XRCogni™ MC-320 "Color Match"

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: XRCogni MC-320 *("Color Match")* V1.2.8

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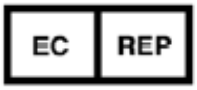

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1. Abbreviations and Symbols

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

MC-320 XRCogni MC-320 (“Color Match”)

Latest Version Version 1.2.8

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2. General Information

Intended use

The MC-320 ("Color Match") is a physical medicine and motor-cognitive rehabilitation software, as a medical device, intended for use in upper extremity, full body and motor-cognitive conventional rehabilitation. The software enables:

- Tracking motion and movement kinematics.
- Guiding patients in the performance of motor-cognitive exercises according to the treating medical practitioner's guidelines.
- Monitoring changes in patient's measurements over time

MC-320 is not intended to be used for diagnosis, treatment, decision making, or as a stand-alone device.

Intended user populations

MC-320 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 MC-320 to support the performance of their prescribed motor-cognitive exercises as part of their conventional rehabilitation.

Intended use environment

MC-320 software is intended to be used only in the following environments or areas:

- Physical medicine hospital units;
- Physical therapy clinics;

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- Any other facility that utilizes physical activity treatment;
- Home environment;

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3. Contraindications

Before using the Color Match software, the Health Care Provider (and/or the end user) shall make sure that they do 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; If the user feels any discomfort, they 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, they 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 do not fit under the VR headset or have other major visual abnormalities 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.
8. Balance disorders – as VR experience is immersive, Health Care Providers are advised to use their clinical judgement before exposing the patient to the

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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 XRCogni 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.

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 XRCogni software series) are applicable when used with XRCogni MC-320 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 MC-320.
3. XRHealth R&D 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 XRCogni 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. MC-320 Overview

Software description

6.1. The MC-320 is a physical medicine and motor-cognitive rehabilitation software, as a medical device, which delivers an immersive experience for patients to stimulate and engage them to their specific conventional motor-cognitive rehabilitation treatment through the use of games and entertainment features.

6.2 The MC-320 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 MC-320 includes a single game: “Color Match.”

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

6.5. MC-320 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 cognitive task (module);
- Difficulty of task;
- Desired area for active movements;
- Goal movements pace;
- The total duration of the training session.

6.6. MC-320 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 Menus settings). 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; MC-320 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.

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 MC-320 software requires a pre-purchase of a high-end off-the-shelf VR platform:

- The compatible VR platforms for the use of MC-320 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 R&D 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.

7. Instructions for use

7.1. The following instructions shall serve as a check-list for operating the MC-320 software:

- □ Carefully read the instructions for use by the VRH manufacturer (list of compatible hardware for MC-320 available in Appendix A, below).
- □ Carefully read the Health and Safety Warning of the VRH manufacturer (list of compatible hardware for MC-320 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 MC-320 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 MC-320 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.

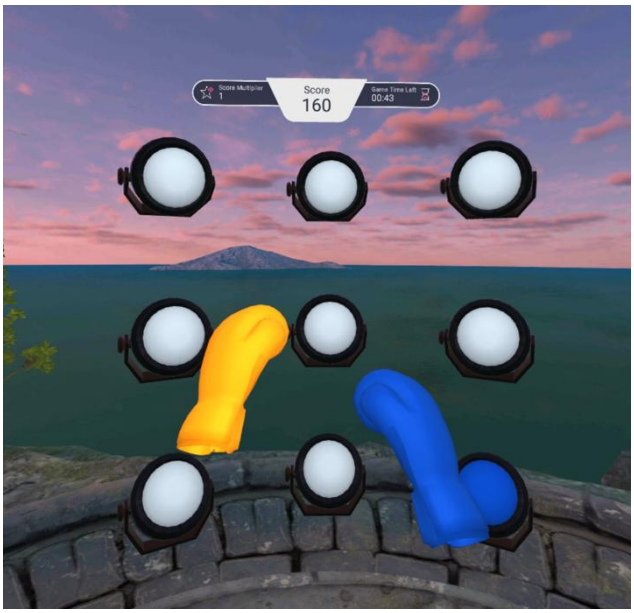
7.4. If you suspect that the trouble is related to hardware malfunction/calibration, you can reset the VRH and restart the training session.

7.5. If you suspect that there is a problem with the MC-320 software, immediately contact XRHealth R&D 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. MC- 320 Training Experience

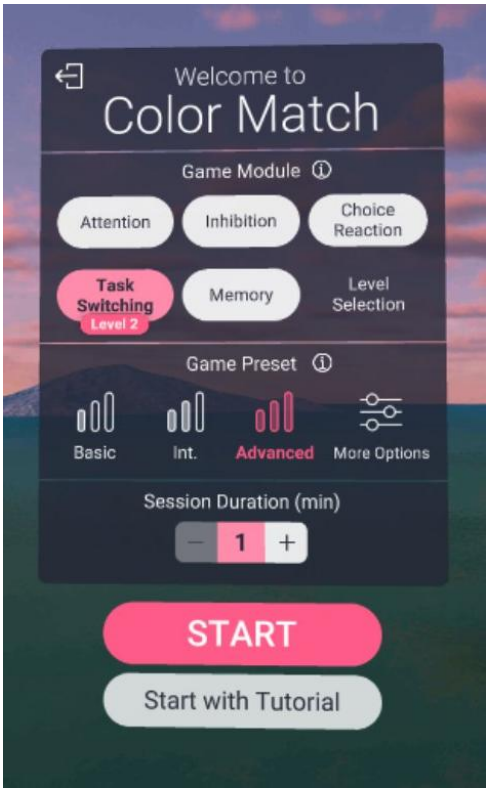
Color Match



"Color Match" is a motor-cognitive training game. In the game the player is positioned in front of a grid of 9 buttons. During the game the buttons light up in different colors according to the module selected (each module has different game rules). The user is holding gloves and is instructed to touch the colored buttons according to the specific module rules.

Each step in the game (when the user presses a button) – the performance is monitored and analyzed. When the session ends all the session results are displayed (summary screen is explained below). The results can also be accessed via the XRHealth Data Portal (also explained below).

The game modules are:



1. **Attention:**

Buttons will light up in only one color.

2. **Inhibition:**

Buttons will light up in two colors - one to press and one not.

3. **Choice Reaction:**

Buttons will light up in 3 colors, one for the right hand, one for the left and one not to press.

4. **Task Switching:**

The colors of the gloves and buttons will change every once in a while.

5. **Memory:**

The user will have a specific memory task defining when to press the buttons.

Each module also has specific levels that give more in depth differentiation. The levels selection will be explained below.

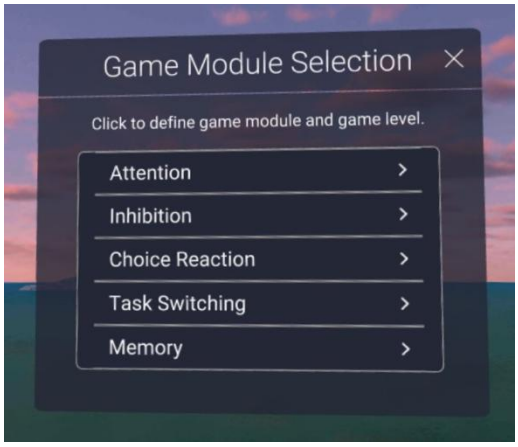
Menus

Settings screen

The following parameters can be changed in the settings screen:

Game module – As explained above – selecting the game module changes the rules of the game. If necessary, the specific rules are explained in the tutorial.

Level Selection - Each modules (Exept Attention) has different levels that further change the game rules. The level selection is possible using the "Level selection" button. This opens a specific menu (displayed on the right).



The levels are:

Attention:

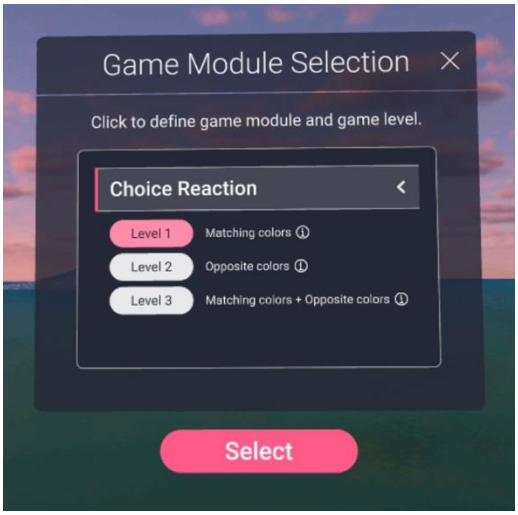
Level 1 - In this module, both gloves will receive one color for the entire session. When a button lights up, it will only appear in the same color as the gloves.

Inhibition:

1. Level 1 - Two different colors - The buttons will light up in one of two different colors. Press the same color as gloves.
2. Level 2 - Two similar colors - The buttons will light up in two similar colors - the color of the gloves + a similar shade not to press.

Choice Reaction:

1. Level 1 - Matching colors - In this level the object of the game is to touch the same colored gloves and buttons. Each glove has a different color. E.g. Red buttons with Red glove and Blue buttons with Blue glove, avoid white buttons.
2. Level 2 - Opposite colors - In this level the object of the game is to touch the opposite colored gloves and buttons. Each glove has a different color. E.g. Touch Red buttons with Blue gloves, Blue buttons with Red gloves, avoid white buttons.



3. Level 3 - Matching/Opposite switch - In this module there is a cue that tells the player if he needs to press the matching colors, or opposite colors.

Task Switching:

1. Level 1 - Both hands same color - In this level, both gloves receive the same color. There are 2 colors - one to press and one not to press. When a task switch occurs, the colors change to new ones.
2. Level 2 - Each hand different color - In this level each glove has a different color. Each hand should touch the matching color. When a task switch occurs, the colors change to new ones.
3. Level 3 – As in Level 2 + hit opposite colors - This level has the same logic as level 2, but the object of the game is to press the OPPOSITE colors. When a task switch occurs, the colors change to new ones.

Memory:

1. Level 1 - Corsi Task - repeat in presented order:
    a. At the start of the test, a subject needs to keep track while a specific sequence of buttons are lit up (The “demonstration” phase)
    b. To help the encoding process and to make the game more playable, each button on the grid should possess unique color and sound fixed for the module.
    c. Game flow:
        i. The game begins with in round #N. N is defined on the setting screen (Memory task length) and defines the length of the preliminary sequence.
        ii. Each round there is a demonstration of the flow to press followed with time for the user to respond (mimicking the demonstration).
        iii. The sequences are selected randomly.
        iv. If a user succeeds two rounds in a row - the sequence increases by N+1.
        v. If two errors occur in a row it will reduce the next sequence by N-1.
        vi. To differentiate between the demonstration phase and response phase - The demonstration is terminated by a specific sound, after which the subject has to repeat the observed sequence.
        vii. There shall be two levels:

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viii. Level 1 - the user is requested to repeat the sequence in the presented order (beginning to end)
ix. Level 2 - the user is requested to repeat the sequence backwards (end to beginning)
x. This instruction should be displayed in a popup before the session begins (presented/backwards)

d. Dynamic speed should be disabled (Speed fixed on selected setting).
e. Unset grid:
i. In order to make the task more difficult to code the grid (3*3) should be unset grid as shown below (image for illustration)
ii. The position of the buttons will be manually set during development in a stationary position (all tasks same grid positioning).
iii. The size presets (small, med, large) will be disabled and the positioning will always be set.

2. Level 2 - Corsi Task - repeat in reversed order (see above instructions)
3. Level 3 - Sequence :
a. In this level the user is presented with a sequence of colors. The length of the sequence is defined in the advanced menu.
b. One the level begins, the user needs to press touch the last button of the memorized sequence, if it appears (if it doesn't - he presses nothing).
c. There shall be a preliminary phase where the memory sequence is displayed to user. A pop-up message visually displays the sequence (for example - RED, BLUE, GREEN). The pop-up should have a continue button for the user to press when he/she are ready to continue.
d. There shall be 3 randomly selected colors for this level regardless of the sequence length
e. Both gloves receive the same color.

4. Level 4 - Position based NBACK:
a. In this level, the user is presented with a sequence of stimuli, and the task consists of pressing the button when the current stimulus matches the one from n steps earlier in the sequence.
b. We shall add an “easier” level of NBACK where the user selects the NBACK based on position and not color:

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c. Level 4 - Position based NBACK - (visual spatial simple n-back) stimulus should be in one color appearing on the grid randomly, and the user tries to track the position of the n- back stimulus

5. Level 5 – "Regular" NBACK :
    a. In this level, buttons light up one by one in from of the user, and the task consists of pressing the button when the current color matches the one from N steps earlier in the sequence.
    b. N is defined in the advanced menu.
    c. There shall be a preliminary phase where the N of the task is presented. a pop-up message visually displays the N for the task. The pop-up should have a continue button for the user to press when he/she are ready to continue.
    d. Both gloves receive the same color.
    e. There shall be 3 randomly selected colors for this level

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Game Preset – selecting a game preset defines different parameters from the "More Options" menus Automatically. You can edit the parameters manually using the "More Options" menu (see below)

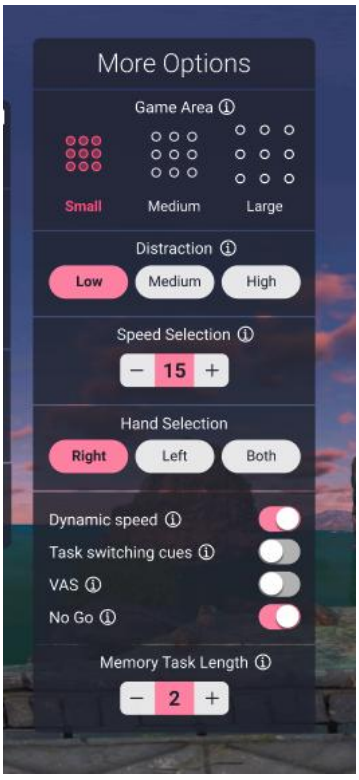
	Basic	**Intermediate**	**Advanced**
Game Area	Small	Medium	Large
Speed Level (Configable)	4	8	15
Hand selection	Both	Both	Both
Dynamic Speed	On	On	On
Task Switching Ques (for task switching module)	On	On	On
VAS	Off	Off	Off
No Go (for Choice reaction and Task Switching)	On	On	On
Memory Task length (for Memory module only)	2	2	3

Session Duration – select the duration of the training. At the end of the duration the session will end, and the user will be able to see results.

Start/Start with tutorial – When using each module for the first time, it will automatically start with a tutorial (for the selected module & level). After that, to view the tutorial again select “Start with Tutorial” – this will play the tutorial for the selected module & level and start the training immediately after.

More Options

The following parameters can be changed using “More Options”



Game Area - The game area defines the physical distance between the buttons. A larger game area will require larger motions.

Distraction - There will be 3 basic environments:

1. Low Distraction - the grid will be visible with a basic island (with nothing on it) environment
2. Mild Distraction - the grid will be visible with the same environment as in current MC320 version (Thailand environment)
3. High Distraction - we should include a dynamic environment where moving objects are visible within the users field of view while playing the game.

Speed selection - The speed selection represents the speed in which the buttons appear and disappear. The speed levels are defined by two specific speed variables:

- Button Time Out – This variable defines the time in which the player must press the button before it disappears, or else a mistake will be charted.
- Time between buttons – This variable defines the time between the end of one step (successful or not) until the next button lights up.

See Appendix B for a table of Speed Levels

Hand selection – Defines if the training will be performed in one (left/right) or both hands.

Dynamic Speed - Enables speed changes in the game according to performance. The game will speed up after consecutive success and speed down after consecutive errors.

Task Switching Cues - Enabling task switching cues will give the user an audio cue when a task switch occurs. This is only relevant for the Task Switching module.

VAS - Add a VAS pain/Attention selection phase before and after training.

No Go - Disabling the No Go selection will remove the No Go options from all modules. Buttons will only appear with the colors of the gloves.

Memory Test Length - This parameter signifies the length of the memory task –

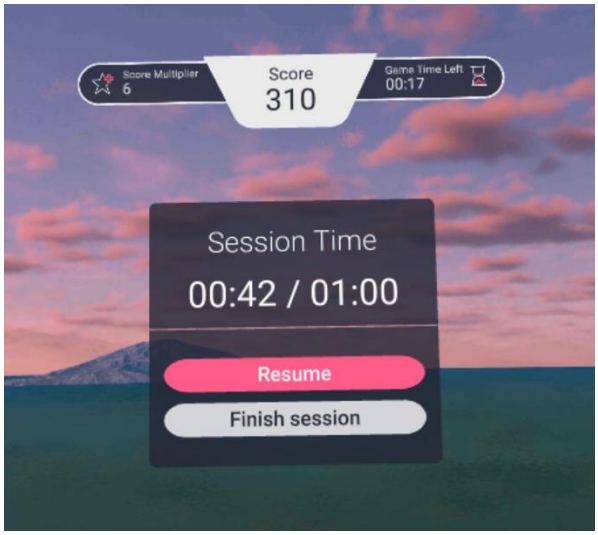
- In Level 1+2 – the length of the preliminary Corsi task
- In level 3 - the length of the sequence
- In Level 4+5 - the "N" of the NBACK

Pause Menu

Pressing the Menu button on the left Quest controller will pause the session and open the Pause menu.

In the Pause menu you have the option to Finish the session or to resume.

Pressing the Menu button in any other stage of the game opens a pop-up menu enabling different options.



Summary screen

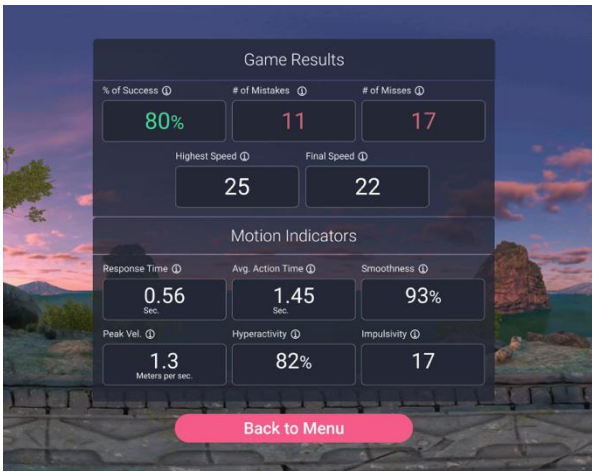
The following game results are displayed in the summary screen:

% Success - Percentage of overall successful selections.

# of mistakes - Number of wrong selections performed.

# of misses - Number of buttons that should have been pressed but were missed.

Highest Speed - The highest speed level achieved during the game.



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

Motion Indicators:

Avg. Response Time - Response time is measured from when a button lights up, until a motion is initiated in the direction of the button.

Avg. Action Time - Action time is measured from when a button lights up until it is pressed.

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

Peak Velocity - Indicated the peak velocity of the motion, measured in meters per second.

Hyperactivity- Indication of Total Excessive motor Movement, beyond specific target motor movement.

Partial Impulsivity – Indication of motor movements towards NO-GO targets ending without pressing the NO GO button (should include amount, length, reaction time and stop time)

VAS – Visual Analog Scale

If selected in the menu the Visual analog Scale can display one of two VAS scales:

1. Alertness
2. Pain

This records the user's subjective selection before and after the session. The selection is on a scale of 0-10. If the user doesn't select anything of closes the scale the phase is skipped.

Calibration Phase

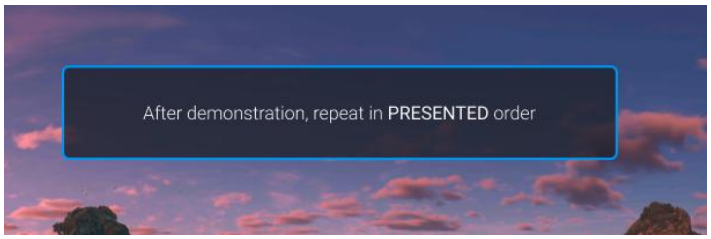
Before each training session the user will be requested to look forward so the system can automatically calibrate his/her position. This will re-center the VR

experience to the current standing position and ensure that all the measurements are accurate.

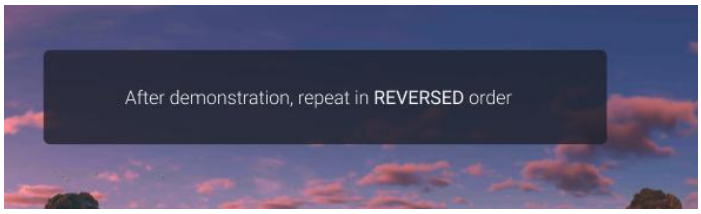
Memory menus

When using the memory module, the user is presented with special menus explaining the instructions. Here are examples for the instructions.

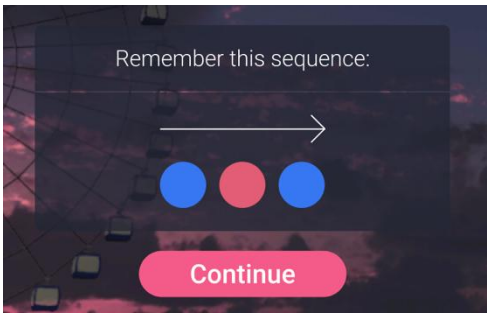
Memory Level 1 – Corsi task “Regular



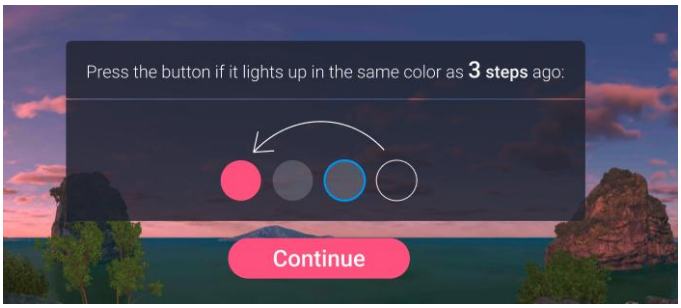
Memory Level 2 – Corsi task “Reversed”



Memory level 3 – Sequence



Memory level 4 – Positional NBack



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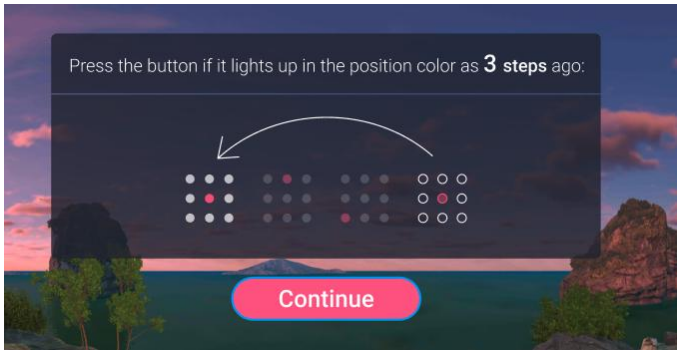
Memory level 5 – Color based NBack



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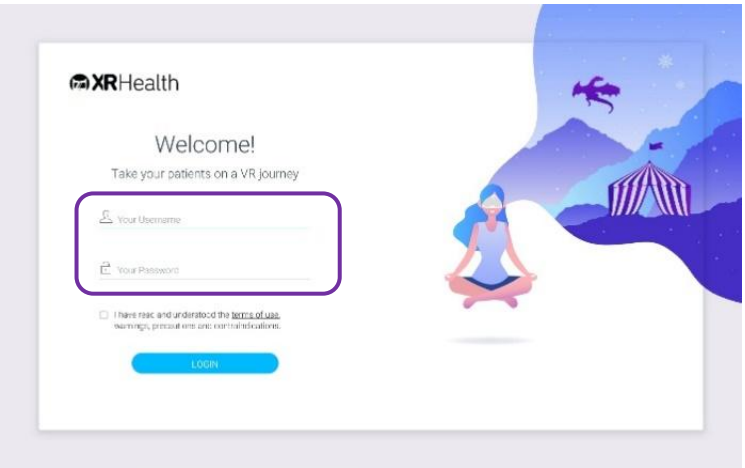
9. External Control

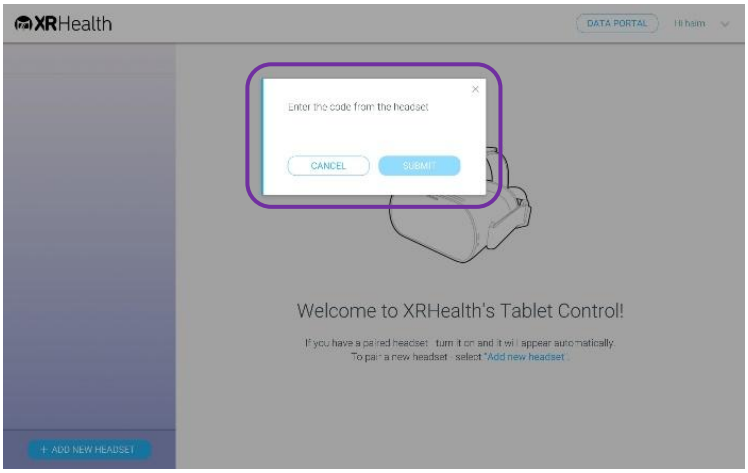
External control over the VR device is available via the XRHealth External Control app. To fully use all features of the External Control App – please fully read its User Manual.

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

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



2. Pair a desired headset to external control device.



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

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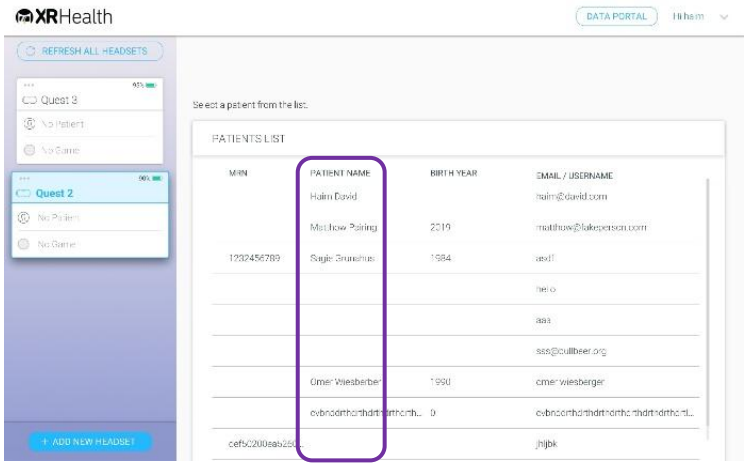
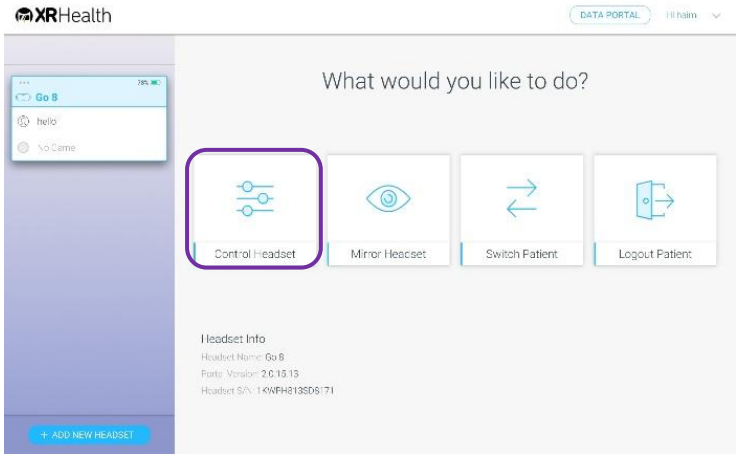
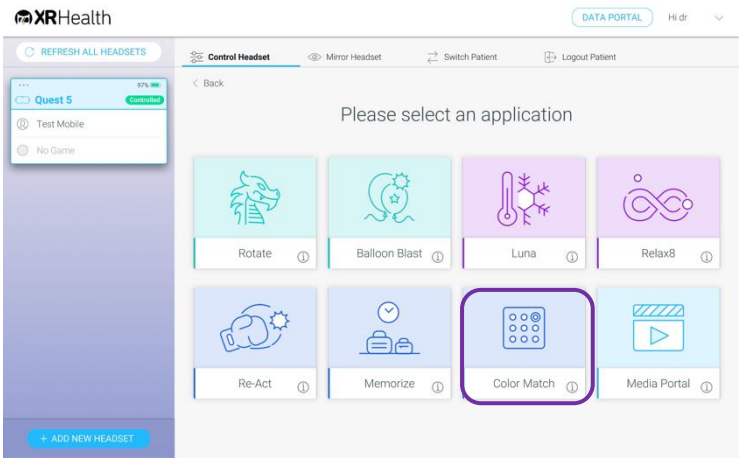


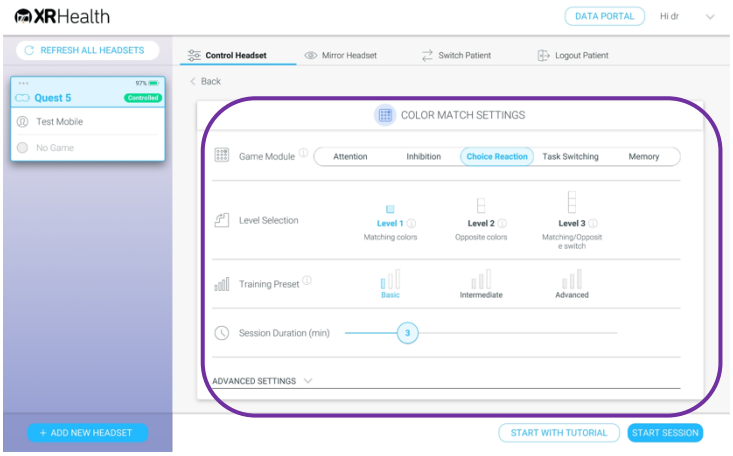
4. Select “Control” to define the training.



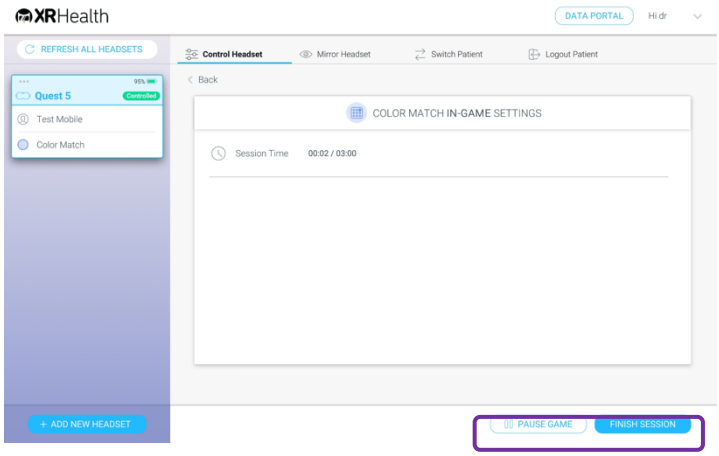
5. Select “Color Match” from the application list.



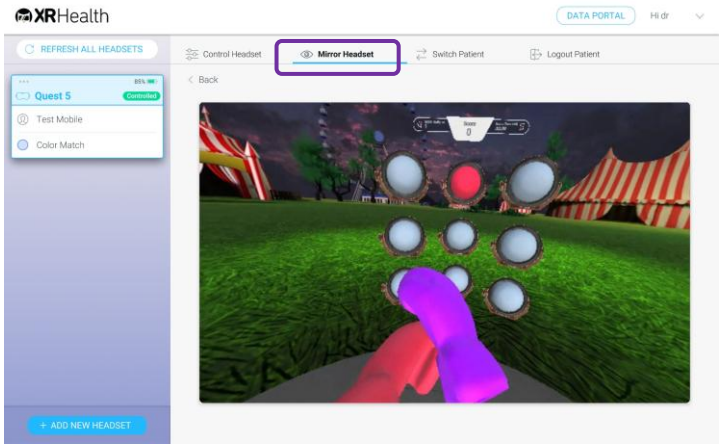
6. Define the desired session settings (See settings screen description above) and select Start Session.



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



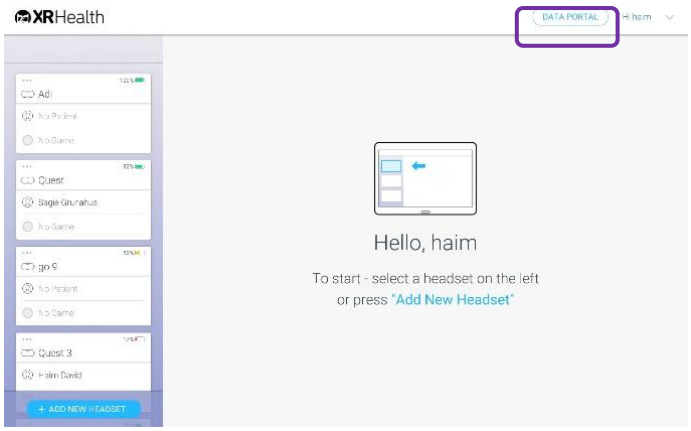
8. Selecting the “Mirror” tab will show you the patient view within VR.



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://platform.xr.health/en
   or via the External Control app on the top right corner

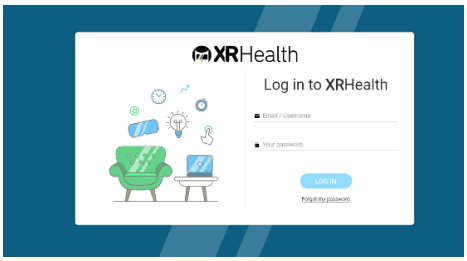


Clinician Onboarding process

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://platform.xr.health/en 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 details, email and new password.

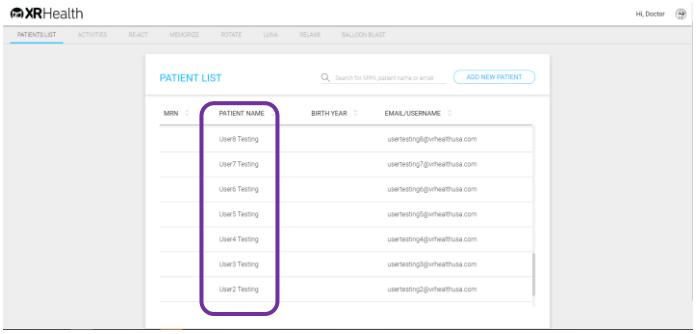
Login

1. Login page is accessible on https://platform.xr.health/en



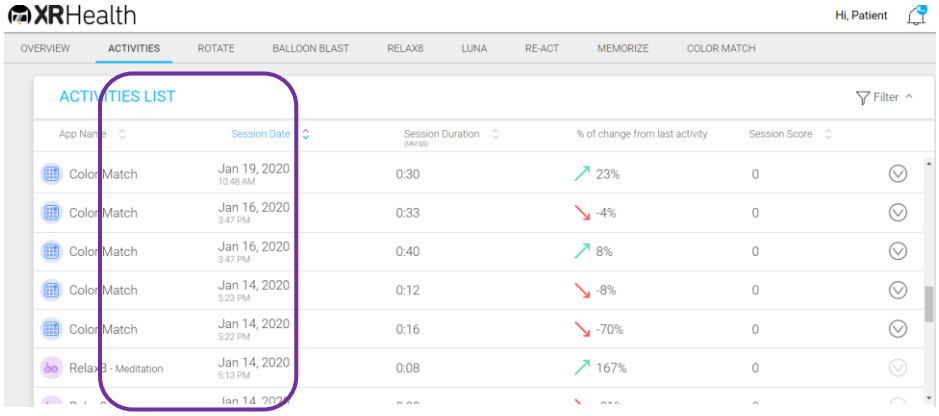
2. In order to login you will need your user credentials (patient or clinician). If you do not have your credentials, please contact support at support@xr.health.
3. For home users – the credentials for log in to the Data Portal are the same one used in the VR Portal.
4. Logout – once logged in – the 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.
6. After login you will see XRHealth welcome page where you can navigate to activities page or one of the dashboards.

The Data Portal includes a 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.



Activities

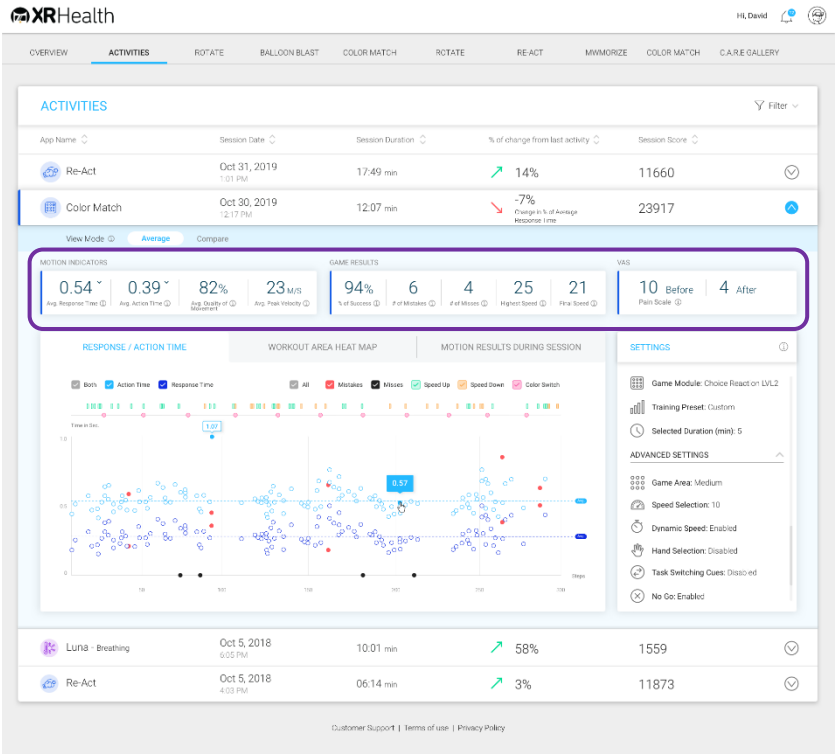
1. In this view you can see a list of all the training session performed (on all XRHealth R&D applications).



2. Each line represents a session you have completed. Expand to see your data for a specific session by clicking a line
3. If you select a specific Color Match session you will be able to view that specific session's result data on the upper tiles of the session:
    a. Motion indicator results – Motion indicators are calculated for each movement user perform to touch a button that lights up – The upper tiles give you the overall average of the indicators for that specific session
        i. Avg. Response time - Measured from when a button lights up in the field of view, until motion is initiated towards it. Measured in seconds
        ii. Avg. Action time - Measured from when a button lights up in the field of view, until it is pressed. Measured in seconds
        iii. 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.
        iv. Avg. Peak velocity - The highest velocity measured for each movement performed to touch a button that lights up during the training. Measured in meter per second
    b. Game Results:
        i. % of success – percentage of overall successful selections

ii. # of mistakes – number of wrong selections performed
iii. # of misses – Number of buttons that should have been pressed but were missed
iv. Highest speed – the highest speed level achieved during the game
v. Final speed – the speed level active at the end of the session

c. VAS results – A scale of 0-10 which reflects the severity of pain. 0 – no pain, 10 – unbearable pain



d. 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.

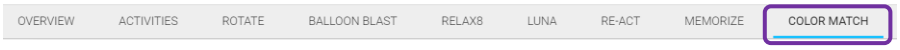
4. In the graph section you will be able to choose one of the following tabs:
   a. <u>Response / Action time</u> – this section will display the action and response times for every hit performed during the session. It also provides information on misses and mistakes, and when speed got faster or slower, and when colors were switched during the session. A legend is available above the graph.
   b. <u>Workout Area Heat Map</u> – In this section you can see a heat map of your training where each dot represents a position in degrees on the

player game area. 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). This view is divided to left / right in order to enable you to see your results for each hand.

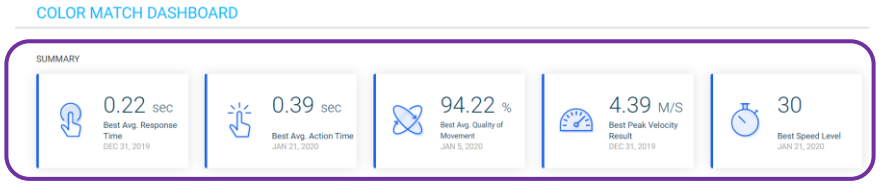
c. Motion Results During Session – This section displays results of each movement performed towards a button that lights up in the game for the following parameters:
    i. Quality of motion – also called smoothness - The ability of the user to create a smooth movement (relatively steady acceleration-deceleration while moving). score is between 0-100.
    ii. Peak velocity - The highest velocity measured for each movement performed to touch a button that lights up during the training. Measured in meter per second

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.

5. Application 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. Select Color Match dashboard on the top tab menu:



    b. High level summary – view the best overall result highlights:



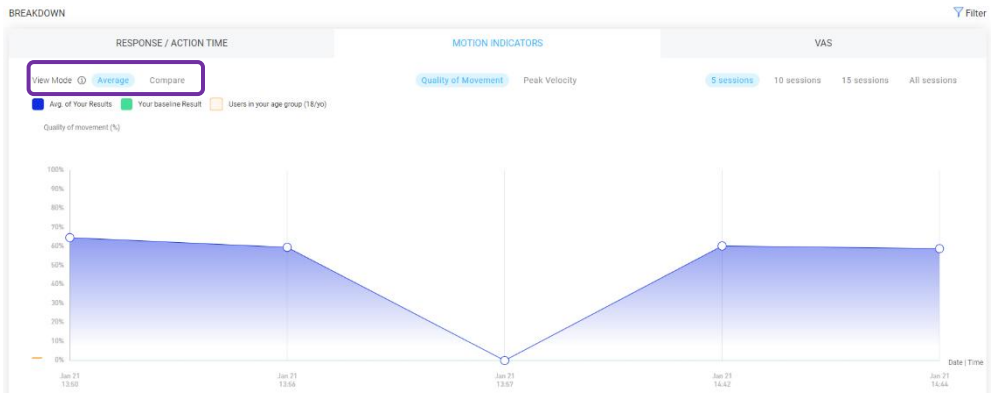
    c. Dashboard Breakdown – In the breakdown the following data can be viewed:

These graphs represent data of the averages from each session; each data point is the average motion indicator for the whole session

i. <u>Response / Action time</u> – you may change between response and action times using the toggle above the graph

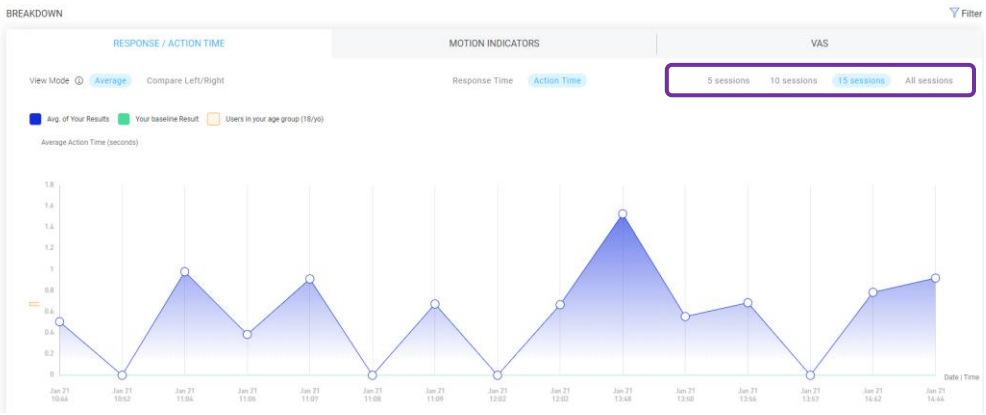
ii. Motion indicators over time – In the dashboard view a motion indicator data point is the average motion indicator for the session – this will enable you to compare between sessions.

d. 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.

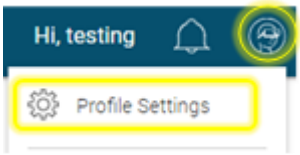


e. VAS results

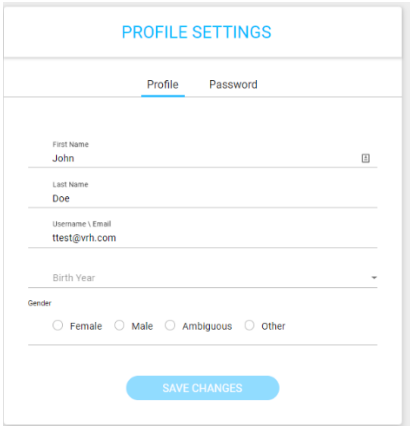
Select the time frame of the graph (last 5/10/15 sessions or all the sessions available)

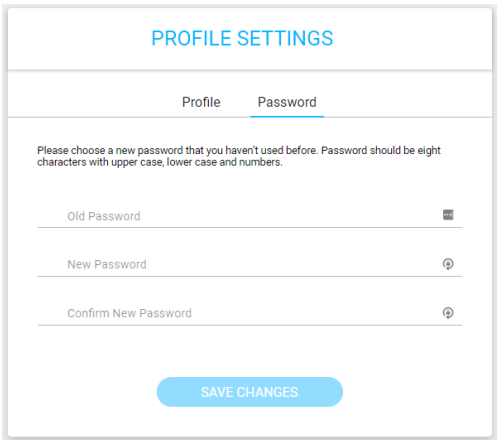


User Profile



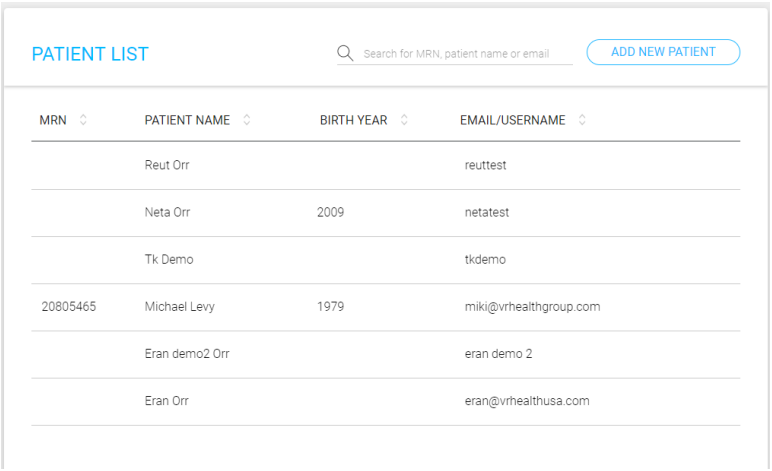
1. Both a patient user and a doctor user can access the user profile from the right side of the top bar.
2. Managing your user profile enables the user to perform 2 things:
   - Change personal details: Name, Last Name, Email/username
   - Change password





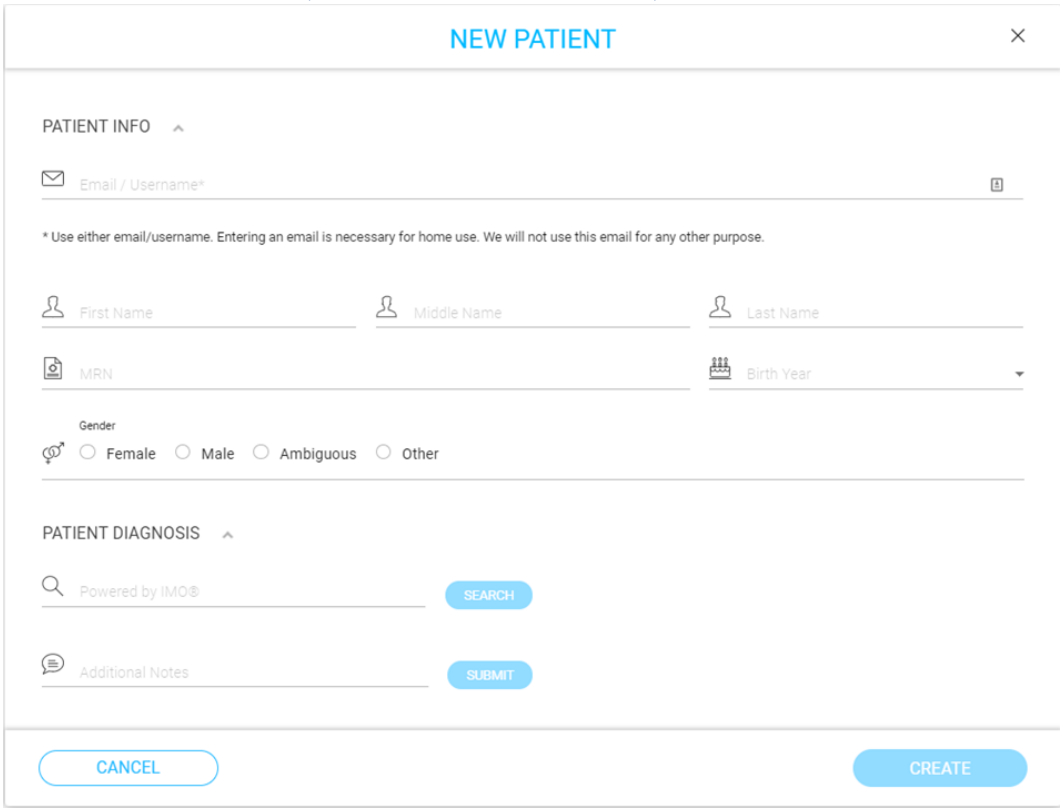
Patient List (For clinician user only)

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 relevant 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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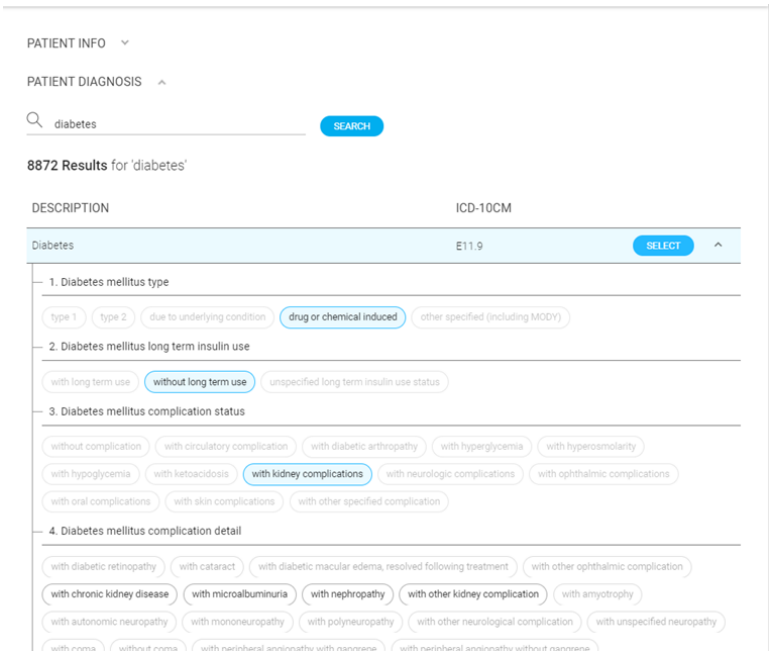
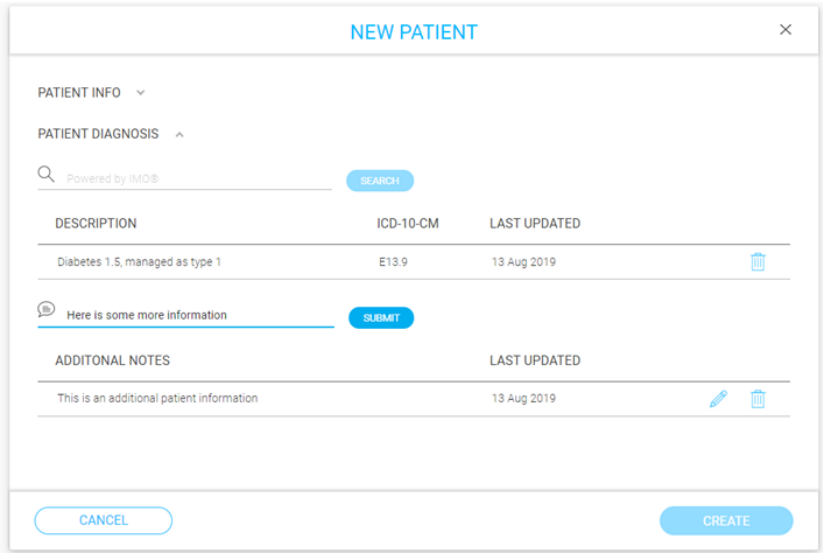
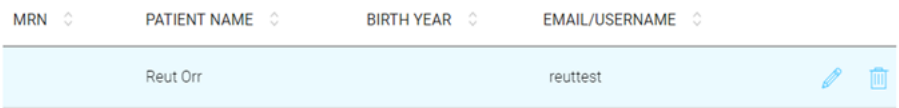


– **Additional notes field –** This field is a free text field to enable you to add any additional notes on your patients

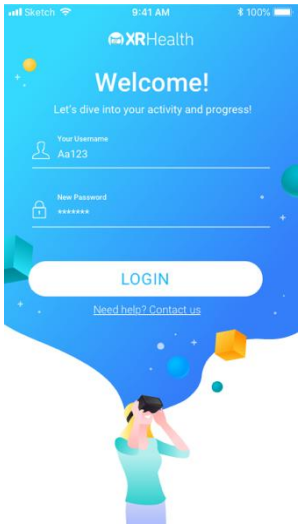


Both patient diagnosis fields save the time of update and enable you to add more diagnosis / edit / delete.

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

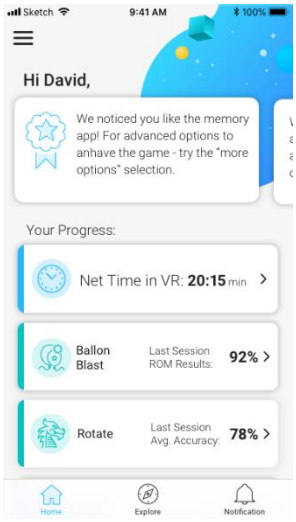


11. Mobile App

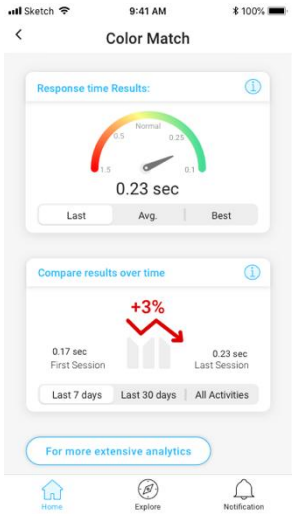


General

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



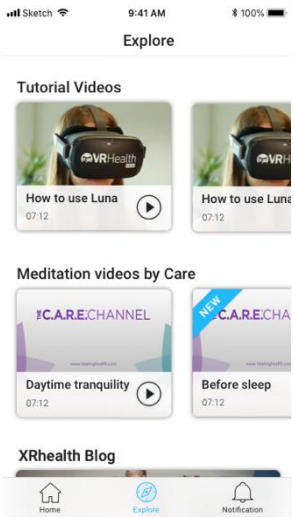
    c. Home screen – displaying:
        i. Recommendations and encouragements about the patients training
        ii. Total net training time in VR
        iii. Last session's main performance indicator result (for each application used)



    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



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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/us/regulatory-information/

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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

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Appendix C: Speed Levels

1. The following table shows the values of each speed selection from 1-30.

2. The time available to press each button is the sum of the Time between buttons (the delay between buttons) + the Time Out time (the time the player has to press before an omission error).

Speed level	General Time between buttons (in seconds)	General Time out (seconds)	White (No go) time out (seconds)	White (No go) time between buttons	Corsi task time out (seconds)	Corsi task time between buttons
1	1.50	7.00	4.00	1.50	7	1.00
2	1.35	6.30	3.76	1.35	6.79	0.98
3	1.22	5.67	3.53	1.22	6.59	0.96
4	1.09	5.10	3.32	1.09	6.39	0.94
5	0.98	4.59	3.12	0.98	6.20	0.92
6	0.89	4.13	2.94	0.89	6.01	0.90
7	0.80	3.72	2.76	0.80	5.83	0.89
8	0.72	3.35	2.59	0.72	5.66	0.87
9	0.65	3.01	2.44	0.65	5.49	0.85
10	0.58	2.71	2.29	0.58	5.32	0.83
11	0.52	2.44	2.15	0.52	5.16	0.82
12	0.47	2.20	2.03	0.47	5.01	0.80
13	0.42	1.98	1.90	0.42	4.86	0.78
14	0.38	1.78	1.79	0.38	4.71	0.77
15	0.34	1.60	1.68	0.34	4.57	0.75
16	0.31	1.44	1.58	0.31	4.43	0.74
17	0.28	1.30	1.49	0.28	4.30	0.72
18	0.25	1.17	1.40	0.25	4.17	0.71
19	0.23	1.05	1.31	0.23	4.05	0.70
20	0.20	0.95	1.23	0.20	3.92	0.68
21	0.18	0.85	1.16	0.18	3.81	0.67
22	0.16	0.77	1.09	0.16	3.69	0.65
23	0.15	0.69	1.03	0.15	3.58	0.64
24	0.13	0.62	0.96	0.13	3.47	0.63
25	0.12	0.56	0.91	0.12	3.37	0.62
26	0.11	0.50	0.85	0.11	3.27	0.60
27	0.10	0.45	0.80	0.10	3.17	0.59
28	0.09	0.41	0.75	0.09	3.08	0.58
29	0.08	0.37	0.71	0.08	2.98	0.57
30	0.07	0.33	0.66	0.07	2.89	0.56

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