

VRCogni™ CT-620 "Memorize"

Instructions for use Rx Only

Caution: Federal law restricts this device to sale by or on the order of a Healthcare professional

Rev: 10 | Last update: Nov 29, 2023 | **Product UDI:** 7290016986112

Software Version: VRCogni CT-620 ("Memorize") V1.2.5

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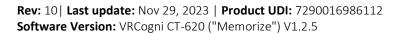
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1. Abbreviations and Symbols

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 MotionDOF Degrees of Freedom

CT-620 VRCogni CT-620 ("Memorize")

Latest Version Version 1.2.5



2. General Information

Intended use

The VRCogni CT-620 ("Memorize") is a prescription only medical device software applications that provide various VR environments to aid mitigate or assess conditions related to cognitive function by providing cognitive exercises and cognitive ability measurements. The cognitive exercises and cognitive ability measurements rely on inputs from visual and auditory stimuli, and functional use of the hands and enable:

- Guiding patients in the performance of various cognitive exercises
- Track and analyze motion and movement kinematics
- Monitoring changes in patient's measurements over time

The VRCogni CT-620 can be used as an assessment aid to determine the level of cognitive function for which there exists other valid methods of cognitive assessment.

VRCogni CT-620 is not intended to be used for diagnosis, treatment, decision making, or as a stand-alone device. Moreover, it does not identify the presence or absence of clinical diagnoses.

Intended user populations

CT-620 software is intended to be used by the following populations:

Software operators

Licensed Health Care Providers (i.e. Physicians, Psychologists, Neurologists, Caregivers, Geriatricians etc.) and/or patients, that utilize physical activity as part of conventional treatment.

End users

Individuals that will benefit from using CT-620 to support the performance of their prescribed physical and/or cognitive exercises as part of their conventional treatment.

Intended use environment

CT-620 software is intended to be used only in the following environments or areas:

- Hospital units;
- Clinics:
- Any other facility that utilizes physical/cognitive activity treatment;

• Home environment;



3. Contraindications

Before using the CT-620 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;
- 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

- 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 preexisting 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 and to use the VRCogni software while sitting. For some balance disorders, the patient might require protective harness and/or belt for support.
- 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 VRCogni 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

- All warnings and general limitations related to the safe use of the VR hardware console (recommended for use with VRCogni software series) are applicable when used with VRCogni 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 VRCogni series software.
- XRHealth IL Ltd shall not be held responsible for any malfunctions, defects, or user errors related to the purchase, installation, and use of the abovementioned hardware.
- Each VR training session using VRCogni 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. CT-620 Overview

Software description

6.1. The CT-620 is a physical and cognitive 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 and cognitive rehabilitation treatment through the use of games and entertainment features.

The CT-620 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 Intended use environment

- 6.2. Intended use environment).
- 6.3. The current version of CT-620 includes a single game: "Memorize".
- 6.4. This game mode supports therapy of patients required to perform physicalcognitive exercises as part of their treatment regime.
- 6.5. CT-620 software guides patients in the performance of movements, according to a customized cognitive task defined and prescribed by the Health Care Provider in charge of the treatment by setting:
 - Difficulty of task;
 - The total duration of the training session;
 - Number of items to memorize.
- 6.6. CT-620 allows the Health Care Provider and the patient to configure the game module parameters to create a customized training program. CT-620 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.
- 6.7. 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 CT-620 software requires a pre-purchase of a high-end off-the-shelf VR platform:
 - The compatible VR platforms for the use of CT-620 software, are listed in appendix A: <u>Approved VRH List</u>.
 - A stable internet connection with an upload speed of at least 3Mb/sec and upload speed of at least 0.5MB/sec is mandatory.

Software installation and software updates via Oculus store

- 6.9. The software shall be downloaded and installed from the VRH store application and can be accessed by entering the applicable credentials (username and password).
- 6.10. The software comes with automatic update capabilities.
- 6.11. When the software is launched it checks if the version being run is the latest version available. If not the user receives a notice and can update the software to the latest version.
- 6.12. For safety reasons, XRHealth IL can define an update as mandatory for all users. If a mandatory update is necessary, the user will receive a notice that he and must download the update for safety reasons.
- 6.13. For regular updates, the user can select if to install the update, or not.

Software installation and software updates via MDM (mobile device management) solution

- 6.14. Any software can be installed, updated and managed by a selected MDM solution for remote headset management.
- 6.15. This solution enables XRHealth IL 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 CT-620 software:
- Carefully read the instructions for use by the VRH manufacturer (list of compatible hardware for CT-620 available in <u>Appendix A</u>, below).
- Carefully read the Health and Safety Warning of the VRH manufacturer (list of compatible hardware for CT-620 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 CT-620 software to ensure safety.
- Make sure the environment in the location designated for training is free from obstacles; It is advisable to clear the surrounding area from any hazardous furniture or other objects. Follow VRH manufacturer's instructions concerning prior usage environment preparations/precautions.
- □ Prior to use, suit the VR Headset and adjust it to your head, as described in the VRH manufacturer's manual.
- Safely secure the HHS (VR remotes) to the wrists, as instructed by the VRH manufacturer.
- If you are wearing glasses, you can choose whether to take them off (most users can see clearly even while not wearing any glasses) or wear the headset over them (some frame types do not fit under the VR Headset, in such cases the use of contact lens or using alternative glasses is required to use the VR Headset).
- 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.
- 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 CT-620 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.
 - In case that the VR environment is not calibrated/centered, press and hold the Oculus button to reset your orientation.
- 7.5. If you suspect that there is a problem with the CT-620 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. CT-620 Training Experience

Game Flow

During the game, a list of items is presented on screen. The user is required to memorize the items as best as possible. Once the list is gone, items start appearing on the conveyor belt/s. The goal is to pick the items that appeared on the list earlier by selecting them



For **3DOF VRH** – select by pointing at an item and pressing the Trigger button on the controller).

For **6D0F VRH** - select by touching the item with the controller.

Settings screen



1. Show tutorial:

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

2.Game preset:

Choose one of the game parameters presets out of 3 options: Easy, Medium, Hard; or choose the "More Options" button for customizing your own settings.

Parameter	Easy	Medium	Hard
List Exposure Time	15	10	5

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Task Length	20	40	70
Speed Level	2	4	8
Dynamic Speed	on	on	on
Feedback	on	on	on

3.Items to memorize:

Choose the number of items need to be memorized from a scale of 1-15 items.

4. Session duration:

Choose the session duration from a scale of 1-10 minutes. This duration is the NET game duration (not including list time and game summary time).

Pausing and stopping the session is available at any time during the session through the Pause menu.

5.List exposure time:

Choose the time the user will have to view the items on the list before starting the selection task. This is the time the user has to memorize the list. The scale goes from "Flash" (0.5 second) to 20 seconds of exposure. Select "no limit" to see the list until the user is ready to continue (and selects the continue button).

6. Task length:

Choose the task length from a scale of 20-180 seconds. All items from the list appear within this time frame. The longer the task length, the longer the user must remember the items. E.g. If there are 4 items on the list and the task length is 30 seconds. All 4 items will appear in the first 30 seconds of the game. If the task length was 180 seconds, the 4 items would spread out across the full 180 seconds (forcing the user to keep the items in his/her memory for a longer duration, making it harder).

7. Number of belts:

Choose the number of conveyor belts (1-4 belts) on which items appear during the game. The items come out randomly between all conveyor belts.

8.Speed level:

Choose the speed level (1-8) in which the conveyor belts move.



9.Dynamic speed:

When playing with dynamic speed mode on, two consecutive successful games (all items picked are correct items from the list) lead to a speed increase and an addition of 1 more item to be memorized. Two consecutive tasks that aren't



successful, lead to a speed decrease and a removal of 1 item from the list.

10. Feedback:

When playing with feedback mode on, every item selected is followed by an audio and animated feedback (correct/incorrect). If feedback is off, when the player makes a selection, they won't receive feedback if the selection was right/wrong until the game ends (and summary appears).

11. Textual description:

When playing with textual description mode on, every item on the list appears with a textual description.

For **6DOF VRH** – In the "more options section there is an option to select which hands will participate in the training – Both, Right or Left.

Pause Menu

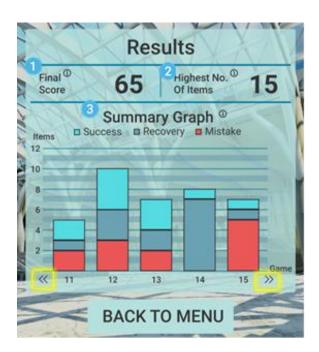
Pressing the pause button on the controller pauses the session and opens the pause menu.

You may control the volume, start over by pressing the "Restart Level" button, finish the session or resume.



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Summary screen



The results are presented in the summary screen at the end of every session (a series of tasks):

1. Final score – The sum of 3 parameters:

- Score per collected task object Each Task Object collected correctly is worth a basic score value (10 points) times the current game's span level (number of items to be memorized).
- Success score multiplier Succeeding in a game (making no mistakes) is rewarded by a multiplier with the value of the game's span level (number of items to be memorized).
- If the span level is 1, there is no multiplier.
- <u>Dynamic Speed Bonus</u> When dynamic speed feature is activated, increased speed gives bonus score. When a game is completed and results in a speed increase, the player will receive a bonus equal to the basic score value times the new speed level.

2. Highest number of items

This parameter represents the highest number of items that have been memorized and selected correctly out of all tasks.

3. Summary graph

The graph is a bar chart, where each bar (X axis) is one game played in the session. Y axis represents the span level (number of items) of the games.

Each bar in the graph is divided into the types of selections made by the player in the specific game.

- Success: A correct item that was selected the first time it appeared on the conveyor belt in the game.
- Recovery: A correct item that was selected, but not the first time it appeared on the conveyor belt.
- Mistake: An item that was selected but wasn't on the list.

In case the session included more than 5 games, the last 5 games are displayed on the screen. Toggling is possible through the X axis arrows to view other games in the session.

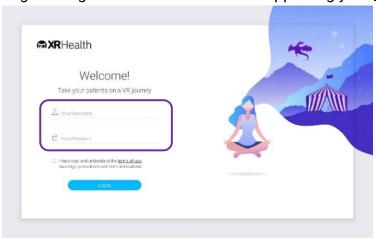


9. External Control

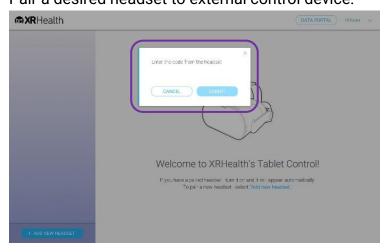
External control over the VR device is available via the XRHealth IL External Control app. To fully use all features of the External Control App – please fully read its User Manual.

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

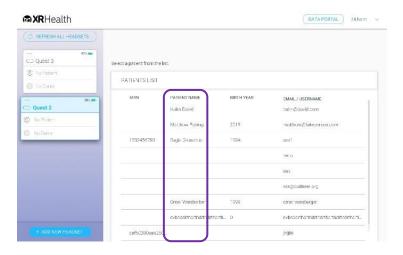
1. Login – Login to the External Control app using your Clinician credentials.



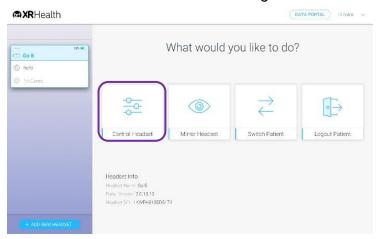
2. Pair a desired headset to external control device.



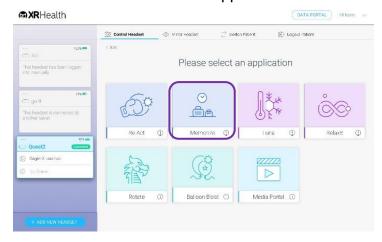
3. Select the patient with the VR device from the patient list.



4. Select "Control" to define the training.



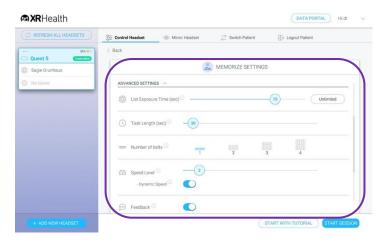
5. Select "Memorize" from the application list.



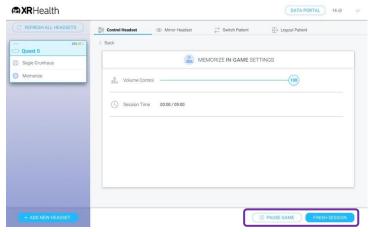
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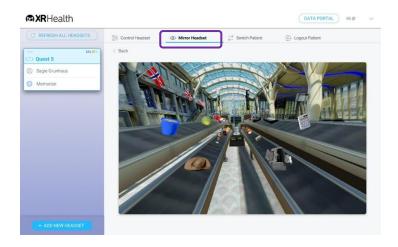
6. Define the desired session settings (See settings screen description above) and select Start Session.



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

- 4.As a clinician you will need to go through an onboarding process in the web portal on your first login.
- 5. Marketing team will supply you with an initial username and password. If you do not have your credentials, please contact support at support@xr.health.
- 6.Go to https://portal.xr.health and login with the supplied username and password to start the onboarding process.
- 7.In the onboarding process you will be required to set up your personal detail, email and new password.

Login

- 8.Login page is accessible on https://portal.xr.heath
- 9.In order to login you will need your user credentials (patient or clinician). If you do not have your credentials, please contact support at support@xr.health.



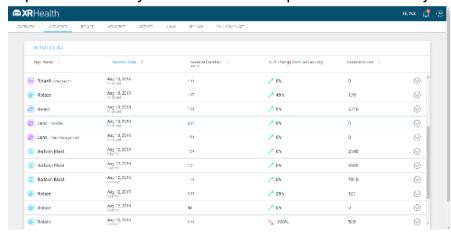
- 10. For home users the credentials for log in to the Data Portal are the same one used in the VR Portal.
- 11. Logout once logged in the option to logout is in the top right corner (press on the profile settings character)
- 12. Auto logout for security reasons, the Data Portal will automatically logout after 15 minutes of inactivity.



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

Activities

14. On the activities page you can view a list of all your sessions sorted from the last session to the first. Each line represents a session you have completed. Expand to see your data for a specific session by clicking a line.



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



- a. Best number of items the highest number of items you remembered in a game.
- b. Average mistakes per game mistakes are items that were selected but did not appear on the list. The average number of mistakes is the total number of mistakes / number of games played.

- c. Average recovered items per game recovered items are items that were missed the first time they passed, but later successfully selected. The average number of recovered per game is the total number of recovered / number of games played.
- d. Performed duration the duration of the whole session
- 16. On the right side you can find the settings for that specific selected activity.
- 17. On the main graph you may see a bar chart, where each bar (X axis) is one game played in the session. Y axis represents the span level (number of items) of the games. Each bar in the graph is divided into the types of selections made by the player in the specific game.
 - Success: A correct item that was selected the first time it appeared on the conveyor belt in the game.
 - Recovery: A correct item that was selected, but not the first time it appeared on the conveyor belt.
 - Mistake: An item that was selected but wasn't on the list.

Dashboards

- 18. In the dashboard view you can see progress overtime and adherence to treatment. This is where you can compare results to others, see activity history and get meaningful insights from sessions.
- 19. Navigate to the desired dashboard by clicking on the application name from the welcome screen or selecting the application name from the top bar.
- 20. 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.



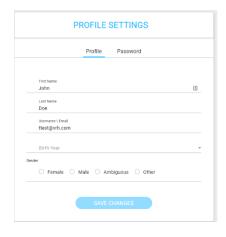


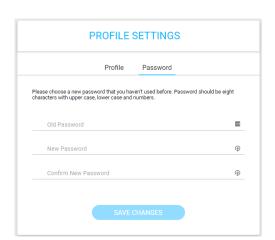
User Profile

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



- Managing your user profile enables the user to perform 2 things: 22.
 - Change personal details: Name, Last Name, Email/username
 - Change password





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Patient List (For clinician user only)

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

- 24. The patient list is a list of all your clinic patients.
- 25. 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
- PATIENT LIST

 Q Search for MRN, patient name or email

 ADD NEW PATIENT

 MRN PATIENT NAME BIRTH YEAR EMAIL/USERNAME ○

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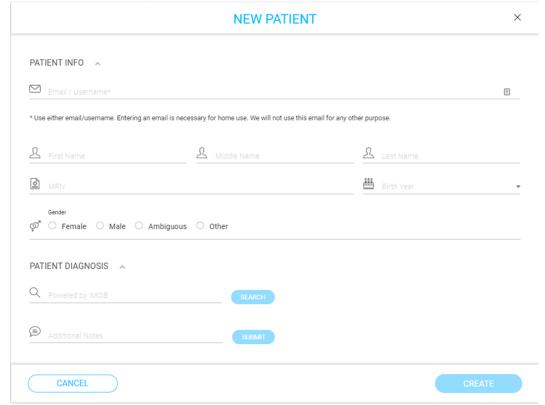
 20805465 Michael Levy 1979 miki@vrhealthgroup.com

 Eran demo 2

 Eran Orr eran@vrhealthusa.com

26. 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)

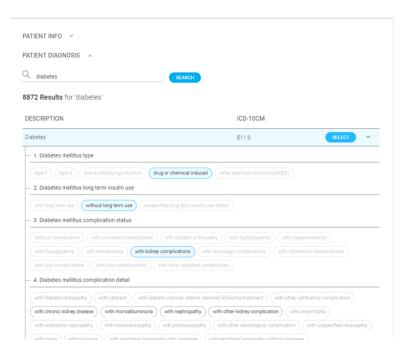


27. XRHealth Data Portal enables a clinician to create / edit / delete patients.

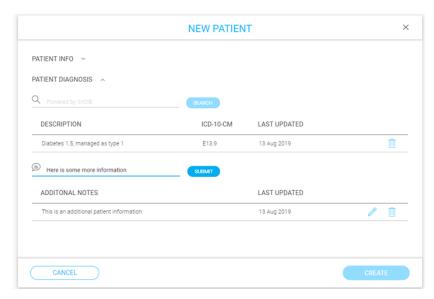


- 28. We highly recommend filling up patient demographic and medical details in order to get the normative values for people in the relevant age group / diagnosis.
- 29. In order to create a new patient, press the "Add New Patient" button on the upper right side of the patient list.
 - Filling Email / Username field is mandatory
 - We recommend you fill Name / MRN in order to easily associate a specific user to a specific patient and track patient's progress over time
 - Birth Year is important to create a relevant comparison to users in the same age group
 - Patient diagnosis field includes 2 fields:
 - Diagnosis field This field incorporates a smart search that goes through the ICD 10 codes and returns the different options to select from.
 - ❖ After the first search you might see an arrow facing down on the right side of a diagnosis – this arrow means this diagnosis has different categories to choose from
 - If you open that field using the arrow you will be presented with filters to select in order to narrow down the options.
 - Under the filter mechanism you can find the relevant list of diagnosis to choose from.
 - At any stage pressing the select button will add that diagnosis to your patient file.





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



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

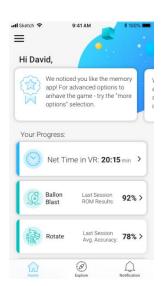
30. In order to edit a patient, hover on the patient row and hit the edit patient symbol on the right



11. Mobile App

General

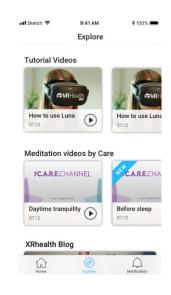
- 31. XRHealth Mobile app is the main patient interface that enables:
 - a. Tracking training performance in the different apps
 - b. Receiving notifications and updates about their training
 - c. Exploring a variety of videos, blog posts and health related information
- 32. The Mobile app is available for both iOS and Android devices.
- 33. The application flow includes:
 - a. Login (with the option of enabling FaceID of FingerID)
 - b. App Tutorial flow showing the different screens in the app
 - c. Home screen displaying:
 - 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:
 - 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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Software Version: VRCogni CT-620 ("Memorize") V1.2.5



Appendix A: Approved VRH List

The software is compatible with 3DOF and 6DOF standalone VR Headsets.

Recommended VRH List

For a list of recommended devices please refer to XRHealth Release Notes available at https://www.xr.health/products



Appendix B: Common Software Troubleshooting

- Cannot Login
 - Make sure you have the correct XRHealth IL credentials received with onboarding e-mail. If you don't have credentials – contact <u>support@xr.health</u>.
 - ❖ Make sure your headset is connected to local Wifi network.
- Application is stuck Close the application using the home button and reopen it.
- Software doesn't load (Stuck in loading animation) If closing and reopening 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.

