VRPhysio Home™ MT-220 "Balloon Blast"

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: VRPhysio Home™ MT-220 (*"Balloon Blast"*) 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 VRH, monitoring and enabling interacting with the VR by using hands/fingers)

ROM   Range of motion

DOF   Degrees of Freedom

MT-220   VRPhysio Home MT-220 software (*"Balloon Blast"*)

Latest Version   Version 1.2.6

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2. General Information

Intended use

The MT-220 ("Balloon Blast") is a physical medicine and rehabilitation software, as a medical device, intended for use in upper extremity and full body conventional rehabilitation and active shoulder ROM assessment. The software enables:

- Tracking motion and movement kinematics.
- Guiding patients in the performance of physical exercises according to the treating medical practitioner's guidelines.

MT-220 is not intended to be used for diagnosis, treatment, decision making, or as a stand-alone device.

Intended user populations

MT-220 software is intended to be used by the following populations:

Software operators

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

End users

Individuals that will benefit from using MT-220 to support the performance of their prescribed physical exercises as part of their conventional rehabilitation.

Intended use environment

MT-220 software is intended to be used only in the following environments or areas:

- Physical medicine hospital units;
- Physical therapy clinics;
- Any other facility that utilizes physical activity treatment;
- Home environment;

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3. Contraindications

Before using the MT-220 software, the Health Care Provider (and/or the end user) shall make sure that the patient does not suffer from one or more of the following conditions:

1. Tumors or other space occupying lesion (SOL) of the cervical region ;

2. Undiagnosed neurological symptoms/signs ;

3. Acute fracture of the cervical spine (especially fracture of odontoid process (Dens));

4. Pathological fractures of the spine ;

5. Post MVA (Motor Vehicle Accident) with no previous physician screening, where spinal structures may be compromised;

6. Any condition where it is otherwise contraindicated to move cervical region actively or passively;

7. Any condition where it is otherwise contraindicated to move shoulder and/or arm and/or wrist's anatomical structures actively or passively;

8. Any recent unexplained loss of consciousness.

9. Seizures or taking antiepileptic medications.

10. Any acute/chronic condition causing tiredness, dizziness, nausea or vertigo .

11. Being under the influence of alcohol or recreational drugs;

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4. Additional Precautions

1. Neck movement may adversely affect users with cervical spine abnormalities, pain or other acute/chronic condition; Health Care Providers are advised to disable or limit movements that may be harmful to the patient. If the user feels any discomfort, he should terminate the session immediately.

2. Upper limb (shoulder, arm and wrist) movements may exacerbate any pre-existing pain or discomfort. If the user feels any excessive pain or discomfort, he should terminate the session immediately.

3. Some users with existing vertigo or nausea may experience an exacerbation of these symptoms in VR environment; If the user feels any discomfort, they should terminate the 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. Health Care Provider discretion is advised.

5. Weak neck muscles/Acute neck pain – patients with weak neck muscles or irritable suffering from acute neck pain may experience difficulties carrying the weight of the VR headset. Health Care Providers are advised to use their clinical judgement before exposing the patient to the VR hardware weight.

6. Heart conditions - CHF (Congestive Heart Failure) or other conditions that limit aerobic capacity, requiring adapting the training to suitable pace to prevent an excessive aerobic requirement. This may require the Health Care Provider to use a third-party monitoring device (such as heart rate monitor) to ensure patient safety or instruct patient to limit game speed to a comfortable pace.

7. If the user has a defibrillator, pacemaker, hearing aid or any other implanted medical device, he should not use the VR hardware without first consulting his physician or the manufacturer of the medical device as the VR hardware may interfere with its proper function.

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8. Balance disorders – as VR experience is immersive, Health Care Providers are advised to use their clinical judgement before exposing the patient to the VR hardware if the patient has any pre-existing disorder affecting balance (e.g. Parkinson's disease, multiple sclerosis, dementia). patients showing any balance associated symptoms should be supervised closely. For some balance disorders the patient might require protective harness and/or belt for support.

9. Contagious conditions – in order to avoid transferring of contagious conditions (like pink eye), the VR headset should not be shared with users with contagious conditions, infections or diseases, particularly of the eyes, skin or scalp.

10. Health Care Providers are advised to use their clinical judgement before exposing the patient to VR hardware if he is taking medications which may provoke seizures or impair his vision or balance.

11. Although the VRPhysio Home 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, 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 not already under the care of a clinician such as: Dissociative disorders, psychotic disorders, or severe depressive, trauma or anxiety disorders.

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5. Warnings and General Limitations

1. All warnings and general limitations related to the safe use of the VR hardware console (recommended for use with VRPhysio Home software series) are applicable when used with VRPhysio Home MT-220 software.

2. Prior the usage of the commercial "off-the-shelf" VR hardware, it is required from the user and the health care provider to carefully read all instructions, limitations, and precautions in the Health, Safety, and Warranty Guide attached to the hardware. It is the Health Care Provider's responsibility to confirm that it is safe and continues to be safe for a specific patient to use the Virtual Reality Hardware (VRH) before using the MT-220.

3. XRHealth IL Ltd shall not be held 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 VRPhysio Home series software shall not last longer than the continuous duration as recommended by the hardware manufacturer.

5. If the user is experiencing symptoms associated with loss of consciousness, involuntary movements/seizures, visual abnormalities(blurred vision, double vision, etc.), tiredness, dizziness, vertigo, nausea, digestive problems, emotional stress or anxiety, disorientation, impaired balance, being under the influence of alcohol or drugs, suffering from cold, flu or headaches, migraines or earaches or any physical or emotional pain or discomfort, 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

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6. MT-220 Overview

Software description

6.1. The MT-220 is a physical medicine and rehabilitation software, as a medical device, which delivers an immersive experience for patients to stimulate and engage them to their specific conventional physical rehabilitation treatment through the use of games and entertainment features.

6.2. The MT-220 software is intended to be operated by Health Care Providers providing self-administered therapy to their patients or by the patients themselves, as part of their conventional rehabilitation, in medical facilities or at home (see

6.3. Intended use environment). The current version of MT-220 includes a single game: "Balloons Blast."

6.4. This game mode supports therapy of patients required to perform active movements of their upper body as part of their treatment regime.

6.5. MT-220 software guides patients in the performance of movements, according to a customized session plan defined and prescribed by the Health Care Provider in charge of the treatment by setting:

- Types of movements to be performed;
- Desired area for active movements (expected ROM);
- Goal movements pace;
- The total duration of the training session.

6.6. MT-220 allows the Health Care Provider and the patient to configure the game module parameters to create a customized training program or choose between three pre-sets of training – Basic, Intermediate, and Advanced (see **Error! Reference source not found.**). The pre-set configurations differ from one another by training parameters: selected movements, desired training area, movement pace and total duration of the training session. However, these pre-set training configurations are not a recommendation for treatment of any individual using the system; MT-220 software is not intended to be used for diagnosis, making treatment decisions, or as a stand-alone device. Health Care Providers who choose to guide a patient to use a pre-set training feature are obligated to understand the parameters and associated training goal of each program and use their independent medical judgment to determine its suitability for any specific patient.

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6.7. 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

6.8. The usage of the MT-220 software requires a pre-purchase of a high-end off-the-shelf VR platform:

- The compatible VR platforms for the use of MT-220 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

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

6.10. The software comes with automatic update capabilities.

6.11. 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.

6.12. 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.

6.13. 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

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

6.15. 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 check-list for operating the MT-220 software:

☐ Carefully read the instructions for use by the VRH manufacturer (list of compatible hardware for MT-220 available in Appendix A, below).

☐ Carefully read the Health and Safety Warning of the VRH manufacturer (list of compatible hardware for MT-220 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 MT-220 software to ensure safety.

☐ Make sure the environment in the location designated for training is free from obstacles; Keep in mind that some training sessions require extensive arm movement. 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, stand comfortably or sit on a stable chair. 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).

☐ The physician shall thoroughly evaluate the user's functional status and assign a rehabilitation program most suitable for the patient's functional ability, level of impairment and diagnosis. patient's health history shall be taken into consideration.

☐ Train only according to the training program assigned you by the physician after diagnosis and evaluation of functional ability and level of impairment. Specifically, any shoulder movement (also after medical procedure) shall be performed only per the physician recommendations, do not overdo these recommendations.

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□ 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 MT-220 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.

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 defined by you physician, immediately stop the training.

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

7.5. If you suspect that there is a problem with the MT-220 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 and discontinue using the VR headset.

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8. MT-220 Training Experience

8.1. The Balloon Blast MT-220 application includes 2 main elements:
   a) Shoulder Range of Motion measurement
   b) Upper extremities and full body training application

8.2. Range of Motion (ROM):

   a) In this measurement phase, the application will measure the patient's shoulder active ROM in 3 different planes:
      i. Flexion
      ii. Abduction
      iii. Horizontal abduction

   b) The measurement takes place in a virtual measurement room, and the patient is guided by demonstrations from a virtual 3D human guide.

   c) The patient will see an "avatar" of themselves in a virtual mirror. Seeing themselves in the mirror will help the patients correctly perform the measurement.

   d) The first time the measurement is launched an animated tutorial will begin explaining how to correctly perform the measurement.

   e) If you wish to view the tutorial video again, select the "start with tutorial" option on the settings screen (explained below).

   f) Range of Motion test flow:
      i. The test begins with a calibration to correctly position the virtual environment.

      Note: it is recommended to verify that the floor level is calibrated correctly according to the VRH manufacturer's manual

      ii. The patient is requested to stand up straight, hand to the sides (the neutral position) and press both trigger buttons. This measures the patient's body dimensions and is important for an accurate measurement.

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iii.   Flexion measurement – The patient is requested to raise his/her arms forward as high as possible and back to the neutral position.

iv.   Abduction – The patient is requested to raise his/her arms to the sides as high as possible and back to the neutral position.

v.   Horizontal abduction – The patient is instructed to raise his/her arms forward and to begin the measurement from a "new" neutral position. Once there the patient is instructed to open both arms to the sides as far as possible and the back to the neutral position. This concludes the measurement and the patient can lower his/her arms.

8.3. Balloon Training game:

a)   The Balloon Blast training is a game that consists of the patient holding virtual sword and an array of balloons that inflate in front of him/her. The object of the game is to pop the balloons when they appear in continuous motions. The area in which the balloons appear, the speed of the game and other parameters (detailed bellow) control the specific task and level of difficulty of the game.

b)   The Grid – The grid of balloons that inflates in front of the user is built from a 9*9 array of pipes. From each pipe nozzle a balloon inflates. The area of the pipes is approximately 140 degrees horizontally and 95 vertically (see illustrations). In the settings menu

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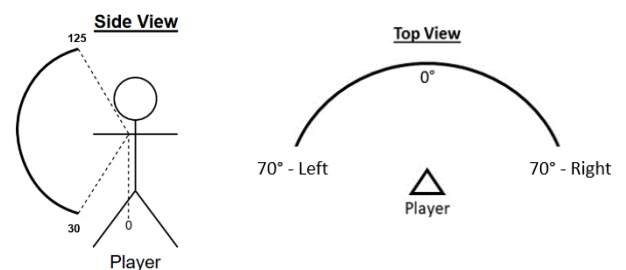
the clinician can select any activity area in from the full grid (minimal area 3*3). Multiple areas can be selected.

c)   Modules - The game consists of 2 different training modules:

i.   Swipe – In this module, sequences of balloons will appear in the training area with no specific color. The user is free to pop the balloons with either hand.

ii.   Match the Color - In this module, each sequence of balloons should be popped with a specific hand. This is performed by matching the sword color with the color of the balloon sequence.

Note: colorblind users may find color distinguishing task difficult.

d)   Speed – The speed of the game is defined by the balloon "time-out" – the time the user has to pop the balloons before they disappear and a "miss" is granted. The speed in the game is defined by the following speed levels:

Speed Level	Time out time (seconds)
1	15
2	14
3	13
4	12
5	11
6	10
7	9
8	8
9	7
1	6
11	5

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12	4
13	3
14	2
15	1

e) Points:
   i. The Basic Score parameter is the amount of score the player gets for popping a single balloon.
   ii. The game's combo mechanic is based on the player's ability to pop all the balloons of a single motion in one swoop of the sword.
   iii. When the players succeed in this, they get a score bonus that is equal to 100 times the number of consecutive swoops they performed.
   For example, if the player swoops 2 motions in a row:
      a. After the first swoop, the player gets a 100 points bonus.
      b. After the seconds swoop, the player gets a 200 points bonus.

f) Calibration and standing position:
   i. Each game begins with a calibration phase. In this phase the environment and grid are calibrated to the patients position and height.
   ii. Height calibration has limits – the recommended minimal height is 1.3 meters/4.2 feet (about the height of an average adult sitting on a chair). Under this height the patient will have difficulty reaching the edges of the balloon grid.
   iii. Because these are average heights – if a patient still has difficulty reaching the edges of the balloon grid due to height/other limitations it is recommended to select a smaller size grid that better fits his/her reach.
   iv. Standing position – once calibrated – in VR the patient can see the recommended standing position marked on the floor by two footprints.

g) Tutorials:
   i. The application has 2 different video tutorials depending on the Module:
      a. Swipe module – explains in detail how to play Swipe.

b. Match the Color module – explains in detail how to play Match the Color.

ii. The tutorials play automatically the first time the application is launched on the headset.

iii. If you wish to view the tutorial video again, select the "start with tutorial" option on the settings screen (explained below).

h) Out of FOV indicator:

i. FOV means "Field of View". In the context of this document, FOV means the frame that is visible to the player, inside the VR Headset.

ii. Sometimes, balloons will be present, but the player will look elsewhere, so they will not be in the FOV.

iii. When this happens, a blue arrow will appear in the center of the player's view, to encourage the player to look at the balloons.

iv. This arrow is called the FOV Indicator.

v. There will be only 1 arrow, and it will point to center of the balloon sequence.

vi. Once the balloon is back inside the player's FOV, the FOV Indicator will disappear.

8.4. Menus:

a) The **Settings screen** includes the following game options:

i. Training selection:
a. ROM only
b. Training only
c. ROM + Training

ii. Game Module:
a. Swipe
b. Match the Color

iii. Game Preset – selecting a game preset defines the following parameters:
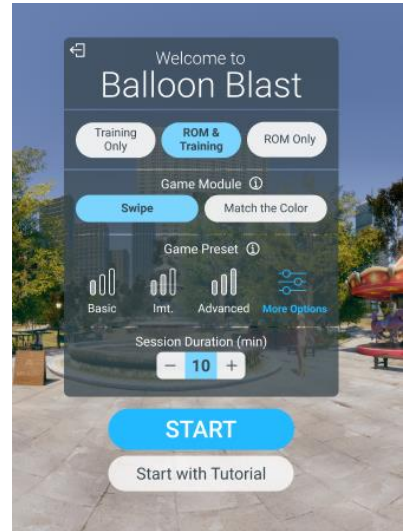
	Basic	**Intermediate**	**Advanced**
Grid Size	Bottom 5 rows, Middle 5 columns	Bottom 7 rows, Middle 7 columns	Full Grid
Speed	Level 7 (9 second time out)	Level 9 (7 second time out)	Level 11 (5 second time out)

Motion Selection	Vertical	Vertical + Diagonal	Vertical + Diagonal + Horizontal

iv. Session Duration – Duration in minutes
v. More Options – selecting the "More options" opens the following advanced options:
a. Grid selection – select any active area. Minimum area 3*3. Multiple area selection possible.

<u>Note:</u> When performing the training while sitting, some users would not be able to reach the 2 upper rows in the grid.

<u>Warning:</u> Training in full grid means full body workout. Movement of the back and neck are also required. These movement should be considered prior to full grid selection.
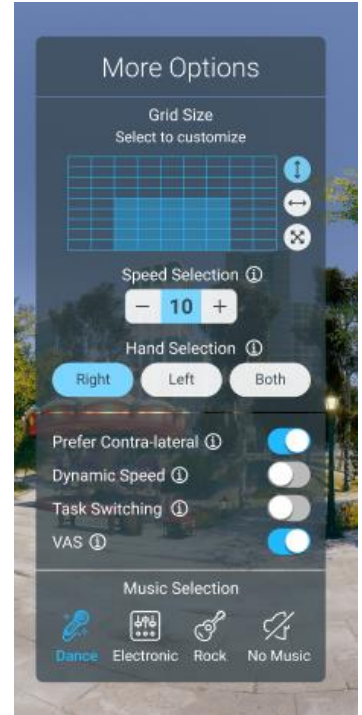
b. Motion Selection:
1) Vertical
2) Horizontal
3) Diagonal
c. Speed selection – 1-15
d. Hand selection – Right, Left or Both
e. Prefer Contra-lateral - This option will prefer contra-lateral motions where the user is required to use their right hand to pop balloons on the left side and use their left hand to pop balloons on the right. This is available for Match the Color module only.
f. Dynamic Speed - Enables speed changes in the game according to performance. Successfully popping a full sequence will cause the game to speed up, unsuccessfully popping (errors/misses) balloons from the sequence will cause the game to slow down.
g. Task Switching - The color of the swords will randomly change during the game. This is available for Match the Color module only.
h. VAS - Add a VAS pain selection phase before and after training.

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      i.   Music selection – Select music for the training session from the following options:

        1) Dance

        2) Electronic

        3) Rock

        4) No-music

vi.   Start - Begin the training

vii.   Start with tutorial – Begin the training with the tutorial video before each part of the training (ROM and Training).

b) The summary screen includes the following results:

i.   ROM results – in the ROM results you can see the value in degrees of each measurement performed for both right and left hands.
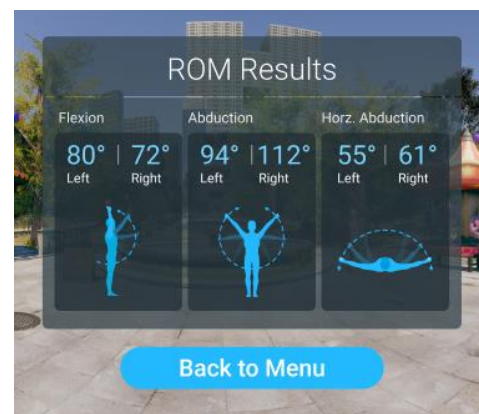
ii.   Session results – the following results appear on the summary screen:

    1) % of Success - The % of balloon successfully popped

    2) # of Mistakes - The number of balloons popped using the wrong hand

    3) # of Misses - The number of balloons that weren't popped in time before they deflated

    4) Response Time - Response time is measured from when a balloon sequence appears (starts to inflate), until a motion is initiated in the direction of the balloons.

    5) Smoothness - Smoothness indicates how smooth the swiping movements were. A high percentage signifies smooth motion.

    6) Peak Vel. - Indicated the peak velocity of the motion, measured in meters per second.

    7) Efficiency - Indicates how efficient the motion was. High efficacy signifies motions that were performed in the shortest

path from where the hand began the motion until it finished the motion.

c) Pause menu – The pause menu appears when the session is paused (using the pause button on the left controller/pausing using the external control). It includes the following options:

i. Session duration display
ii. Music – an option to change the music selection
iii. Volume – an option to change the game volume
iv. Resume
v. Restart
vi. Finish session
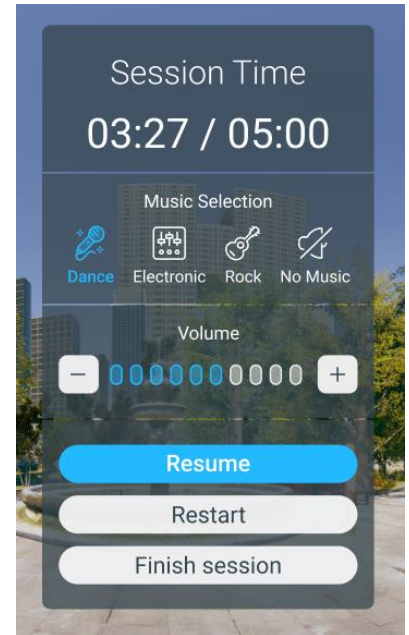
9. External Control

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 Luna via the External Control:

1. Login – Login to the External Control app using your <u>Clinician</u> credentials.
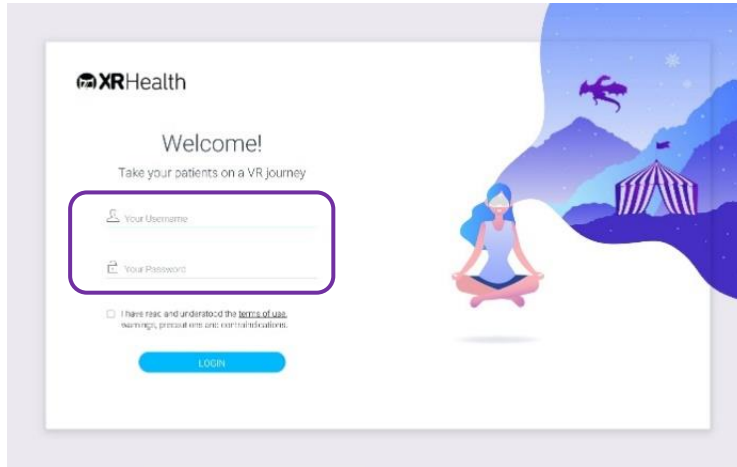
2. Pair a desired headset to external control device.
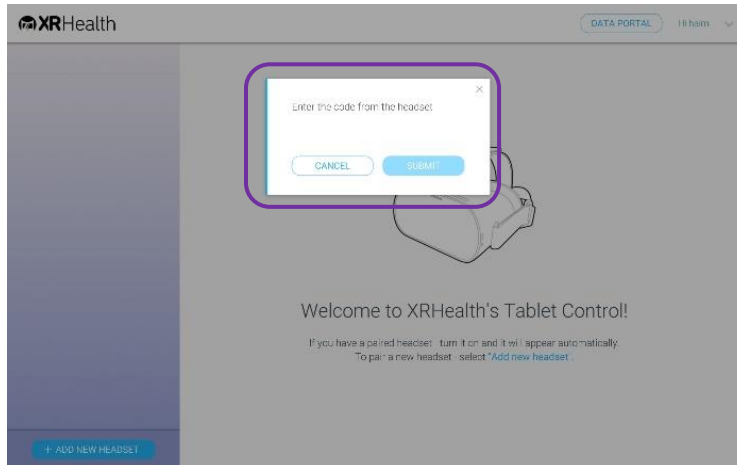
3. Select the <u>patient</u> with the VR device from the patient list.
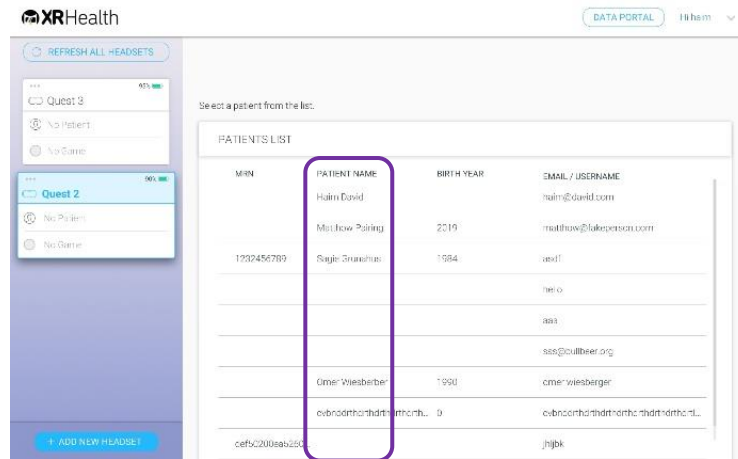
4. Select "Control" to define the training.
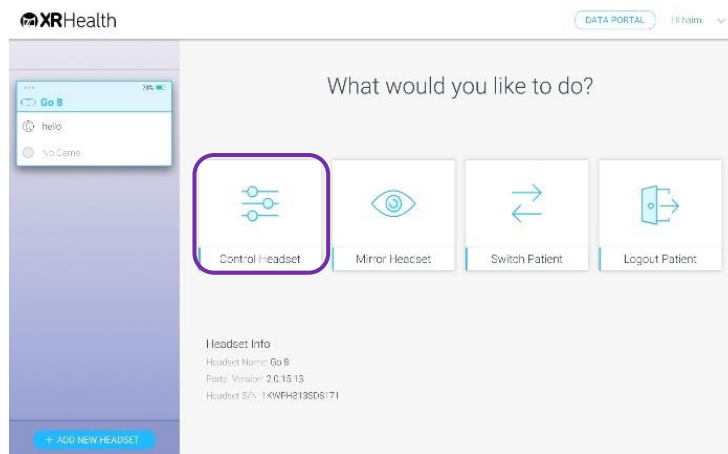
5. Select "Balloon Blast" from the application list.
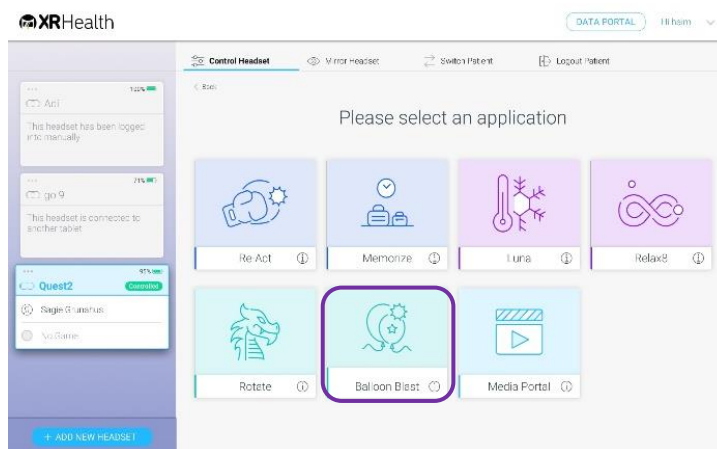
6. Define the desired session settings (See settings screen description above) and select Start Session.
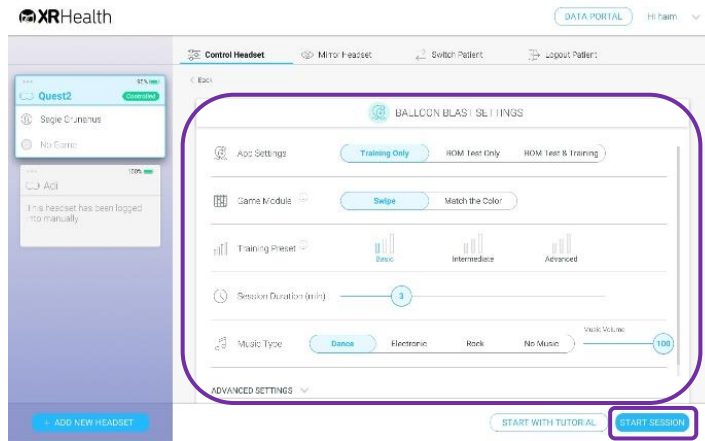
7. You can Pause or Finish the session at any time.
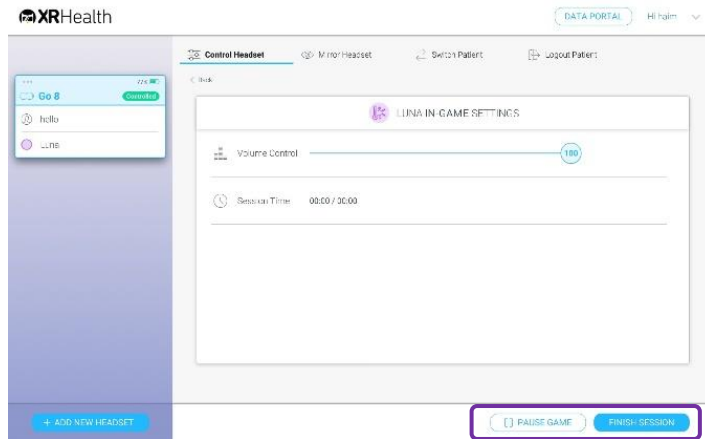
8. Selecting the "Mirror" tab will show you the patient view within VR.

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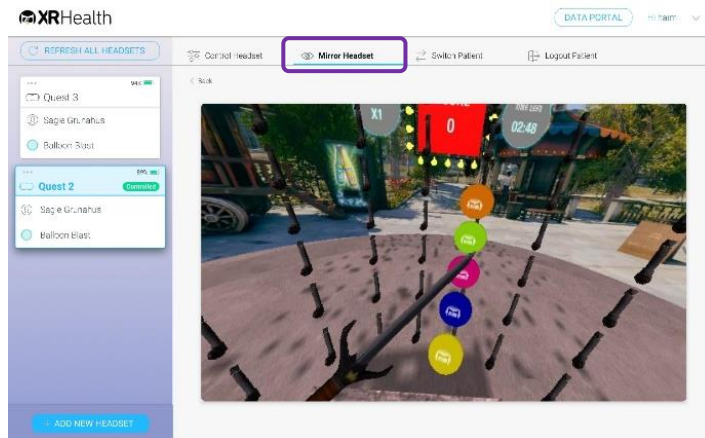
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10. Data Portal

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
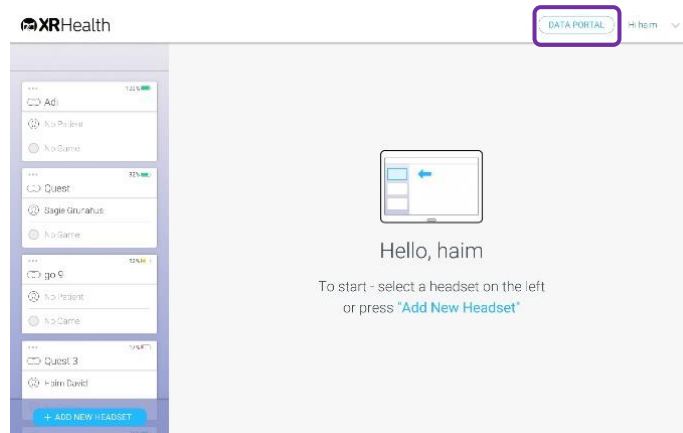
The Data Portal includes the following options:

1. Patient list (Only relevant for clinicians) – If you are a clinician, here you can select which patient data you want to view, create new patients and edit existing patients.
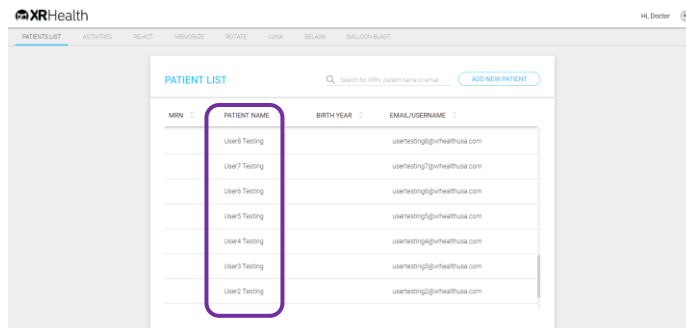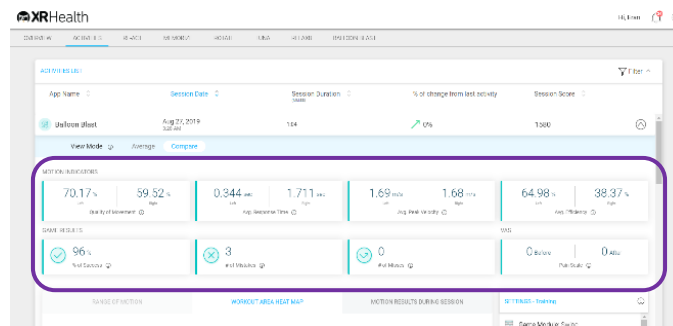

2. Activities view:
   a. In this view you can see a list of all the training session performed (on all XRHealth applications).

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b. Each line represents a session you have completed. Expand to see your data for a specific session by clicking a line

c. If you select a specific Balloon Blast session you will be able to view that specific session's result data on the upper tiles of the session:

    i. Motion indicator results – Motion indicators are calculated for each line of balloons you pop – The upper tiles gives you the overall average of the indicators for that specific session

        1. Avg. Quality of motion – also called smoothness - The ability of the user to create a smooth movement (relatively steady acceleration-deceleration while moving). score is between 0-100.

        2. Avg. Response time - Measured from when the first balloon appears in the field of view, until motion is initiated towards it. Measured in seconds

        3. Avg. Peak velocity - The highest velocity measured for each movement performed to pop up balloons sequence during the training. Measured in meter per second

        4. Avg. Efficiency - The ratio between the length of the hand's path during the movement and the length of the theoretical trajectory

    ii. Game Results:

        1. % of success

        2. # of mistakes

        3. # of misses

    iii. VAS results

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iv. Compare / Average mode – in the upper tile of an open session you can find the compare / average mode – toggling between the 2 states will change the results display where compare will show you results for left hand / right hand separately and average will show the average results for both.

d. In the graph section you will be able to choose one of the following tabs:

i. <u>Range of motion</u> – This section will be available only in case you performed a range of motion test. In this section you can see your range of motion test results in 3 plains of motion – Flexion / Abduction / Horz. Abduction for Left / Right hand.

ii. <u>Workout Area Heat Map</u> – This section will be available only in case you performed a training session (and not just a Range of motion test). In this section you can see a heat map of your training where each dot represents a position in degrees on the balloon greed. The color of the dot represents the amount of milli-seconds that you worked in that specific location in space – the darker the dot, the more time you worked in a specific location (hover on the dot to get the number of milli-seconds). The blue marking represents your play area selection. This view is divided to left / right in order to enable you to see your results for each hand.

iii. <u>Motion Results During Session</u> – This section will be available only in case you performed a training session (and not just a Range of motion test). In this section you can see the result of each line of balloons in the game for the following parameters:

1. Quality of motion – also called smoothness - The ability of the user to create a smooth movement (relatively steady acceleration-deceleration while moving). score is between 0-100.

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2. Response time - Measured from when the first balloon appears in the field of view, until motion is initiated towards it. Measured in seconds

3. Peak velocity - The highest velocity measured for each movement performed to pop up balloons sequence during the training. Measured in meter per second

4. Efficiency - The ratio between the length of the hand's path during the movement and the length of the theoretical trajectory

With this view you can see how your results change during the time of the session. Compare mode will divide these graphs to 2 different graphs for left and right.

3. <u>Application Dashboard view</u> – 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. Select Balloon Blast dashboard on the top tab menu:
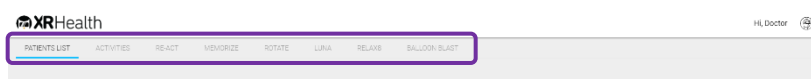
   i. High level summary – view the best overall result highlights:
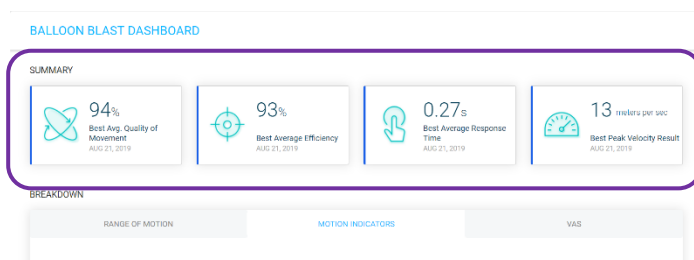
   b. Dashboard Breakdown – In the breakdown the following data can be viewed:

     i. Range of motion results over time for each hand

     ii. Motion indicators over time – In the dashboard view a motion indicator data point is the average motion indicator for the session – this will enable you to compare between sessions.

       1. Compare / Average mode- like the activity page, using the compare mode on the motion indictors

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graphs will let you see your results over time for each hand separately. Toggle back to average mode to see your progress for both hands together.

2. Avg. Quality of movement
3. Avg. Response time
4. Avg. Efficiency
5. Avg. Peak velocity

iii.   VAS results

Select the time frame of the graph (last 5/10/15 sessions or all the sessions available)
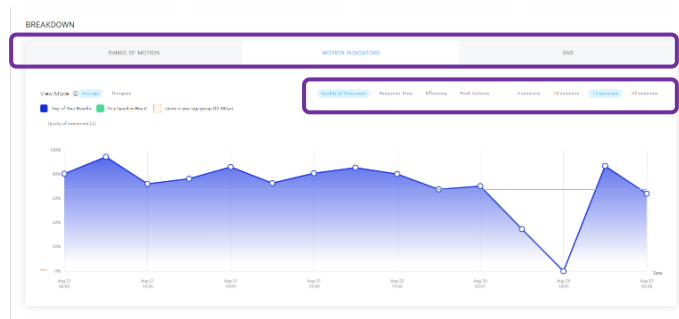
11. Mobile App

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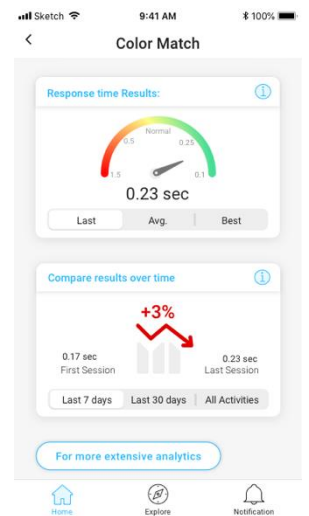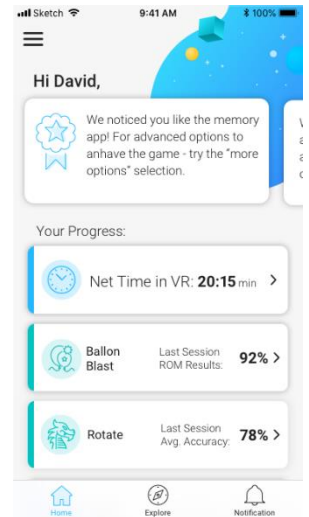
e. Explore – a variety of videos, blog posts and health related info

f. Notifications – notifications generated based on patient data giving insights and metrics about the patients results
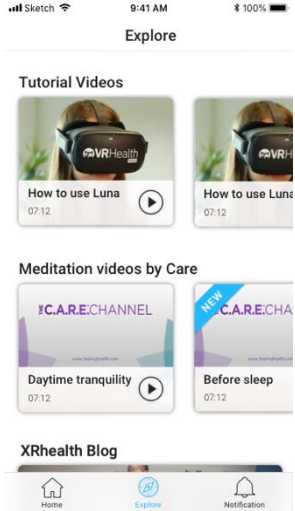
Appendix A: Approved VRH List

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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