XRHealth

VRPhysio Home™ N-140 "Rotate"

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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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

N-140   VRPhysio Home N-140 software (*"Rotate"*)

Latest Version   Version 1.2.5

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2. General Information

Intended use

The N-140 ("Rotate") is a physical medicine and rehabilitation software, as a medical device, intended for use in cervical region conventional rehabilitation and active cervical spine 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.

N-140 is not intended to be used for diagnosis, treatment, decision making, or as a stand-alone device.

Intended user populations

N-140 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 N-140 to support the performance of their prescribed physical exercises as part of their conventional rehabilitation.

Intended use environment

N-140 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 N-140 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. Odontoid (Dens) fracture;

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

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

9. Any recent unexplained loss of consciousness.

10. Seizures or taking antiepileptic medications.

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

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

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. Malignant conditions – patients diagnosed with SOL or other malignant condition require extra attention to prevent any damage associated with affected anatomical structures.

4. 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.

5. 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.

6. 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.

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.

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 N-140 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 N-140.

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.

6. N-140 Overview

Software description

6.1. The N-140 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 N-140 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).

6.4. The current version of N-140 includes a single game: "Rotate".

6.5. This game mode supports therapy of patients required to perform active movements of their cervical spine as part of their treatment regime.

6.6. N-140 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:

- Desired area for active movements (expected ROM);
- Speed of motion;
- Difficulty of motion;
- The total duration of the training session.

6.7. N-140 allows the Health Care Provider and the patient to configure the game module parameters to create a customized training program. N-140 software is not intended to be used for diagnosis, making treatment decisions, or as a stand-alone device. Health Care Providers who choose a specific game configuration 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.

6.8. 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.

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Hardware and Software requirements

6.9. The usage of the N-140 software requires a pre-purchase of a high-end off-the-shelf VR platform:

- The compatible VR platforms for the use of N-140 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

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

6.11. The software comes with automatic update capabilities.

6.12. 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.

6.13. 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.

6.14. 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

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

6.16.　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 N-140 software:

☐ Carefully read the instructions for use by the VRH manufacturer (list of compatible hardware for N-140 available in <u>Appendix A</u>, below).

☐ Carefully read the Health and Safety Warning of the VRH manufacturer (list of compatible hardware for N-140 available in <u>Appendix A</u>, 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 <u>contraindications for use</u> and <u>additional precautions</u> for the use of N-140 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 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 neck movement (also after medical procedure) shall be performed only per the physician recommendations, do not overdo these recommendations.

☐ Immediately terminate the VR session and discontinue using the VR headset in any case of pain, discomfort, dizziness or nausea resulting from

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the usage of the N-140 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 N-140 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.

8. N-140 Training Experience

8.1. The Rotate N-140 application includes 2 main elements:
   a) **Neck Range of Motion measurement** – Measures the user's active range of motion in 6 different planes: R/L Rotation, Flexion, Extension and R/L side bending.
   b) **Neck training game** – A training game in which the user moves his/her gaze in a defined training area in combined neck movements. The training gameplay is described below.

8.2. **Neck Training Gameplay:**

   a) Evil Nasty creatures have STOLEN ALL THE COLOR FROM THE WORLD!
   b) The only ones that can bring it back are cute little dragons.
   a) The player needs to follow the cute dragon with their gaze, while that dragon collects energy pellets to bring back color to the game world.
   b) In more detail, the dragon will fly from one pellet to the next, while the Evil Nasty creatures attempt to touch it and siphon its energy.
   c) When the player looks at the dragon, a magical beam of energy touches the dragon and it is then engulfed in an energy shield that repels the Evil Nasties.
   d) Sometimes the dragon will come across an energy pellet that is shielded and will have to munch on it for a while before eating it, which will force the player to look at the same spot for a while.
   e) The users have a limited time to play in each environment.
   f) If they return all the colors to the environment before the time is done, they advance to the next level.

8.3. **Settings screen:**

1. Start Tutorial:
   • Play the training tutorial.

- Tutorial will run automatically while using the application for the first time

2. Select training modules:
- <u>Training Only</u> – Neck training session only, no ROM Test
- <u>ROM & Training</u> – ROM test followed by neck training session.
- <u>ROM Only</u> – ROM test only, no neck training

3. Training Area:
- Choose the size of the area in space in which the game shall take place (Small, Medium, Large). This parameter sets the degrees for the movement elements: Rotation (left/right), Flexion and Extension.
  a) <u>Small</u>:
     I.   35 Deg rotation
     II. 25 Deg flexion/Extension

  b) <u>Medium</u>:
     I.   45 Deg rotation
     II. 30 Deg flexion/Extension

  c) <u>Large</u>:
     I.   60 Deg rotation
     II. 35 Flexion/Extension

  d) <u>"Based on ROM"</u> - Training area will be set according to last ROM test performance. Choose the desired percentage of movement elements of the training session from ROM values.

<u>NOTE:</u> To perform a session that is based on ROM test results, you need a ROM test result in your training history.

4. Difficulty:

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- Choose the motion difficulty of the required training out of 3 levels: Basic, Intermediate, Advanced. This parameter sets the curviness of the dragon's movement; The higher the difficulty, the curvier the flight route.

5. Speed Level:
- Select the training speed level:
   a)   Slow = $4\frac{Deg}{Sec}$
   b)   Medium = $8\frac{Deg}{Sec}$
   c)   Fast = $12\frac{Deg}{Sec}$
   d)   Custom − $1\text{-}15\frac{Deg}{Sec}$

Each level will set the maximum speed of the dragon's flight in the current session. Choosing the "Custom" option will let you set a desired maximum speed on the speed scale. Speed values are presented in degrees per second.
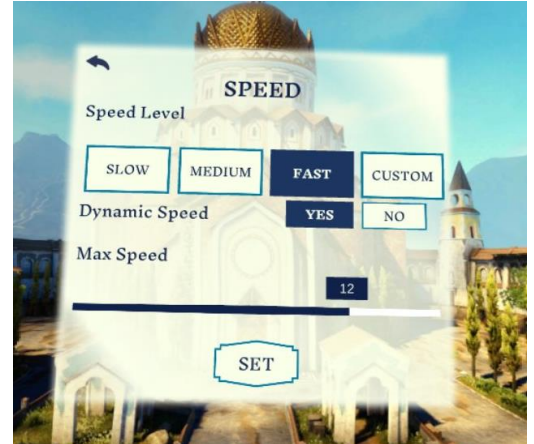
- "Dynamic Speed" − choosing "YES" will allow the speed level to change during the session according to the user's average accuracy. Accurate tracking will result in the dragon speeding up. Non-accurate tracking will cause a speed down.

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

7. Music:
   7.1. Choose the type of music you would like to listen to while performing the session (Fun, Workout, Relaxing) or select "No Music" if you wish for no music. Volume control is available.
   7.2. Changing the music or volume are available at any time through the Pause Menu.

8. VAS:

8.1. Choose if to ask the patient to rate their pain on a scale of 0-10 before and after a session.
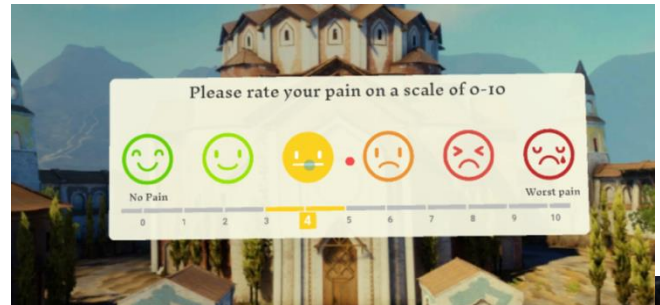
8.4. Pause Menu

a) Pressing the pause button on the controller will pause the session and open the pause menu. You may change the type of music played and the volume. Furthermore, you can choose whether to finish the session or resume.

8.5. Summary screen

a) The summary screen includes both ROM test results and training session results.

b) If only one module was chosen (ROM/Training), summary screen will present the relevant results only.

c) ROM Results:

    I. Displays the range of motion measurement result in each direction measured.

    II. Smoothness – indicates the quality of movement performed during the ROM test (percentage). A high percentage signifies smooth motion.

d) Session results:

    III. **Score** – Collecting energy units grant the dragon points. When the tracking is accurate the user collects more points. This displays the total points collected in the session.

    IV. **Speed Level** – Represents the speed level at the end of the session.

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V.   **Accuracy** – Indicates how accurate the user's tracking is. It represents the difference between the gazing point compared to the location of the dragon.

VI.   **Response Time** – Response time is calculated when the dragon stops for "eating points" and returns to flight. The calculation measures the time from the moment the dragon starts to move until the user begins their movement in the same direction.

8.6. ROM Test

a)   In this measurement phase, the application will measure the patient's neck active ROM in 6 different planes:

    I.   Right Rotation
    II.   Left Rotation
    III.   Flexion
    IV.   Extension
    V.   Right Side bend
    VI.   Left Side bend

b)   ROM test Tutorial - The ROM Test tutorial will run automatically while using the application for the first time. Skipping the tutorial is possible by pressing the "Start ROM Test" button.

c)   Access the tutorial at any time during the ROM test by pressing the "Watch Tutorial" button.

8.7. <u>Range of Motion test flow:</u>

a)   The test begins with a calibration to correctly position the virtual environment.

<u>NOTE:</u> For 6DOF VRH users - it is recommended to verify that the floor level is calibrated correctly according to the VRH manufacturer's manual.

b)   The user is requested to sit up straight and move only the head (not shoulders/chest).

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c)   In each measurement the user should move his/her neck in the designated direction until he/she feels pain, or they reach the end of their range - <u>and then back to the center</u>.

<u>NOTE:</u> While performing a ROM test, move in a direct plane of motion and reduce combined movements of the cervical region to a minimum. In addition, make no radical movements or movements that might exceed the personal limits.

8.8. General

a)   During any part of the application the user can pause the session and access a menu enabling skipping, terminating or continuing.

b)   The menus are accessed by pressing the pause button.
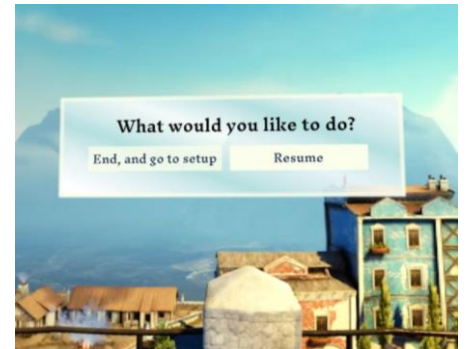
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9. External Control

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

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

1. Login – Login to the External Control app using your <u>Clinician</u> credentials.
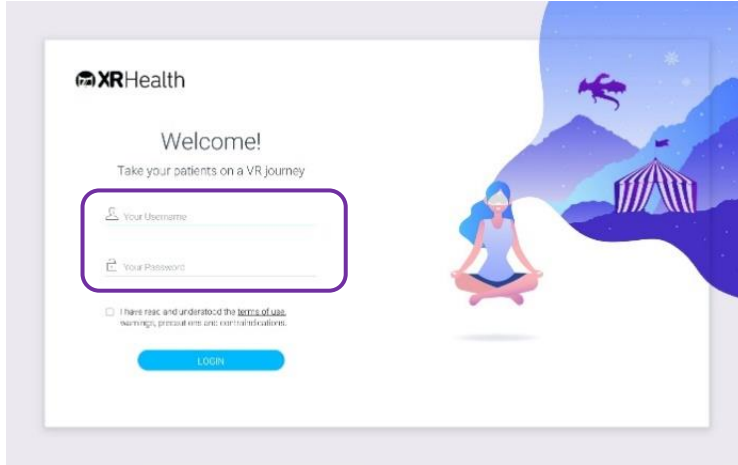
2. Pair a desired headset to external control device.
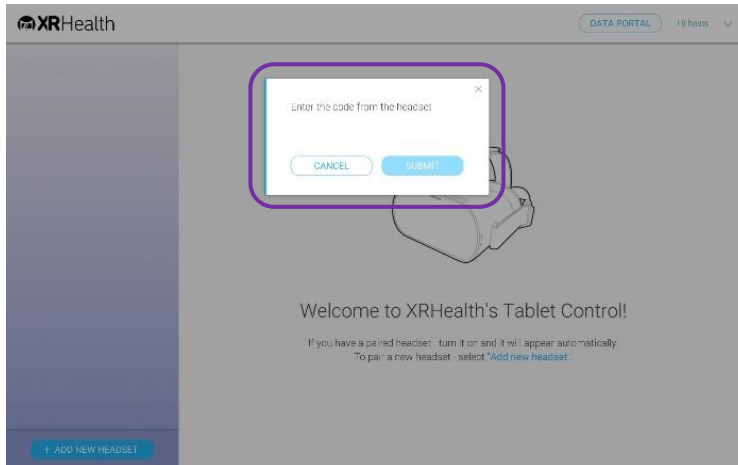
3. Select the <u>patient</u> with the VR device from the patient list.

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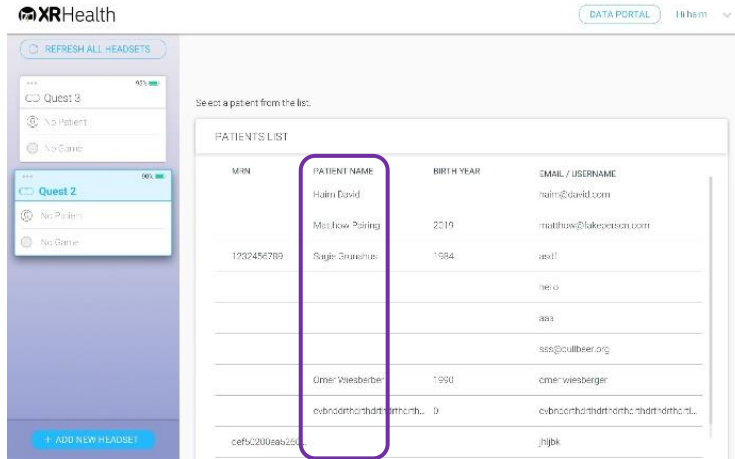
4. Select "Control" to define the training.
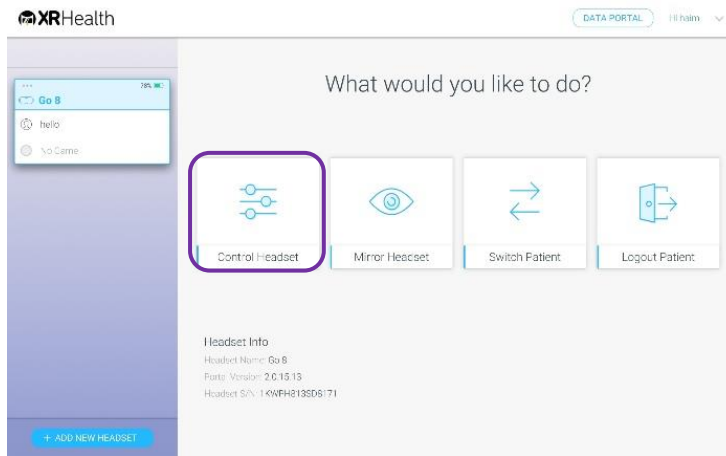
5. Select "Rotate" from the application list.
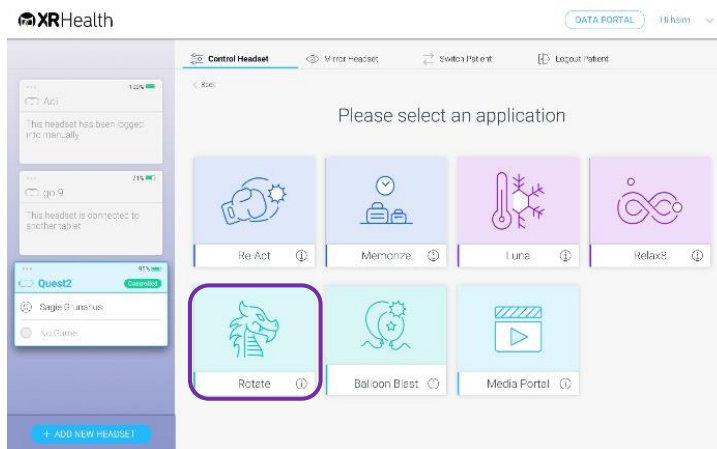
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6. Define the desired session settings (See settings screen description above) and select Start Session.
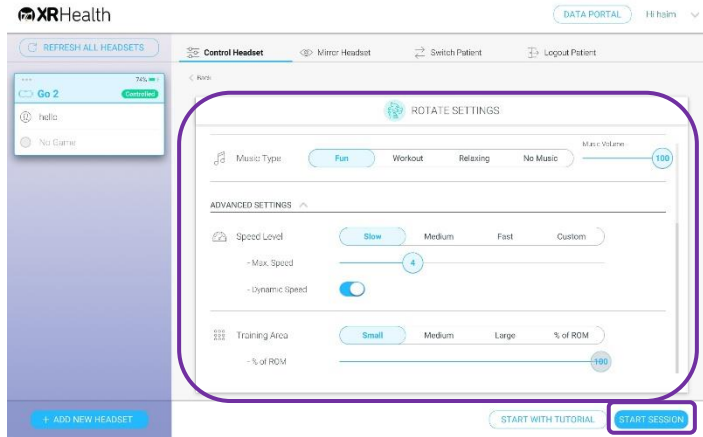
7. You can Pause or Finish the session at any time.
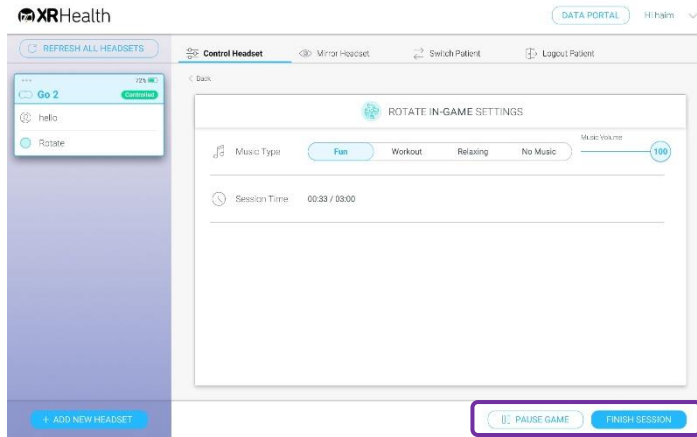
8. Selecting the "Mirror" tab will show you the patient view within VR.
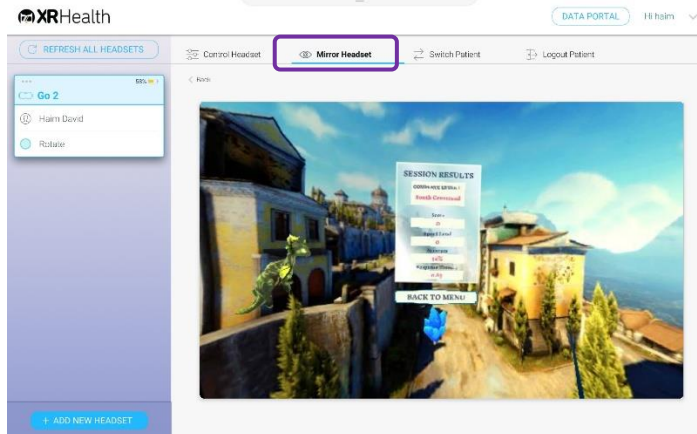
10. Data Portal

General

1. XRHealth Data Portal is a web interface, accessible from any device, that enables patients and clinicians to interact with user data and performance.

2. The Data Portal is the main interface for a clinician to create and manage his patients.

3. XRHealth Data Portal is accessible in the following URL: https://portal.xr.health

Clinician Onboarding process

1. As a clinician you will need to go through an onboarding process in the web portal on your first login.

2. Marketing team will supply you with an initial username and password. If you do not have your credentials, please contact support at support@xr.health.

3. Go to https://portal.xr.health and login with the supplied username and password to start the onboarding process.

4. In the onboarding process you will be required to set up your personal detail, email and new password.

Login

1. Login page is accessible on https://portal.xr.heath

2. 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.

3. For home users – the credentials for log in to the Data Portal are the same one used in the VR Portal.

4. Logout – once logged in – the option to logout is in the top right corner (press on the profile settings character)

5. Auto logout – for security reasons, the Data Portal will automatically logout after 15 minutes of inactivity.
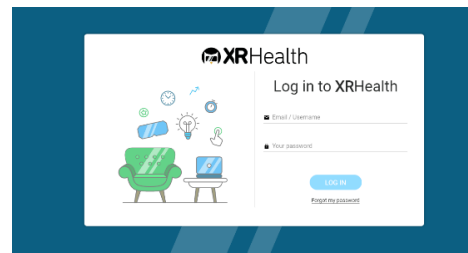
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6. After login you will see XRHealth welcome page where you can navigate to activities page or one of the dashboards.

Activities

1. 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.

2. The Rotate activity page will enable you to see your average results for session:

   a. Average Response Time – Response time is the interval between the appearing of an object and the initiation of movement in response to that object. Measured in seconds.

   b. Average Quality of Movement – The ability of the user to create a smooth movement (relatively steady acceleration-deacceleration while moving). Score is between 0-100%.

   c. Average Accuracy – This index show how well the user accurately followed the game objects, representing overall ability to produce the controlled movement required by the game.

   d. Final Speed Level -The speed level at the end of session.

3. On the right side you can find the different settings for that specific opened session

4. On the main graph you have 3 sections:

   a. Range of Motion – Here you can see the session range of motion results – Your baseline (First measurement), Your session result and the normative values for users in your age group.

   b. Accuracy during session – this graph will enable you to see how accurate you were in following the dragon during the session.

   c. Response time during session – each time the dragon stops for a snack we calculate how quick you were to start following him again. This enables us to calculate your response time. This graph will show you for every dragon stop the calculated result.

Dashboards

1. 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.

2. Navigate to the desired dashboard by clicking on the application name from the welcome screen or selecting the application name from the top bar.

3. Dashboards have 3 main sections:
   - Best Results: The upper tiles of the dashboard show the user best score in the application for various metrics monitored over time.
   - Main Graph: The main graph shows how the user metrics changes over time.
   - 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.

4. Different dashboards offer an extra functionality in a form of a calendar to show retention or a progress bar.

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User Profile

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

6. Managing your user profile enables the user to perform 2 things:
   - Change personal details: Name, Last Name, Email/username
   - Change password
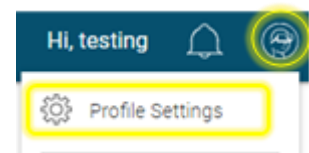
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Patient List (For clinician user only)

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

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

3. 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

4. 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)

1. XRHealth Data Portal enables a clinician to create / edit / delete patients.

2. We highly recommend filling up patient demographic and medical details in order to get the normative values for people in the age group / diagnosis.

3. 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.

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


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

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

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| MRN	PATIENT NAME	BIRTH YEAR	EMAIL/USERNAME		
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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
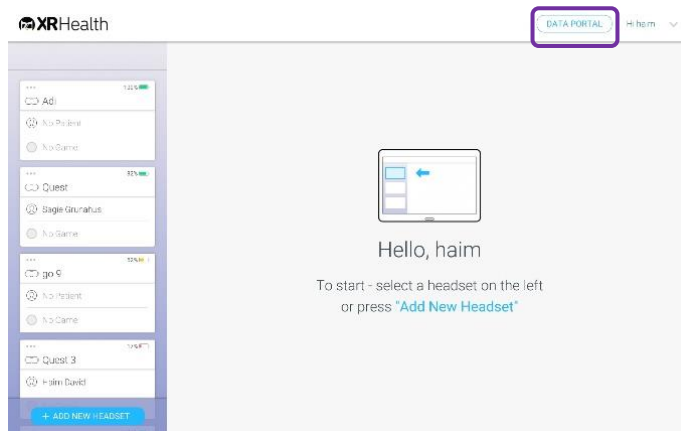
The Data Portal includes the following options:

1. <u>Patient list</u> (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.
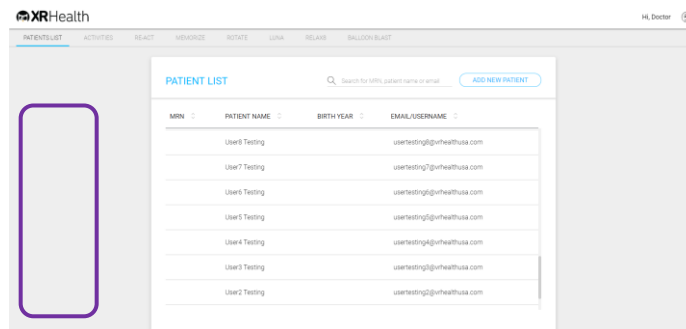
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2. <u>Activities view</u>:
   a. In this view you can see a list of all the training session performed (on all XRHealth applications).

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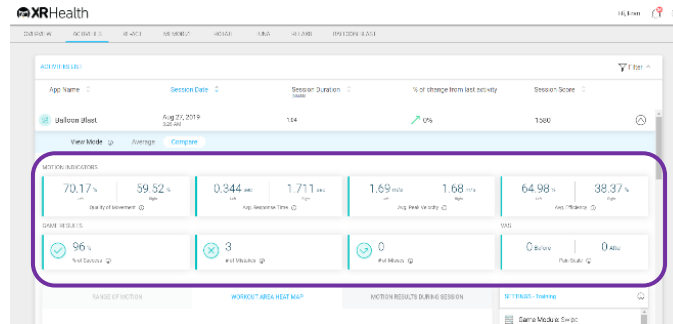
iv. Compare / Average mode – in the upper tile of an open session you can find the compare / average mode – toggling between the 2 states will change the results display where compare will show you results for left hand / right hand separately and average will show the average results for both.

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

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(relatively steady acceleration-deceleration while moving). score is between 0-100.

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 Rotate dashboard on the top tab menu:
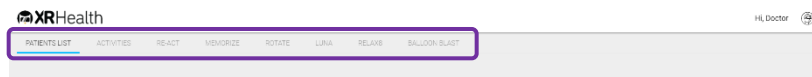
   i. High level summary – view the best overall result highlights:
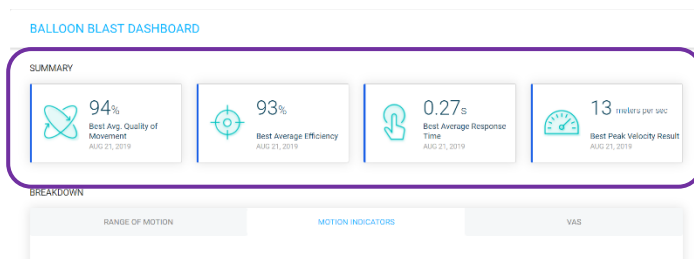
   b. Dashboard Breakdown – In the breakdown the following data can be viewed:

   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 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)
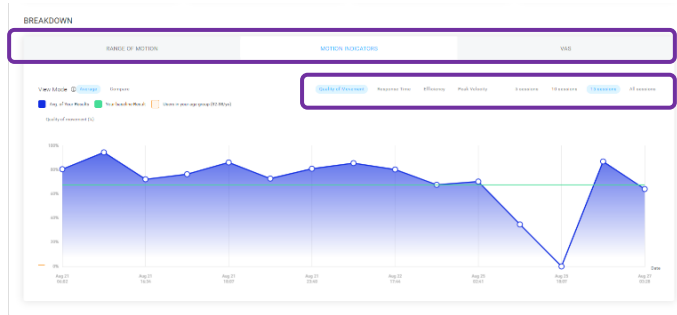
11. Mobile App

General

5. 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

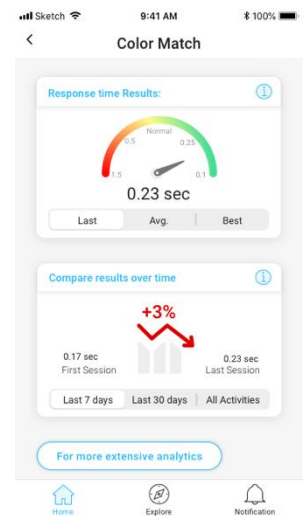 c. Exploring a variety of videos, blog posts and health related information

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

7. 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)
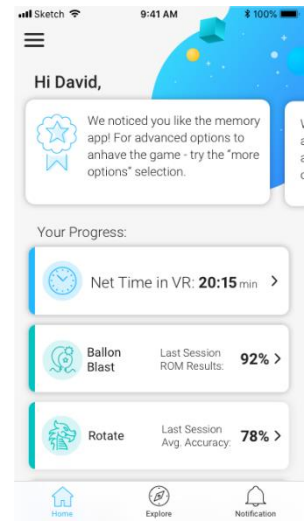
  d. In depth data screen (for a specific app) shows the following data:

    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
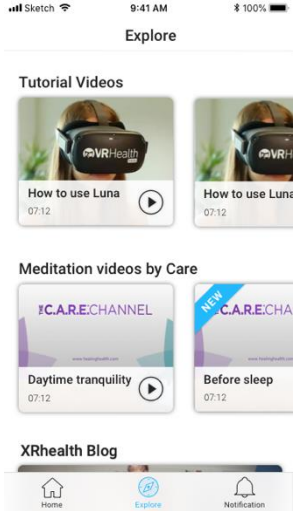
Appendix A: Approved VRH List

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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