:
- Type of module – Hot Flashes, Pain Management, Guided Breathing)
- Training duration – User's choice or Health Care Provider's recommendation;
- Position calibration – lying down or sitting position

1.4. CB-510 software is not intended to be used for diagnosis, making treatment decisions, or as a stand-alone device.

1.5. At the end of each session, training results are presented in the XRHealth data web portal. The data shown only represents actual training summary and is not considered a professional recommendation nor intended to be used for diagnostic purposes.

Hardware and Software requirements

1.6. The usage of the CB-510 software requires a pre-purchase of a high-end off-the-shelf VR platform:
- The compatible VR platforms for the use of CB-510 software, are listed in appendix A: *Approved VRH List.*
- A stable internet connection with a download speed of at least - 3MB/sec and upload speed of at least 0.5MB/sec is mandatory.

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Software installation and software updates via Oculus store

6.1. The software shall be downloaded and installed from the VRH store application and can be accessed by entering the applicable credentials (username and password).

6.2. The software comes with automatic update capabilities.

6.3. 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.

6.4. 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.

6.5. 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

1.1. Any other software can be installed, updated and managed by a selected MDM solution for remote headset management.

1.2. This solution enables XRHealth to fully manage the software version and update status in each device.

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7. Instructions for use

7.1. The following instructions shall serve as a checklist for operating the CB-510 software:

☐ Carefully read the instructions for use by the VRH manufacturer (list of compatible hardware for CB-510 available in Appendix A, below).

☐ Carefully read the Health and Safety Warning of the VRH manufacturer (list of compatible hardware for CB-510 available in Appendix A, below)

☐ Assess the medical condition of the user and confirm that it is suitable for using a VR device.

☐ Read the contraindications for use and additional precautions for the use of CB-510 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, sit or lie down on a stable chair or bed. 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 in any case of pain, discomfort, dizziness or nausea resulting from the usage of the CB-510 software or the attached VRH. Some users may have a transient mild negative sensation associated with the VR environment.

7.2. The duration of each VR session shall not last longer than the VRH recommended continuous minutes per patient (see Appendix A: Approved VRH List).

7.3. If you suspect at any time that the performance and/or game instructions do not fit the training plan you defined, immediately stop the training.

7.4. If you suspect that the trouble is related to hardware malfunction, you can reset the VRH and restart the training session.

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7.5. If you suspect that there is a problem with the CB-510 software, immediately contact XRHealth IL LTD. (or the relevant distributor in your country). Meanwhile, stop using the device.

7.6. 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.

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8. CB-510 Training Experience

Luna offers VR experiences that engage the brain to support the healing process and self-management of symptoms associated with pain and hot flashes.

Game Flow - The application includes three main modules: "Hot Flashes", "Pain Management" and "Guided Breathing", as seen in the main menu (Image 1). Both "Hot Flashes" and "Pain Management" modules take place in the Frosty environment, a frozen winter land.

Use the trigger button for selecting a desired module, language and for selecting the severity of the symptoms. In addition, it is possible to skip some of the voiceovers and subtitles by using the trigger button during the session.

Pressing the pause button pauses the module and opens a Quit pop-up when in the module or Main Menu.

Image 1: Main Menu

VAS – Visual Analogue Scale - At the beginning and end of each experience the user is requested to rate the severity of the symptom (hot flashes, pain, general feeling) on a scale of 0 to 10.

Position and Calibration - An automatic horizontal calibration occurs every time the app is uploaded. Horizontal calibration can be performed any time by long pressing on the calibration button. Switching to a lying down point of view is possible at any point while in main menu screen or Frosty experience by looking vertically up 90 degrees and select the headset button "Select to lie down" (Image 2). Pressing the headset button in front - "select for upright position" leads back to upright position. Generally, it is recommended to use the app while sitting down.

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Image 2: Position Calibration Buttons

Language – Switching the game flow language is available by clicking the three dots button -> "Language" and choosing the relevant language (Image 3). Choice will be saved for the next app uses. Currently the application supports English interface or Hebrew interface (Image 4).
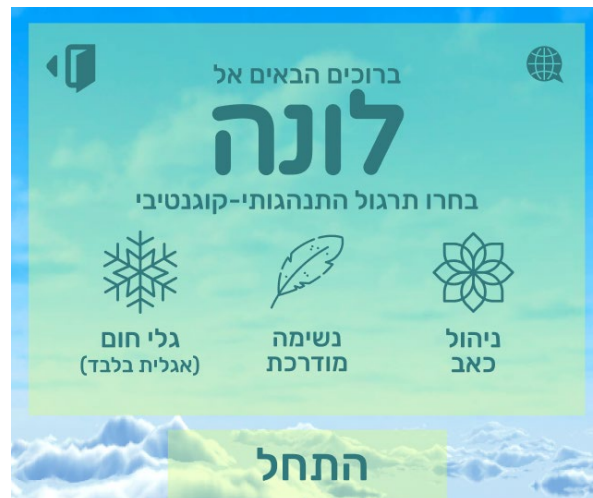

Image 3: Language Sub-Menu

Image 4: Hebrew Menu

No Guidance – It is also possible to possible to play Luna without a voice guidance. Click the three dots button -> "No Guidance" (Image 5) in order to active No Guidance mode, then start a session.

Image 5: No Guidance mode

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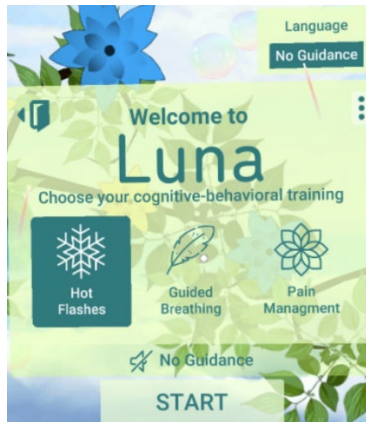
9. Modules

Hot Flashes/Pain Management - Frosty

An experience that combines cognitive behavioral therapy (CBT) elements in a frozen world, designed to assist in self-management of pain or hot flash symptoms.

Main features:

1. Freezing objects - While touring the Frosty world, the user is asked to scan the objects around. Whenever a snowflake is showing upon an object, gazing at the object will freeze it (Image 6+7).
2. The session is not time-framed, users can spend as much as time as they like in the Frosty environment. When the narration finishes – the user is informed and can select if to finish their session or continue in the environment as long as they like.
3. Pressing the pause button pauses the module and leads back to main menu (Image 7).

Image 6: Flashing Snowflake

Image 7: Freezing Objects and Back Button

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Guided Breathing

Practicing paced breathing by Inhaling for 5 seconds and exhaling for 5 seconds while a bubble is formed (Image 8).

Image 8: Bubble Forming

Main features:

1. Pressing the arrow button leads back to main menu (Image 9).
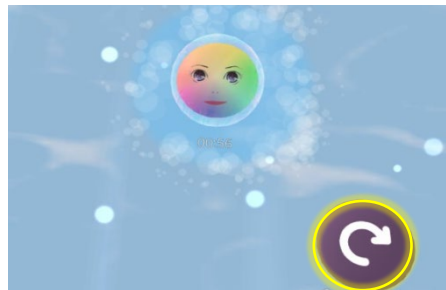
Image 9: Back Button

2. Progression - This is a 28-day progressing module, Starting with a 3-minute session for the first week. Continues with a 5-minute session for the second week. Third week will present a 10-minute pace breathing session. Sessions on the fourth week will last 15 minutes.
3. Each session ends with a counter that shows pace breathing progress, and a growing tree that forms with every finished session (Image 10).

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Image 10: Sessions Counter and a Growing Tree

10. 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 Luna via the External Control:

1. Login – Login to the External Control app using your <u>Clinician</u> credentials.

2. Pair a desired headset to external control device.

3. Select the <u>patient</u> with the VR device from the patient list.

4. Select "Control" to define the training.
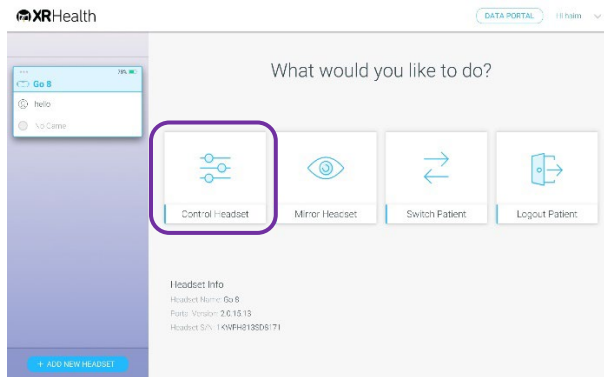
5. Select "Luna" from the application list.
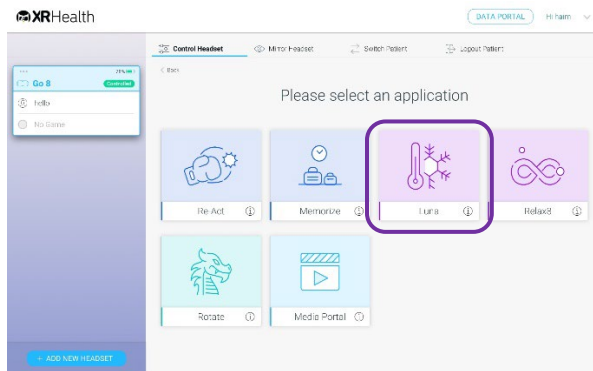
6. Define the desired module (Hot Flashes, Pain Management or Paced Breathing) and press "Start".
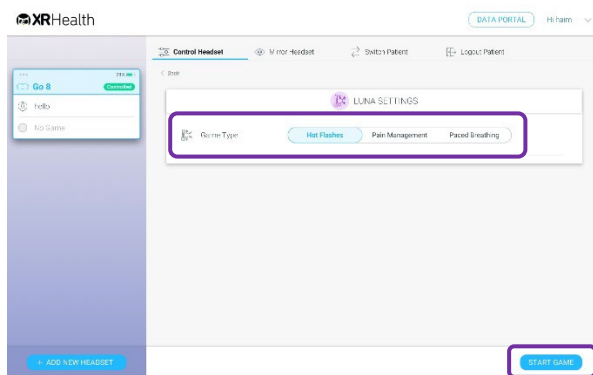
7. You can Pause or Finish the session at any time.

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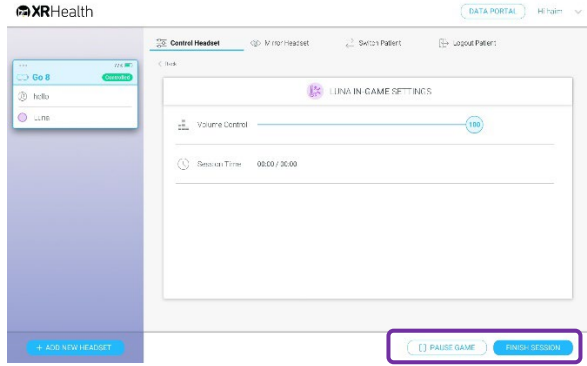
8. Selecting the "Mirror" tab will show you the patient view within VR.
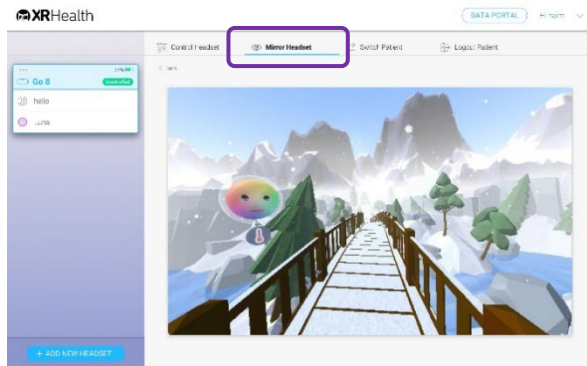
11. Data Portal

The Data Portal enables viewing patient performance and statistics. It is accessible both for the clinician and the patient. For full information please refer to XRHealth portal user guide.

The Web Portal can be accessed via any web browser at – https://portal.xr.health or via the External Control app on the top right corner
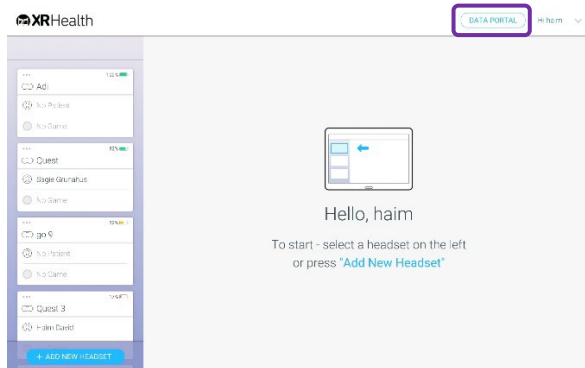
The Data Portal has 2 main sections where you can see your results and progress over time

1. Activities view – In the activities view 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

Each opened line in Luna will give you results regarding the following:

1. VAS scale – in a scale of 0 of 10 how bad were your symptoms – before and after.
2. Session duration in Minutes: Seconds
3. Level of expertise for Breathing module

2. Dashboard view – In the dashboard view you can see your progress overtime and how adherence you are to your treatment. Check the dashboard view to see how persistence you are.
   a. High level summary – These results show you the following:
      i. Weekly record – total number of sessions per week
      ii. Longest streak - number of Consecutive days you used the application
   iii. Total number of sessions
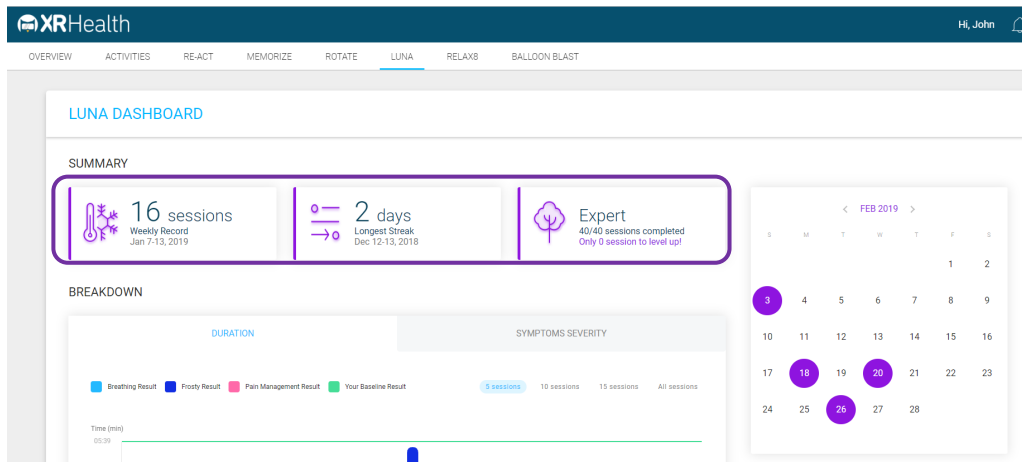
b. Session Breakdown:

    i. Duration – you can see your duration in minutes for every different type of session. Choose the number of sessions you wish to view with the upper top right (5,10,15, All).
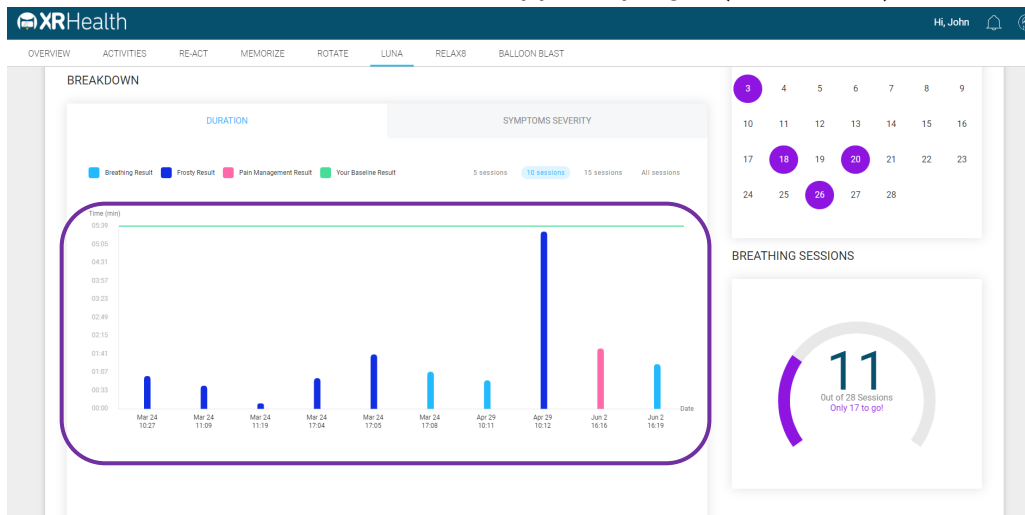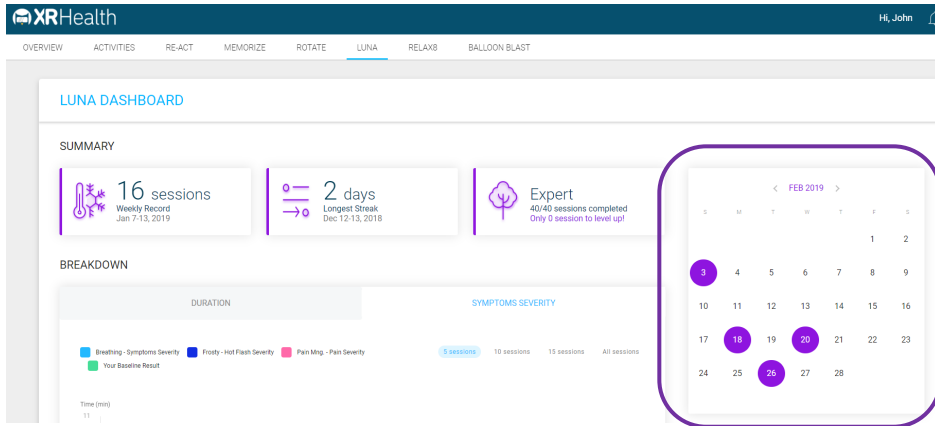

    ii. Symptoms severity – you can see your Visual Analog Score (VAS) for your symptoms on a scale of 0-10 before and after each session in order to track your symptoms over time.
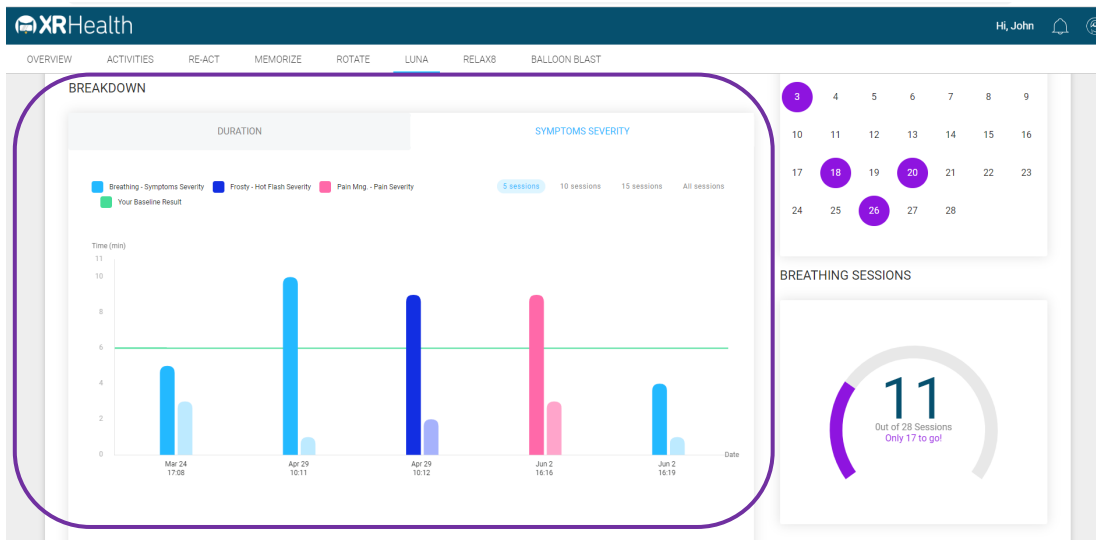
c. Training Calendar – on the training calendar you can see all of the days in which you have been active in Luna.

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d. Breathing session progress – In the breathing session module you will see your progress toward achieving a goal of 28 sessions. The breathing session progress bar will enable you to track your progress in the Breathing module.
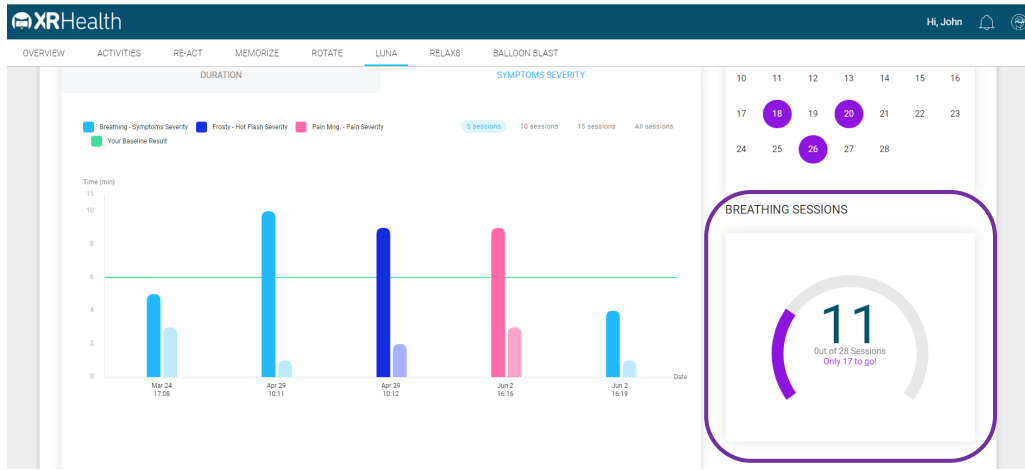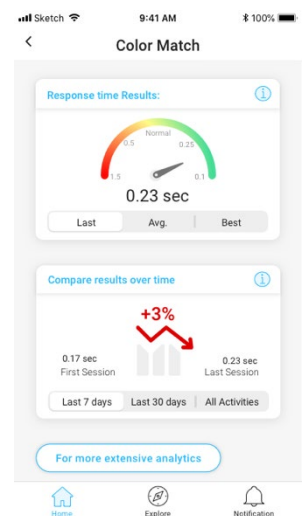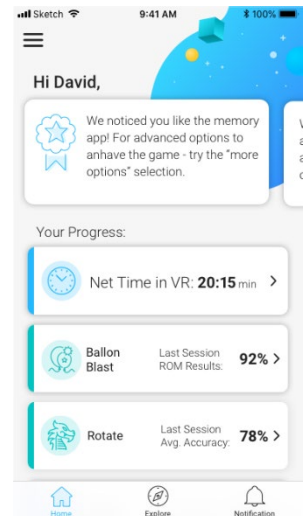
12. Mobile App

General

1. 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

2. The Mobile app is available for both iOS and Android devices.

3. The application flow includes:

    a. Login (with the option of enabling FaceID of 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
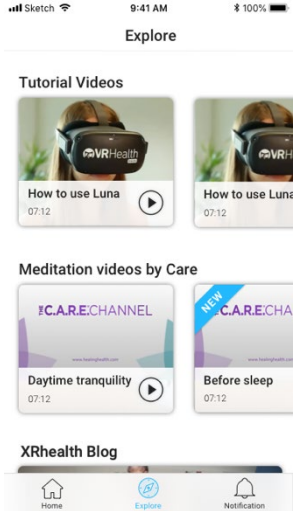
Appendix A: Approved VRH List

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

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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.

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