

Instructions for Use

ROHKEA™

V1.0.0, 24.01.2025

ROHKEA™ VR Therapy

and

ROHKEA™ Companion application

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1 What is ROHKEA™?

ROHKEA™ VR Therapy and ROHKEA™ Companion application forms the ROHKEA™, which is intended to be used by people living with chronic musculoskeletal pain.

ROHKEA™ VR Therapy is a virtual reality (VR) experience designed with pain management and pain psychology professionals to provide digital therapeutic content for people with chronic pain to treat fear of movement and improve pain management in daily life. ROHKEA™ VR Therapy consists of 12-week long treatment program including psychological therapeutic modules as well as physically activating exercises specifically designed for people with chronic musculoskeletal pain. The whole program is guided by a built-in virtual mentor.

ROHKEA™ Companion application is a support tool to complement the ROHKEA™ VR Therapy. It is designed to provide easy access to account management, progress tracking, homework, and extra materials.

- Account management: Consent to data collection.
- Progress tracking: Number of daily sessions completed.
- Homework: Reminders about homework assignments.
- Extra materials: Example stories or other short readings to deepen understanding and provide support with homework.

2 Read the Instructions for Use



Caution, consult electronic Instructions for Use.



Caution, consult accompanying documents.

3 Warnings and Cautions



Read warnings and cautions before using the product.

3.1 Warnings



Warning

Headset contains a rechargeable Lithium-Ion battery, and controllers may come with user-replaceable AA batteries. Please read and familiarize all information and warnings in Meta Quest 2 Safety and Warranty Guide related to batteries, charging, temperature, and electric shock.



Warning

Use the VR system away from fire!



Warning
Use the VR system away from stairs!



Warning
Clear the required area of glass fixtures and use the application away from windows!

3.2 Cautions



Caution
The VR application usage may cause motion sickness and/or losing balance!



Caution
This software is intended to help the subject overcome fear of movement!



Caution
Please consult your health care professional before use!



Caution
To avoid collision e.g., to furniture, ensure sufficient and safe play area [2x2 m (6.5 by 6.5 ft) free space] for using the VR system!



Caution
The VR Therapy Application is for personal use only!
In a case, another person uses the therapy software, it may cause incorrect data and/or results and it can cause the activities to be too easy or too hard for the user.



Caution
Do not use unprotected network (WIFI/Internet) connection!



Caution
The daily usage of this software should be limited to max 60 minutes per session to avoid risk of harm!



Caution
Use of virtual environment could cause epileptic seizure or psychosis.



Caution
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established!

**Caution**

Ensure that small children or house pets cannot enter to the play area.

**Caution**

Ensure, that you are using correct operating system to run the application!

**Caution**

Contact support for technical issues; issues with application / hardware updates, accidental uninstallation, other issues.

**Caution**

For cleaning the VR device, please refer to Meta Quest 2 Instructions for use!

3.3 Meta Quest 2 Warnings

The manufacturer of the Meta Quest 2 lists the following warnings and pre-existing conditions in the Meta Quest Health and safety warnings.

3.3.1 Pre-existing Medical Conditions

**Warning**

Consult a doctor before using your Meta Quest if you are pregnant, elderly, have pre-existing binocular vision abnormalities or psychiatric disorders, or have a heart condition or other serious medical condition.

**Warning**

Seizure Risk. Virtual content may include flashes of light or patterns that may trigger seizures or other symptoms. Immediately stop use and consult a doctor if you experience severe dizziness, seizures, eye or muscle twitching, or black out while using your Meta Quest. Consult a doctor before use if you previously have had a seizure, loss of awareness or other symptoms linked to an epileptic condition.

3.3.2 Interference with Medical Devices and Restrictions in Certain Places

**Warning****Interference with Medical Devices and Restrictions in Certain Places**

Magnetic components. Your Meta Quest may contain magnets and components that emit magnetic/electromagnetic fields which could affect the operation of nearby electronics and medical devices, including cardiac pacemakers, hearing aids and defibrillators. If you have a pacemaker, hearing aid or other implanted medical device:

- o Maintain a safe distance between the medical device and your Meta Quest headset and controllers.
- o Consult a doctor or the manufacturer of your medical device before using your Meta Quest.
- o Stop using your Meta Quest if you observe interference with your medical device.

- o Follow restrictions and instructions provided in certain places to limit or avoid use of radio electronic devices (for example, in hospitals, on airplanes, or at gas stations).

3.3.3 Prohibited Use



Warning

Do not use in hazardous situations.

Never use in hazardous physical world situations, where a task requires focused attention and high coordination or precision of movement, like running or driving. Do not use while handling dangerous objects or materials, like using a knife to chop food.



Warning

Do not use when impaired.

Do not use the headset when you are impaired as it may increase your susceptibility to adverse symptoms and negatively affect your motion and balance. Impairments you should avoid when deciding to use the headset include:

- o Influence of alcohol or drugs;
- o Hangover or upset stomach;
- o Fatigue, exhaustion or sleeplessness;
- o Emotional stress or anxiety or
- o Infectious disease, headache, migraine, or earache.

3.3.4 Hearing loss



Warning

Do not use high volume levels for prolonged periods to prevent possible permanent hearing damage.

Please read and familiarize all information and instructions in Meta Quest 2 Safety and Warranty Guide.

4 How to use ROHKEA™?

ROHKEA™ VR Therapy is a 12-week treatment program consisting of 60 therapeutic VR sessions. It is intended to be used once a day for five consecutive days, after which it is recommended to take a two-day break from the VR. For your safety, the use of the application has been restricted to one session per day. Daily usage of the VR application should be limited to max 60 minutes/session to avoid increased risk of harm.

ROHKEA™ Companion application is a support tool for the ROHKEA™ VR Therapy. The mobile application offers an easy way to monitor your progress, familiarize yourself with short articles, and revisit homework assignments outside the VR application. Once you have logged in, accepted the Terms of use, and consented to the collection of data, there are no restrictions on using the mobile application.

5 Intended Purpose

The intended purpose of the Rohkea™ VR Therapy is to provide an automated intervention based on cognitive behavioral therapy intended to help the subject overcome fear of movement. The device is intended for in-home use and to be assigned by health care professionals.

The product is intended to be used by competent adult (age ≥ 18 years) patients with fear of movement caused by chronic musculoskeletal pain.

5.1 Additional Product Description

ROHKEA™ consists of digital therapy ROHKEA™ VR Therapy (Medical device) and ROHKEA™ Companion application (mobile application, Non-medical device). Support functions consists of ROHKEA™ admin dashboard (Non-medical device) and ROHKEA™ API (Non-medical device). ROHKEA™ VR Therapy is utilized with commercially available hardware products, which are infrastructure for the software only medical device product. There is no medical intended use for the hardware.

6 Intended User

The product is intended to be used by competent adult (age ≥ 18 years) patients with fear of movement caused by chronic musculoskeletal pain.

7 Clinical Benefits to Be Expected

The following clinical benefits can be expected from the usage of ROHKEA™ VR Therapy:

- Get help to overcome fear of movement and re-injury.
- Improve self-management of pain.
- Enter a safe virtual environment that encourages exploration and movement.
- Learn, in a safe virtual environment, to make good decisions and to socialize normally.
- Practice feared movement, and access self-affirming cognitive therapy frequently.
- Set behavioral goals safely and achieve lasting behavioral change.

8 Contra-Indications

Persons with the following contra-indications must not use ROHKEA™.

- The contraindication for the use of the product is age under 18 years.
- History of epilepsy, migraine, vertigo or psychosis.
- Treatment requiring motion sickness.
- Pregnancy.
- Severe or acute structural pathologies that the intervention (ROHKEA™ VR Therapy) could make worse, as assessed by a physician.
- Psychotherapy in the previous 2 years or is currently receiving psychotherapy.
- Condition that affects posture or balance.

9 Possible side effects

VR application usage can cause the following side effects:

- motion sickness, anxiety, or imbalance.
- experience that features and/or elements from the virtual environment appear in the physical world. Headache, eye strain, dizziness, nausea, and psychosis effects.
- in order to avoid skin irritation, clean the device. For cleaning the VR device, please refer to Meta Quest 2 Instructions for use.

To avoid these symptoms, limit the use of ROHKEA™ VR Therapy to max 60 minutes per session.



Caution

The VR application usage may cause motion sickness and/or losing balance!

**Caution**

For cleaning the VR device, please refer to Meta Quest 2 Instructions for use!

**Caution**

Use of virtual environment could cause epileptic seizure or psychosis.

10 When to Contact Healthcare Professionals

ROHKEA™ VR Therapy may not be suitable for everyone. People with conditions listed in chapter 8 Contra-Indications should not use the ROHKEA™ VR Therapy.

Use of VR headset may not be suitable for everyone. Refer to Meta Quest 2 warnings in chapter 3.3.1 Pre-existing Medical Conditions when to contact your healthcare professional.

If the use of ROHKEA™ VR Therapy causes significant discomfort or increased fear of movement, discontinue use, and contact your healthcare professional.

In case of an emergency, call your local emergency number.

11 Information for Healthcare Professionals

People with conditions listed in chapter 8 Contra-Indications should not use the ROHKEA™ VR Therapy.

Also, the manufacturer of the Meta Quest 2 VR glasses has listed prohibited use and conditions of the Meta Quest 2 VR glasses, please see chapters 3.3 Meta Quest 2 Warnings and especially 3.3.3 Prohibited Use.

This section contains information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories.

The intended purpose of the ROHKEA™ VR Therapy is to provide cognitive behavioural therapy intended to help the subject overcome fear of movement. The device is intended for in-home use and to be assigned by health care professional.

The product is intended to be used by competent adult (age ≥ 18 years) patients with fear of movement caused by chronic musculoskeletal pain and whose primary language is English.

A healthcare professional must weigh the possible risks versus benefits before guiding patients with headache or generally a condition that prevents physical rehabilitation to use ROHKEA™ VR Therapy.

Because headache, eye strain, dizziness, and nausea are the most common side effects caused by virtual reality gaming, the use of the device should be seriously considered in patients with a strong tendency to motion sickness or headache, or impaired balance.

12 Supported Hardware

ROHKEA™ VR Therapy can be used only with Meta Quest 2 VR headset.

ROHKEA™ Companion application can be used with any Android device having Android version 9 or higher, or iOS device with version 12 or higher. VR and accompanying app can be used anywhere where an internet connection is available.

Note! An iOS device should not be used with jailbreak installed.



Caution

Ensure, that you are using correct operating system to run the application!

13 Performance Characteristics

It has been clinically proven that an automated intervention based on cognitive behavioral therapy - Rohkea™ VR Therapy- helps the subject to overcome fear of movement caused by chronic musculoskeletal pain. 83 % of the ROHKEA™ VR Therapy users gained clinical benefit from the therapy after six weeks and 73 % of the users gained clinical benefits still five months after the therapy (VIRPI study). Technically, ROHKEA™ VR Therapy requires 1 Gb free disc space on the VR headset.

14 Before Using the Product

Before using the software, consult this Instruction for Use as well as the VR headset user instructions, including Health and safety warnings in Meta Quest Shop (<https://meta.com/quest/warnings>).

To ensure safe environment for using the VR software, take care of the following:

- Clear the indoor play area and ensure adequate free and safe space 2x2 meters (6.5×6.5 feet) to use the system safely.
- Clear the required area of glass fixtures and use the application away from windows.
- Clear the area of electronic devices.
- Ensure you are using the product away from stairs.
- Ensure that small children or house pets cannot enter to the play area.
- Use the VR software away from fire.



Warning

Do not use your VR system if any part of it is broken or damaged.



Warning

Install and use wrist straps or other authorized restraints with controllers and accessories to secure them to your wrist during use so they do not become loose projectiles.



Warning

Use the VR system away from fire!



Warning

Clear the required area of glass fixtures and use the application away from windows!



Warning

Use the VR system away from stairs!



Caution

To avoid collision e.g., to furniture, ensure sufficient and safe play area [2x2 m (6.5 by 6.5 ft) free space] for using the VR system!

14.1 VR Headset Preparations

Start in a quiet and spacious place and make sure there is at least 2 meters by 2 meters (6.5 by 6.5 feet) of unobstructed floor space around you. Prior to use make sure that the VR headset is undamaged, charged, and read and familiarize the following Meta Quest 2 (see Figure 1) Safety and Warranty Guide.



Figure 1. Meta Quest 2 virtual headset and controllers.

Put the virtual reality device on your face and make sure the devices switched are on.

To use the virtual reality applications, use the controllers (see Figure 2).

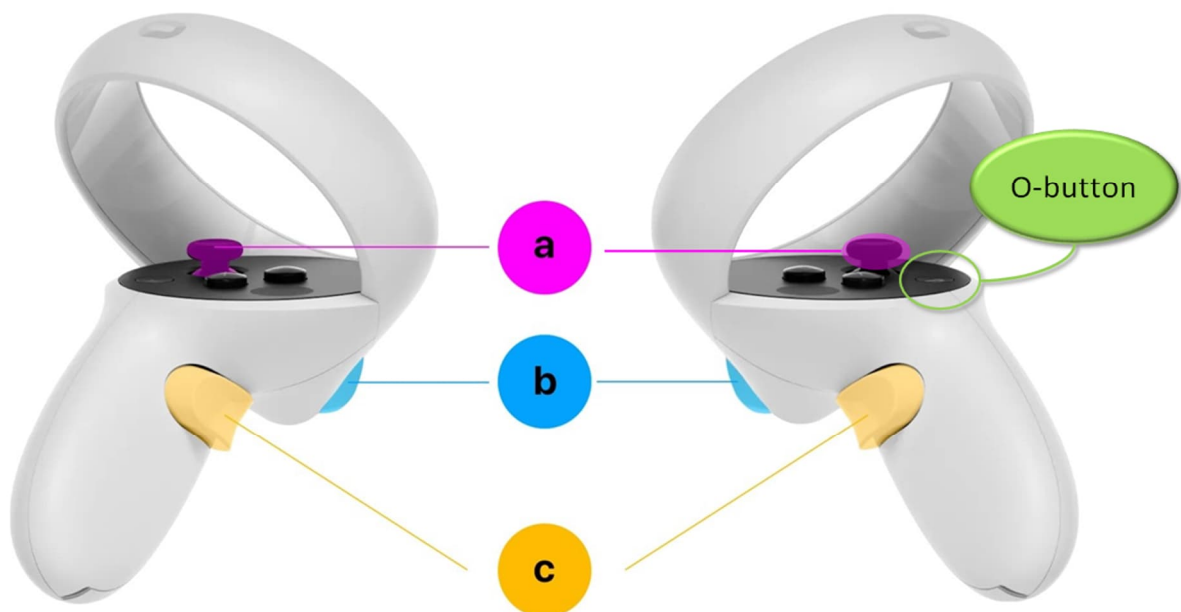


Figure 2. Meta Quest 2 controllers.

The following controllers are used with the ROHKEA™ VR Therapy:

- a) Thumbstick – Teleport and move around.
- b) Front trigger – Select and Activate.
- c) Grab button – Grab and hold objects.
- o) O – button – To exit or discontinue the VR application, this will return you to the Home-screen.
Holding the button recenters your view.

For further details and other controllers, please see the Meta Quest 2 VR headset manufacturer instructions.

14.2 Guardian System

Meta Quest 2 VR headset has a built-in monitoring system, Guardian, that allows you to define the boundaries of a safe playing area. The boundaries in VR appear as a grid (see Figure 3) when you get too close to the edge of your play area.

If you're setting up Guardian for the first time, follow the instructions that you see in your headset.

Ensure safe playing area free of any obstacles on the floor, surroundings, or the ceiling. ROHKEA™ VR Therapy should be used only in 'room scale' mode with minimum of 2×2 m (6.5×6.5 ft) play area.



Caution

To avoid collision e.g., to furniture, ensure sufficient play area [e.g., 2x2 m (6.5x6.5 ft) free space] for using the VR application!



Figure 3. Setting up the play area.

For more detailed information, please refer to the Meta Quest 2 instructions for use/other instruction material.

Note that ROHKEA™ VR Therapy requires both lateral and vertical movement. Since the monitoring system does not recognize or give warning about obstacles inside or above the playing area, please make sure that there are no objects like furniture on the floor or ceiling, nor steps.

14.2.1 View-Through Camera

Meta Quest 2 headset is also equipped with a view-through camera. The view-through camera allows you to perceive your physical environment after putting the device into your eyes.

If you leave the specified playing area, VR will be changed to a view-through camera image of your actual environment. After the headset has powered up, the Guardian System will ask you to set the limits of the play area.

14.2.2 Setting Up the Play Area for the First Time

Please follow the Meta Quest 2 built-in instructions to set up the play area for the first time.

14.2.3 Using Previously Set Play Area

During the following uses after the VR headset has turned on, the monitoring system prompts you to either confirm the previously defined play area or redefine the playing area. Please follow the instructions in the Meta Quest 2 headset.

14.3 Download and Install the Software

Before using the ROHKEA™, the applications must be first downloaded and installed onto your devices. To use the ROHKEA™ VR Therapy, the following software applications are needed:

- ROHKEA™ VR Therapy, which is used with Meta Quest 2 VR headset.
 - o You may receive a VR headset with pre-installed ROHKEA™ VR Therapy from your provider, or
 - o You can download ROHKEA™ VR Therapy on your own device from [Meta Store](#).
- ROHKEA™ Companion application which is used with a smart phone/tablet/iPad
 - o Depending on your smart phone, download the application from
 - [Google Play Store](#) (Android phones & tablets)
 - [Apple Store](#) (iPhones & iPads)

Follow the instructions in the Store to download and install the applications. If there is a problem in installing the software(s), please see chapter 23 Frequently Asked Questions and Troubleshooting.

15 Electronic Instructions for Use, eIFU

The ROHKEA™ VR Therapy includes built in electronic Instructions for Use, eIFU, which can be opened by clicking the eIFU icon. Permanent address for the eIFU is <https://eifu.rohkea.health>



Figure 4. Clicking the eIFU icon opens the electronic Instructiond for Use.

16 Changing the Password

Before you can start to use ROHKEA™, you need to confirm your account by changing the password for it. After your account has been created by your provider, you will receive an e-mail including a link to change

the password. Follow the instructions in the e-mail to change the password. If you have not received the e-mail, please check your junk mail.

17 Login to ROHKEA™ Companion Application

Before you can start to use ROHKEA™ VR Therapy, you need to log in to ROHKEA™ Companion application and agree with Terms of Use and consent to collection of data.

Log in to ROHKEA™ Companion application using your username (e-mail address) and password.

18 Login to ROHKEA™ VR Therapy and PIN Code

After you have agreed with Terms of Use and given your consent to data collection you can proceed to start the use of ROHKEA™ VR Therapy. Log in to the ROHKEA™ VR Therapy by using your username and password. After logging in the first time, you are prompted to create a PIN code.

Note! In a case you are not able to login with your credentials, please check your WIFI/Internet connection, since the login is not possible without the connection.



Warning

Do not use unprotected network (WIFI/Internet) connection!

After creating the PIN code, it is possible to log in to the system by using the PIN code instead of username/password combination.

Note! The Login/PIN screen may be on your side or behind your back!

In a case the e.g., the PIN screen is not on your eyes' level, center the screen by pressing and holding the O-button on the right controller (see Figure 2).

19 Using the ROHKEA™ VR Therapy



Caution

The VR Therapy is for personal use only!

In a case, another person uses the therapy software, it may cause incorrect data and/or results and it can cause the activities to be too easy or too difficult for the user.

When starting the ROHKEA™ VR Therapy and you will be in the Cabin, which is the application's starting point and your "homebase" (see Figure 5).

ROHKEA™ VR Therapy is meant to be used in standing position. It is not possible to use ROHKEA™ VR Therapy in sitting position.



Figure 5. Cabin.

When arriving first time to the Cabin, you'll meet your virtual mentor, SAMI (Figure 6), and you'll get instructed on how to use your Pad. If you don't hear SAMI, please check the volume settings of your VR headset. You will also learn how to move and teleport around. In this chapter you will also find an overall picture of the virtual world you will be using during the following weeks.



Figure 6. Virtual mentor, SAMI.

19.1 ROHKEA™ Virtual World

The Virtual World consists of the following environments:

- Cabin
- Creativity Garden
- Fabrication Forest, and
- Power Mountain

As previously instructed, it is possible to move across these environments by using the map on your virtual Pad.

19.2 Cabin



Figure 7. Cabin and the features.

From the cabin you can find the following:

- a) Goals painting
- b) Values painting
- c) SAMI the mentor
- d) Map
- e) Badge cabinet

19.3 Pad

You can open your Pad by lifting it up from your waist by using the controller. Crab to the Pad with the controller's Grab button (button c in Figure 2) and lift the Pad on the level of your eyes. Point the Pad on the blue floating circle so, that the circle turns brighter and release the grab button.

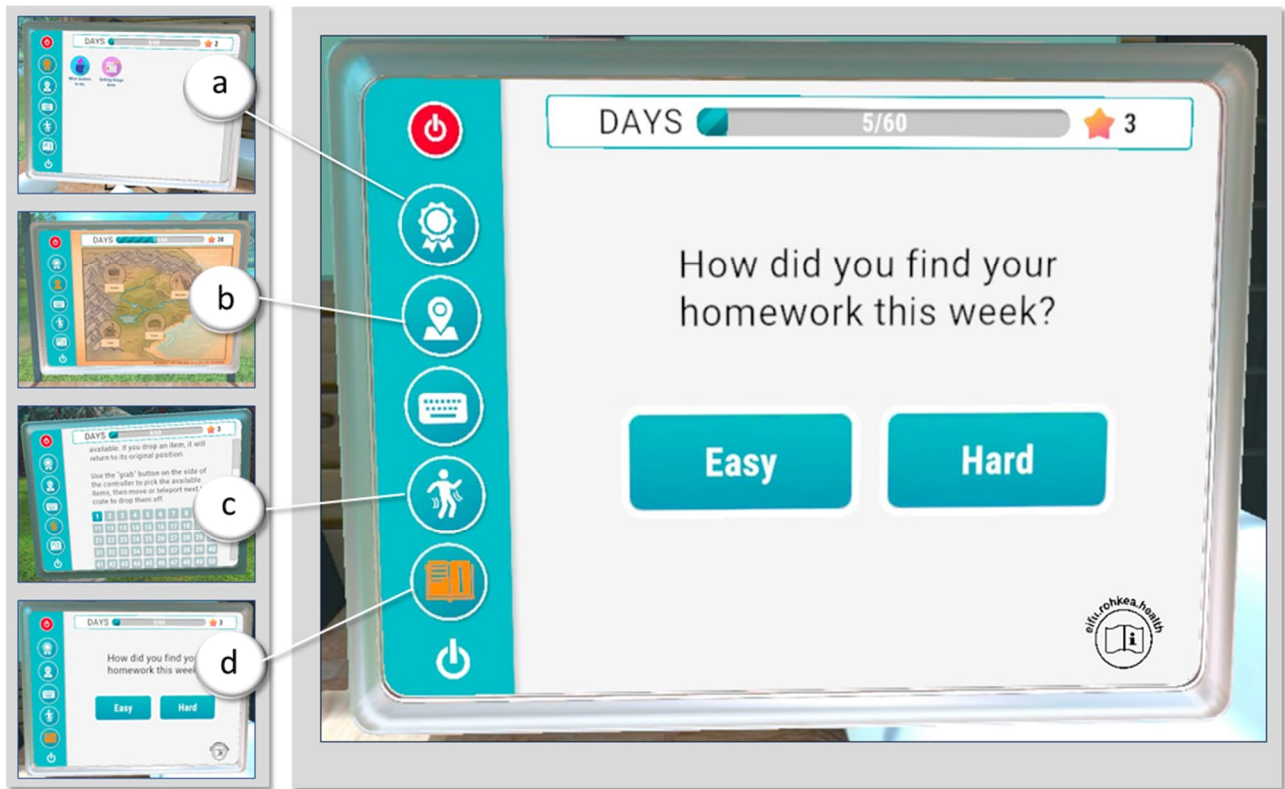


Figure 8. Pad and the functions.

On the left-hand side panel, you can find the following functions:

- a) Badges
- b) Map
- c) Activity level selector (in some cases, you need to scroll down the screen to see the Start Activity and Stop Activity buttons)
- d) Homework reporting and instructions for use

19.4 Moving and Teleporting

There are two different ways to move inside the ROHKEA™ VR Therapy:

- Moving
- Teleporting

19.4.1 Moving

Moving (see Figure 9) happens between different environments e.g., from the Cabin to the Creativity Garden. Moving is done by using the map.



Figure 9. Moving between the environments is done by using the map in the virtual Pad.

19.4.2 Teleporting

Teleporting (see Figure 10) happens inside one environment e.g., in the Cabin. Teleporting is done by pointing with the controller to the place where you want to go and pressing the controller's Thumbstick (button a in Figure 2) gently forward. The area where you are teleporting yourself is indicated as a white arc

and a circle on the ground (see Figure 10). A red arc indicates that you are trying to teleport to a restricted area; try pointing to another spot on the floor/ground.



Figure 10. Teleporting inside one environment is done by pointing with the controller.

19.5 Exiting or Discontinuing the ROHKEA™ VR Therapy

After you have completed the daily session, follow the instructions given by the mentor to exit the ROHKEA™ Therapy. If you want to exit the exercise at any time, please follow the instructions below to exit the app:

- 1) Briefly press the O-button (see Figure 11) on the right-hand controller. This will return you to the Home -screen.
- 2) If you want to stop using the app, please select Quit.
- 3) If you want to continue using the app, please select Continue.

Note! Please note that if you need to discontinue your daily session, next time the experience will continue from the beginning of the interrupted session.

When you're done, take the virtual reality device off your face and plug it back into the charger (if needed).

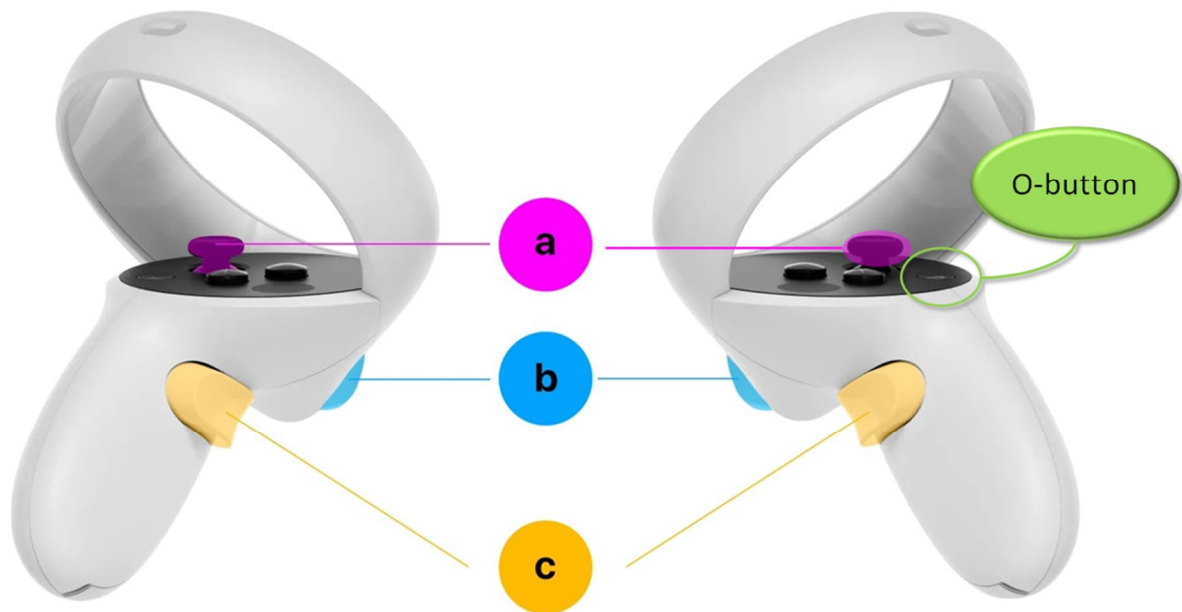


Figure 11. O-button.

20 Using the ROHKEA™ Companion application

The ROHKEA™ Companion application is a smartphone application, which is meant to support the ROHKEA™ VR Therapy usage. The ROHKEA™ Companion application consists of the following functions/screens:

- Login screen
- Main screen
- Menu
- Materials
- Homework
- Questionnaires
- Chat

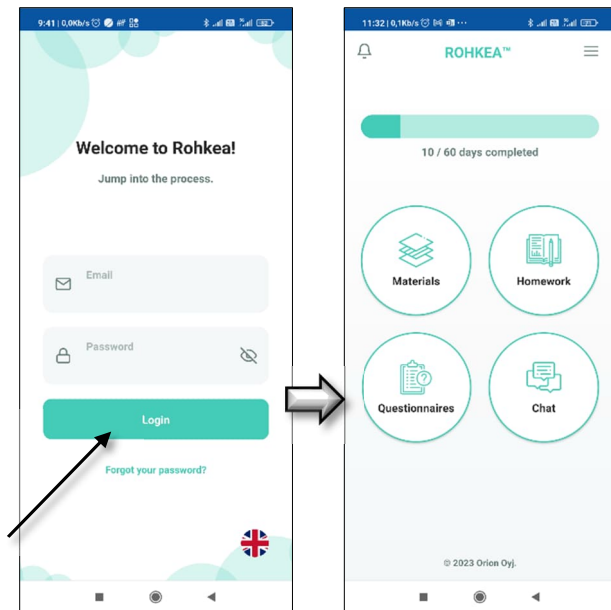


Figure 12. Login screen and Main screen.

Login by using the same email address, which you used previously with ROHKEA™. In a case you have unread notifications in the system, these can be found from the bell symbol on the left-hand upper corner of the screen.

20.1 Menu

Open the menu by pressing the three lines symbol on the right-hand upper corner of ROHKEA™ Companion application. Besides the function on the Main screen, the menu consists of the contact information of the Support and a link to the Instructions for Use.

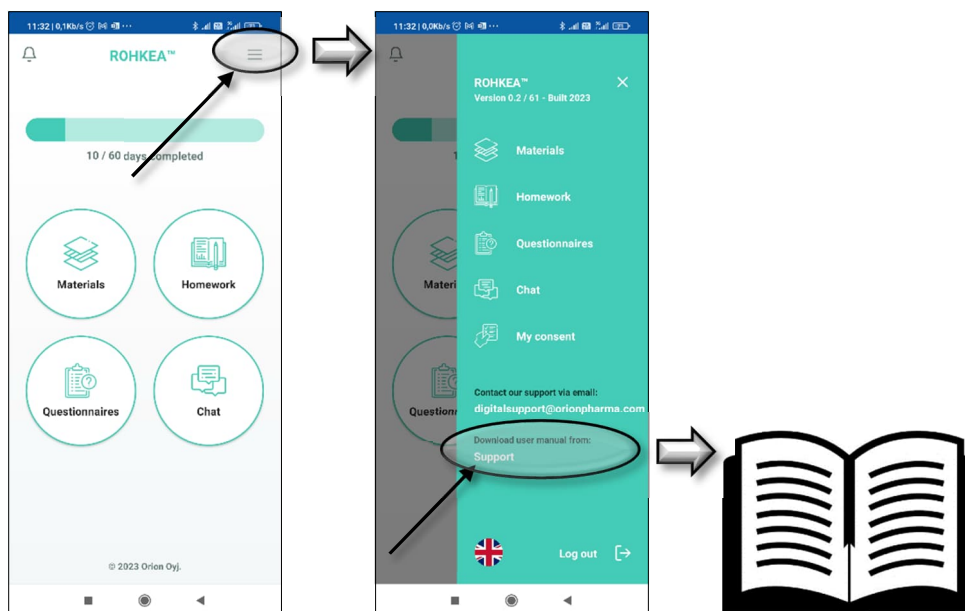


Figure 13. Opening the Menu. The Instructions for Use can be opened from the Menu.

20.2 Materials

The Materials page consists of your Values and Goals. Also, all your paintings can be found here.

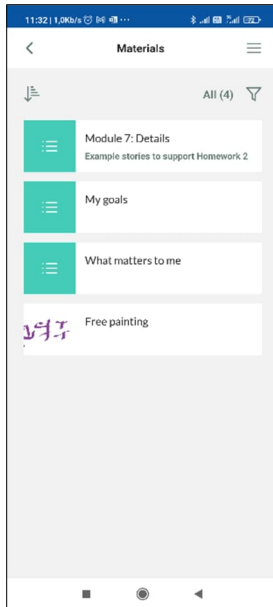


Figure 14. Values, Goals, and your paintings are on the Materials page.

20.3 Homework

The Homework page consists of the homework you have done.

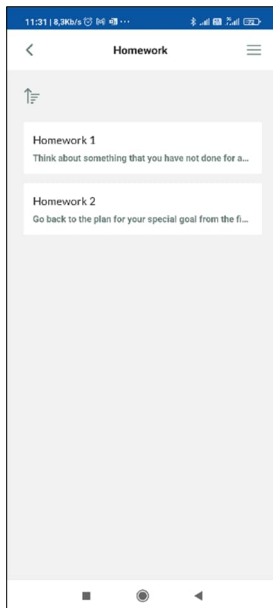


Figure 15. Homework page.

20.4 Questionnaires

The Questionnaires are not available in the first ROHKEA™ version.

20.5 Chat

The Chat consists of your conversation with a healthcare professional. In a case, there is not a professional available, the system shows a notification.

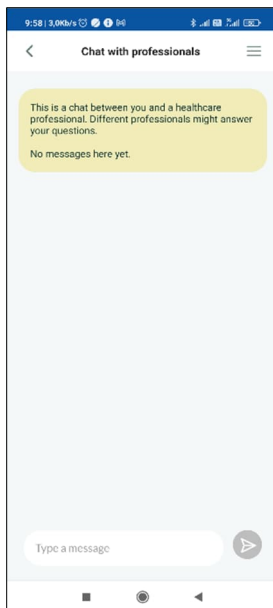


Figure 16. The ROHKEA™ Chat window.

21 Removing the ROHKEA™ VR Therapy

If stop using ROHKEA™ Therapy, you can remove the related software from the VR headset and your phone.

21.1 Removing ROHKEA™ VR Therapy from Meta Quest 2

To remove ROHKEA™ VR Therapy from your Meta Quest 2 VR headset, follow these instructions:

- 1) Power up your device and enter the Meta Quest home screen.
- 2) In the application view, locate the ROHKEA™ Therapy.
- 3) Move the cursor on top of the experience and click on the three-dots icon.
- 4) Click the “Uninstall” option.
- 5) Follow the instructions on the headset.

21.2 Removing ROHKEA™ Companion application from Your Phone

To remove the ROHKEA™ Companion application from your phone, please follow the normal software uninstalling procedures as per your device.

21.3 Removing Your Personal Data form the ROHKEA™

We manage the gathered data as informed in the ROHKEA™ Privacy Policy (found in the main menu of the ROHKEA™ Companion application). If you want to remove your data, please follow the instructions found in the forementioned document.

22 Technical Description

ROHKEA™ is a software system consisting of ROHKEA™ VR Therapy and ROHKEA™ Companion application. ROHKEA™ VR Therapy is a computer-generated three-dimensional virtual environment with scenes and objects that appear to be real, making the user feel they are fully immersed in their surroundings. The user can actively move and interact with their surroundings. This environment can be perceived only through a VR headset (currently Meta Quest 2). ROHKEA™ Companion application is a native mobile application, which has been developed for both Android and iOS.

22.1 System Requirements

ROHKEA™ VR Therapy can be used only with Meta Quest 2 virtual reality headset and the ROHKEA™ Companion application can be used with any Android device having Android version 9 or higher, or iOS device with version 12 or higher. ROHKEA™ VR Therapy and Companion application can be used anywhere where an internet connection is available.

22.2 Installation Requirements and/or Restrictions

Before using the software, the user should consult this Instruction for Use as well as the VR headset user instructions, including Health and safety warnings (<https://meta.com/quest/warnings>).

To ensure safe environment for using the VR software, the following must be taken care of:

- Clear the play area and ensure adequate free space 2x2 meters (6.5×6.5 feet) to use the system safely.
- Clear the required area of glass fixtures and use the application away from windows.
- Clear the area of electronic devices.
- Ensure you are using the product away from stairs.
- Ensure that small children or house pets cannot enter to the operating area.
- Use the solution away from fire.

Before using the application, the following must be installed:

- ROHKEA™ VR Therapy, which is used with Meta Quest 2 VR headset.
- ROHKEA™ Companion application which is used with a mobile phone/tablet/iPad.

22.3 Log in Credentials

After you have agreeing with the Terms of Use and given your consent to data collection it is possible to start the using of ROHKEA™ VR Therapy. Log in to the ROHKEA™ VR Therapy will be done by using the username and password. After logging in the first time, a PIN code must be created. Subsequently the PIN code is used to log in to the system instead of username/password combination.

22.4 Security Maintenance

ROHKEA™ does not contain or transmit sensitive health information; however, it does contain personally identifiable information (username and password). To maintain security, logging in is possible only with a valid combination of username and password. Furthermore, after logging in, the daily sessions are protected with a personally generated PIN code. If a wrong username and password combination or PIN is used, the software will block access and notify the user of wrong username or password or PIN.

22.5 Cyber Security

For the cyber security reasons, do not use ROHKEA™ with unencrypted WIFI and/or Internet connection.



Caution

Do not use unprotected network (WIFI/Internet) connection!

22.6 UDI



Basic UDI: 643210VRP00138

23 Frequently Asked Questions and Troubleshooting

I arrived in the cabin but don't know what to do?

Look around for SAMI the mentor. She provides instructions for next steps. Ensure that your VR device volume is turned up so that you hear the instructions.

I missed the instructions by SAMI, and I am stuck.

Please wait for a moment, SAMI will repeat the instructions after a short while in case the required function is not done. The activity instructions are also available for revisiting in the Pad during the given activity.

When landing into ROHKEA™ VR Therapy, eyesight level is too low.

Please, recalibrate the Guardian System in your VR headset. You will need to reset the floor level correctly.

I cannot reach the objects in the activity.

During the activities you can always teleport closer to the objects if they are out of reach. Try to teleport and ensure that your VR guardian boundaries are set to room scale mode and you have enough space (2×2 meters) for playing.

24 Support

Contact support for technical issues; issues with application / hardware updates, accidental uninstallation, other issues.



Caution

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established!



Caution

Contact support for technical issues; issues with application / hardware updates, accidental uninstallation, other issues.

Support email: rohkea.support@newel.health

In a case a hardcopy version of the Instructions for Use is needed, this Instructions for Use is possible to print from the ROHKEA™ Companion application or it can be sent forward as a PDF file for printing. This Instructions for Use can also be ordered in paper format from the Support email:

rohkea.support@newel.health

25 Manufacturer



Manufacturer: Orion Corporation, Orionintie 1A, 02200 Espoo
Phone: +358 10 4261
www.orion.fi/en/

26 CE-Mark



Medical Device
MDR class IIa



Medical Device as defined in MDR 2017/745