XRHealth

VRBehavior™ VRET-910 "Expose"

Instructions for use
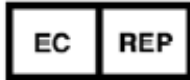
Rx Only

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

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Rev: 01| Last update: Initial release | Product UDI: 07290016986167
Software Version: VRBehavior VRET-910 ("Expose") V 1.0   Page 2 of 37

XRHealth

Contents

Abbreviations and Symbols

VR Virtual Reality

VRH Virtual Reality Approved Hardware (list available, appendix A)

HHS Hand-Held Sensors (part of the VR system, monitoring and enabling interacting with the VR by using hands/fingers)

ROM Range of Motion

DOF Degrees of Freedom

VRET-910 VRBehavior VRET-910 ("Expose")

Latest Version Version

LHP Licensed Healthcare Provider (Mental Health Professional, Social worker, Physicians, Psychologists, Caregivers, Geriatricians etc.)

Rev: 01| Last update: Initial release | Product UDI: 07290016986167
Software Version: VRBehavior VRET-910 ("Expose") V 1.0   **Page 4 of 37**

XRHealth

General Information

Intended use

The VRET-910 ("Expose") is intended as a tool used by a Licensed Healthcare Providers (LHP) to immerse their patients in simulated virtual reality (VR) environments in remote or in-person sessions in order to improve certain mental health conditions, using commercially available VR headsets.

VRET-910 is a prescription only software as a medical device that can be used in clinical settings or at home, with or without the assistance of a licensed health care provider.

VRET-910 provides VR exercises that takes measurements which enables the patient and the LHP to monitor changes over time. VRET-910 is not self-applied treatment and does not provide a report that analyzes the measurements, makes medical diagnoses, or recommends treatment.

Intended user populations

VRET-910 software is intended to be used by the following populations:

- Software operators:

  Licensed Healthcare Providers (LHP) and/or patients that utilize exposure therapy as part of their treatment.

- End users:

  o VRET-910 is intended to assist Individuals/patients as part of therapy session for mental health conditions designed and supervised by Licensed Healthcare Providers (LHP).

  o The LHP must confirm their patients' eligibility for VR sessions through an evaluation session and verify that there are no contraindications to carrying out a VR session (carefully read the relevant sections: Cautions, Warnings and Precautions).

Intended use environment

Expose software is intended to be used only in the following environments or areas:

- Home environment.
- Healthcare facilities (hospitals, clinics).

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Contraindications

Before using the Expose software, the user must be sure that they do not suffer from one or more of the following conditions or disorders :

1. Tumors or other Space Occupying Lesion of cervical region;
2. Undiagnosed neurological symptoms/signs;
3. Pathological fractures of spine;
4. Contagious or infectious conditions (while multiple users use same headset);
5. Facial lesions or superficial lesions that may have contact with the VR headset;
6. Epileptic seizures;

Additional Precautions

1. Neck movement may adversely affect users with cervical spine abnormalities, pain or other acute condition; If user feels any discomfort, they should terminate session immediately.

2. Some users with existing Vertigo or Nausea may experience exacerbation of the symptoms in VR environment; If user feels any discomfort, they should terminate session immediately.

3. 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.

4. Acute neck pain – users suffering from acute neck pain may experience difficulties carrying the weight of the VR headset.

5. Consult with your physician before using the software if you have pre-existing vision abnormalities, psychiatric disorders, suffer from a heart condition or other serious medical condition.

6. VR hardware (including headsets, controllers, and other devices) may contain magnets or components that emit radio waves. The frequencies of these radio waves may interfere with pacemakers, hearing aids, defibrillators, or other implanted electrical devices. If you have a pacemaker or other implanted medical device, do not use the VR Hardware without first consulting your doctor or the manufacturer of your medical device. You must maintain a safe distance between the VR hardware and your medical devices, and stop using the VR hardware if there is persistent interference with your medical device.

7. Although the VRBehavior 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. Also, at times the guided relaxation exercises will ask users to notice and be with their feelings, which can sometimes evoke distress in

XRHealth

some users. Please consult with your LHP before using the software if you have pre-existing mental health diagnoses, such as dissociative disorders, psychotic disorders, or severe depressive, trauma or anxiety disorders.

Warnings and General Limitations

1. Warning and general limitations related to the safe use of the Virtual Reality Hardware console (recommended for use with VRBehavior software series) are applicable when used with VRBehavior VRET-910 software.

2. Prior the usage of the commercial Rx only Virtual Reality Hardware, it is required from the user to carefully read all instructions, limitations, and precautions in the Health, Safety, and Warranty Guide attached to the hardware.

3. The LHP must confirm their patients' eligibility for VR sessions through an in-person trial session and clearly guide them on how to safely experience the environment delivered. If the LHP notices any anomalous events or features in the simulated environment being delivered to the patient, they should remove the patient from the environment immediately.

4. XRHealth IL LTD is not responsible for any malfunctions, defects, or user errors related to the purchase, installation, and use of the above-mentioned hardware.

5. Each VR training session using VRBehavior series software shall not last longer than the continuous duration recommended by the hardware manufacturer.

6. If user is experiencing symptoms associated with: tiredness; dizziness, visual abnormalities (blurred vision, double vision, etc.), disorientation, impaired balance being under the influence of alcohol or drugs; digestive problems; emotional stress or anxiety, suffering from cold, flu or headaches, migraines or earaches the training session must be terminated immediately.

7. If you are, or might be, pregnant, or if you suffer from physical, mental, visual or heart problems, and/or neurological conditions that might make you prone to seizures you should speak with your LHP.

XRHealth

8.   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.

9.   In order to create a safe environment:

- The objects that are seen in the virtual environment do not exist in the real environment, so do not sit or stand on them or use them for support.
- Remove any tripping hazards from the area before using the hardware.
- Do not handle sharp or otherwise dangerous objects while using the headset.
- Make sure the headset is level and secured comfortably on the patient's head, and that they see a single, clear image.
- Ease into the use of the hardware to allow patients to adjust to it; use for only a few minutes at a time at first, and only increase the amount of time using it gradually as each patient grows accustomed to virtual reality.
- Take at least a 10 to 15 minute break every 30 minutes. Each person is different, so take more frequent and longer breaks if a patient feels discomfort. The LHP should decide what works best for each patient.
- Do not use the headset with the sound at a high volume so that patients can maintain awareness of their surroundings and reduce the risk of hearing damage.

10.   During the use of VRBehavior in remote sessions the presence of a guardian is necessary for children under the age of 13 y.o.

11.   VRBehavior environments are designed to be experienced while sitting or, if indicated by the LHP or if the patient prefers it, standing, without walking around while wearing the VR headset to avoid accidents.

12.   If delivered incorrectly, exposing patients to challenging simulated environments may have a negative effect on their mental state and well-being. The LHP should carefully select and/or modulate the simulated environments used according to their patients' needs and capabilities.

13.   VRBehavior uses consumer-grade devices (VR headset, smartphone, tablet) that might be used according to their safety information and instructions for use. To reduce the risk of personal injury, discomfort, or property damage, the LHP and the patients (if needed) should read these warnings carefully before use.

VRET-910 Overview

Software description

1. The VRBehavior is a software medical device used as a tool by Licensed Healthcare Provider (LHP) in order to immerse their patients into virtual reality (VR) and 360º simulated environments, as part of remote or in-person therapy sessions devised to improve certain mental health conditions.
2. VRBehavior is intended to be used in home or clinic environments. VRBheavior is only intended to be used by patients while under the supervision of a LHP and is not intended to have any diagnostic function
3. VRBehavior VR app is integrated on a VR headset (3D), smartphone (3D/2D) or tablet (2D) to experience the simulated environment chosen and controlled in the VRBehavior web platform by LHPs in real-time according to their own professional judgment of their patient's characteristics and needs.
4. At the end of each session, training results are presented on the data portal. 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

1. The usage of the VRBehavior software requires a pre-purchase of a high-end off-the-shelf VR platform:
   - The compatible VR platforms for the use of VRET-910 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

Set up Instructions

1. Smartphone Guide

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

2. Choose your Hardware.

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Smartphone device: Decide ahead of time what device you will use the App on. It can be an Apple or Android smartphone with a good screen resolution (or a tablet, if not using the VR option). You will need a full battery and a reliable internet connection.

VR Headset: If you are going to be using a Virtual Reality headset, make sure you have set it up following the manufacturer's instructions.

3.   App installation

The installation is similar to regular apps installed on smartphone

- Download the VRET-910 VR app from the Google Play store for Android or from the App store for iOS.
- Enter the app and accept all the permissions required.
- When you see the image of a four-character code, you can start the session.

Notes:

To configure VR elements, it may be necessary to install the Google Cardboard app or similar.

Try now: You can try the demo environments without pairing with the platform.

4.   Settings menu: You can change Language, use the Sensor control panel, manage the disk Space Manager, enable VR Mode.

5.   Request support: Your patient can reach out to us for technical support with their device.

6.   Enable VR mode: You can enable VR mode when using a universal VR headset.

7.   Using 2D Mode (no headset):

The first time you open the smartphone app, it will automatically begin in 2D mode.

If you don't have a virtual reality headset, you should stay in 2D mode. This mode is designed for using the phone's screen for viewing the environments without the use of a VR universal headset.

To explore the environment, move the white joystick on the screen with your finger.

8.   Using VR Mode

The first time you open the smartphone app, it will automatically begin in 2D mode.

XRHealth

If you have a Universal/Cardboard VR headset you will need to Enable VR mode.

9.   How to Exit the VR Mode:

At the end of the session, follow these steps to return to 2D mode:

Take the phone out of the headset and press the X in the top left corner.

When the message appears, press Exit.

Please note you cannot exit VR mode whilst in the middle of a live session.

10.   Pairing a device with the platform:

● From your computer, enter the XRHealth platform: mental.xr.health

● Log in to your XRHealth account.

● In the bottom-left corner of the platform you'll see the Pair device button.

● Once you launch the app on your device (Pico VR headset or Smartphone), you will see a pairing code.

● Enter the 4-character code and hit Pair. The headset will now be paired with the platform. You can begin a session with a patient.

Minimum computer requirements For VRET-910 to function properly, these minimum of requirements must be met.

For the XRHealth web platform, the use of the following operating systems:

- Windows
- Mac
- Linux

The use of the Google Chrome web browser to access the web platform.

For the XRHealth smartphone app, the use of following operating systems:

- iOS
- Android

11.   Troubleshooting Information

When a problem occurs, troubleshooting helps to anticipate and provide solutions for any problems the user may have with setup, operation, or maintenance.

a)   If the app stops working:

XRHealth

Firstly, check in the Google Play/Apple App store whether there are any pending updates. Install them if necessary.

Next, close the application on the phone (go to the home screen and close the app from background running applications) and reopen it.

b) Everything appears off center when enabling VR mode

Close the application in the phone from background running apps and reopen it with the back camera facing straight forwards (the view is centered to the direction that the camera is facing when the app is opened or VR mode is enabled).

c) If the screen goes black when viewing an environment:

Check that the phone has not gone into sleep mode, and disable battery saving mode. Before entering the environment or a session make sure the battery is full or at least at a high level.

d) If you entered VR mode without VR headset:

Follow the instructions in the section How to exit VR mode to disable VR mode. The cursor will be difficult to see without a VR headset.

e) Difficulties playing in the VR mode even if wearing a VR headset:

Please make sure that the phone has the gyroscope sensor built into the system, as without this sensor it is not possible to play environments in VR mode.

f) Difficulties downloading environments in the mobile app:

If you are using a WiFi network, try using your mobile data with a good signal.

If you are already using your phone's data, try using a wifi network to discard connection issues.

Ensure that the mobile has sufficient storage space to download environments (We recommend that when using VR environments, such as Imagery for Relaxation, a minimum of 1GB of storage is required and when you are using 360 environments, such as Swimming with Dolphins, 5GB storage is required to ensure the environment plays well.

Software updates - scenes

1. The software comes with automatic update capabilities.
2. When a scene update is available – it will be automatically updated and applicable on all headsets.

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

1. XRHealth IL software can be installed, updated and managed by a selected MDM solution for remote headset management.
2. This solution enables XRHealth IL to fully manage the software version and update status in each device.

Instructions for use check list

1. The following instructions shall serve as a check-list for operating the VRET-910 software:
   - □ Carefully read the instructions for use by the VRH manufacturer (list of compatible hardware for VRET-910 available in <u>Appendix A</u>, below).
   - □ Carefully read the Health and Safety Warning of the VRH manufacturer (list of compatible hardware for VRET-910 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 VRET-910 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.
   - □ If applicable, 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).
   - □ 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 VRET-910 software or the attached VRH. Some users may have a

XRHealth

transient mild negative sensation associated with the VR environment. In any case that you experience symptoms which are not transient, contact your physician.

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).

3. If you suspect at any time that the performance and/or session instructions do not fit the training plan defined by your physician, immediately stop the training.

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

5. In case that the VR environment is not calibrated/centered, press and hold the calibration button to reset your orientation.

6. If you suspect that there is a problem with the VRET-910 software, immediately contact XRHealth IL LTD. (or the relevant distributor in your country). Meanwhile, stop using the device.

7. 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.

Training experience

How to pair your device

1. Turn the headset On to see a 4 digit code/ Open the Expose app on your phone to see the 4 digits code.

2. In the XRHealth web platform, click on the option **Pair Device** located at the left bottom of the page.

XRHealth
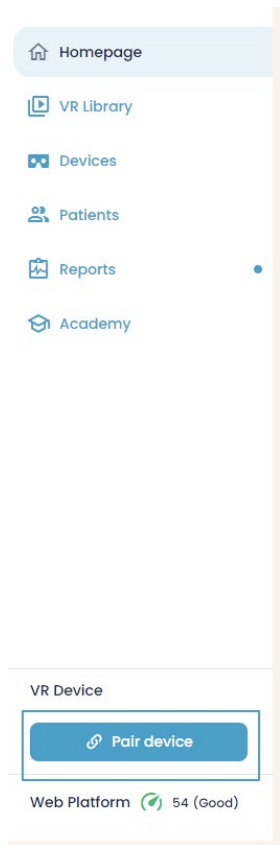
3. Enter the 4 digits code you see in the headset/smartphone, on the pairing box of the platform (always use lowercase letters).
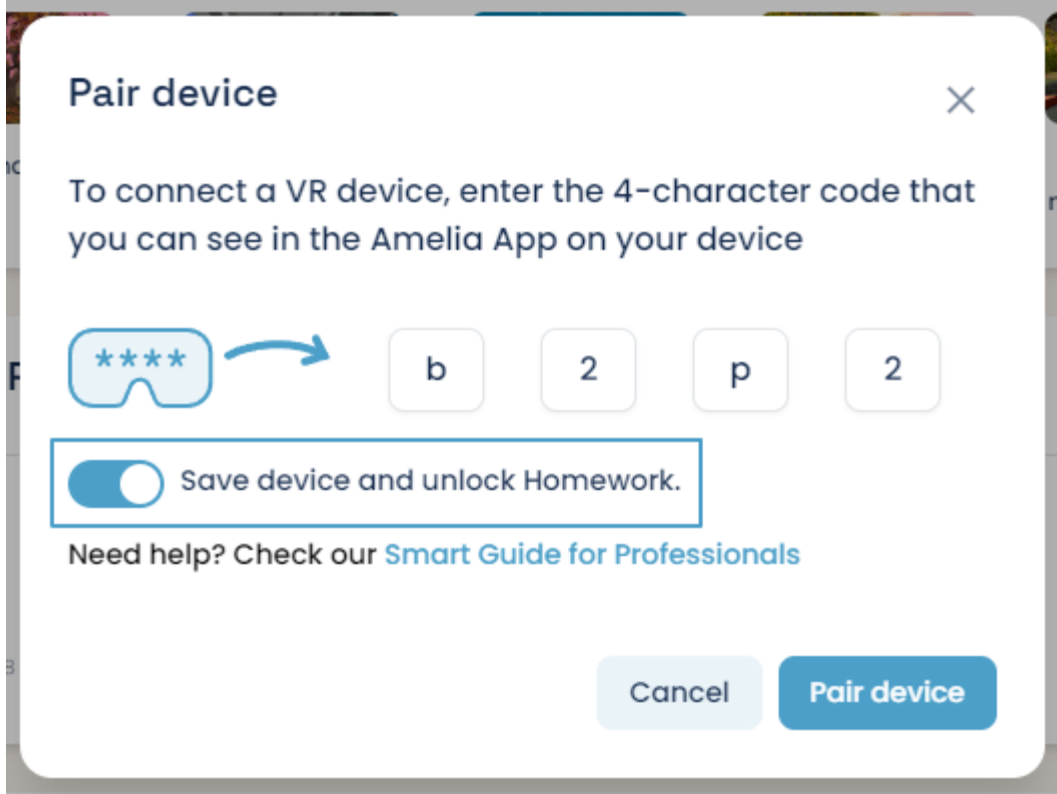
4.   Click on **Pair Device**
5.   You are now ready to start using the environments.
6.   If the Pairing is unsuccessful, you should restart your Pico headset, or fully close and reopen the smartphone app to generate a new code.

Homework

The XRHealth Homework add-on consists of predefined, automatic environments. The selection of environments are variations of events from the Mindfulness and Relaxation areas.

The homework add-in improves continuity of care and improves outcomes, helps provide a better service for clients between visits with this enhanced client experience, is easy to assign and easy for patients to access, and comes with reporting functionality to better support practice management.

You can use the homework feature in **3 DIFFERENT MODES:**

1. Homework mode:
   - Prescribe practice activities between sessions.
   - Improves the efficiency of therapeutic procedures.
   - Promotes the generalization of coping strategies.

- Promotes patient autonomy.
- Increased billing

2. Automatic mode**:**
   - Easier application of Virtual Reality (easy mode).
   - Reduced planning and execution time of virtual environments.
   - Perform automatic remote sessions.
   - Set up a Mindfulness-room in your clinic

3. Automatic group sessions**:**
   Host group sessions using Homework.

   In the platform
   Two ways of adding Homework:
   I. Pair the device and unlock the Homework feature:
      - When selecting **Pair device**, you must select **"Save device and unlock Homework".**
      - The device will be automatically saved.

   II. Select "+ New device" in the Devices section:
      - You will be able to select the name of the device and associate a patient with it.
      - A code will appear that you can share in a number of ways.

Rev: 01| Last update: Initial release | Product UDI: 07290016986167
Software Version: VRBehavior VRET-910 ("Expose") V 1.0   **Page 20 of 37**

🌀**XR**Health
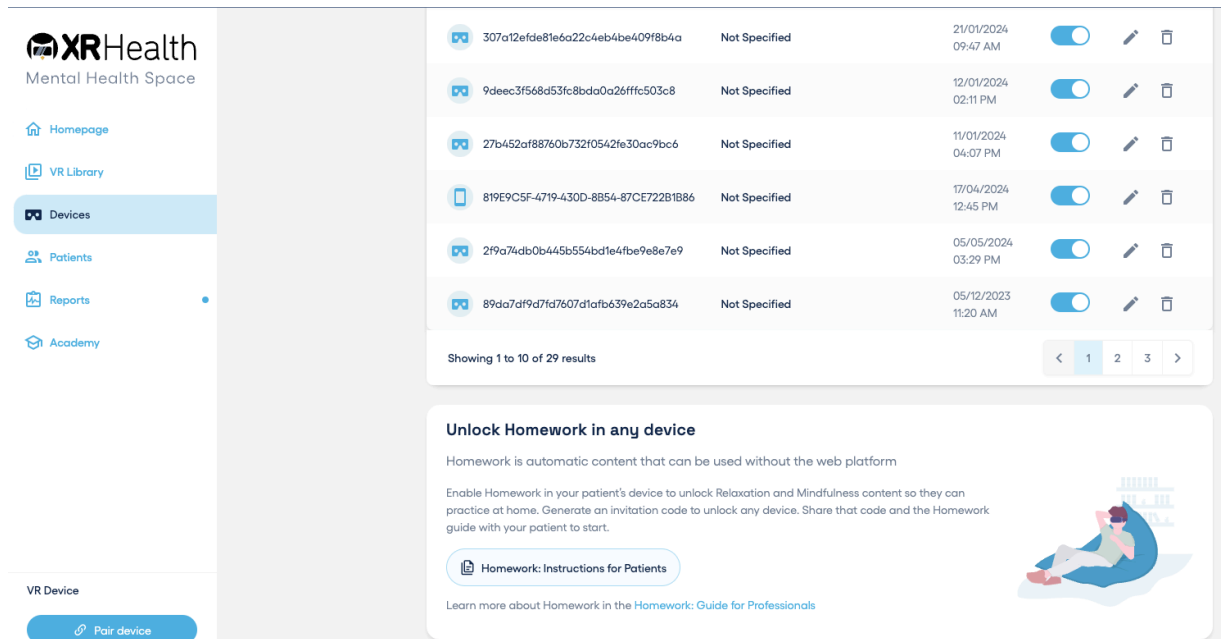
In the DEVICES section you can: enable-disable Homework on already saved devices, modify the information of each device, and delete a device.

Reports:

The report generated by Homework will have a different icon from the reports generated in the session.
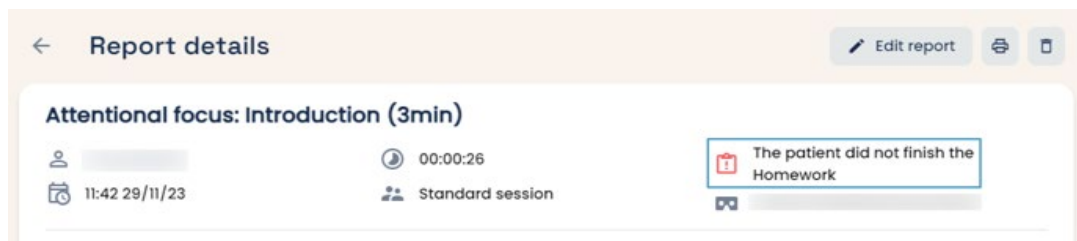
By selecting the report, you will be able to get all the recorded information of the session.
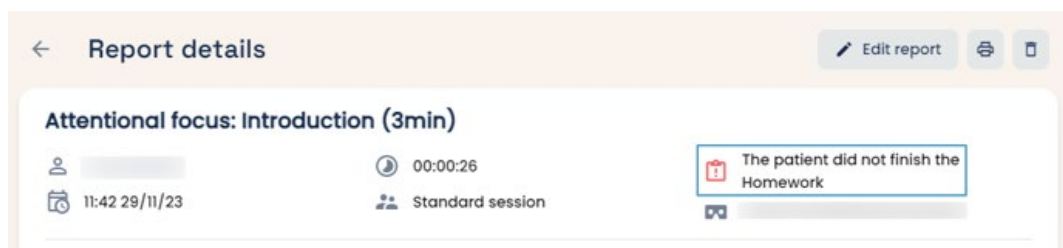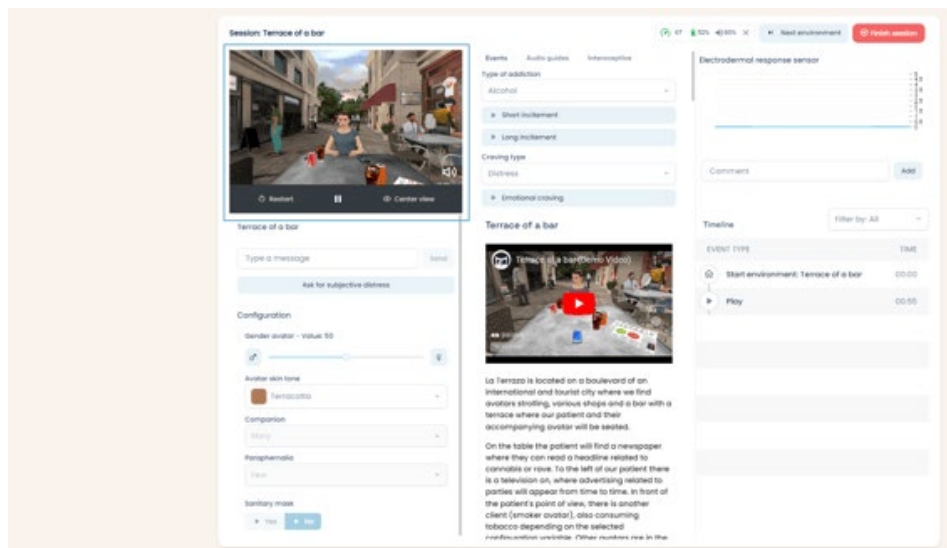
How to lunch an environment correctly

1. In the different areas of the VR library, you have different environments to choose from. The majority of these environments have additional configuration options and events available to use after the environment has been launched!

2. The first thing you need to do would be to pair your device to the platform. Once is paired, you can see information in the pairing box such as connection, battery, volume, and the "X" symbol to unpair the device.
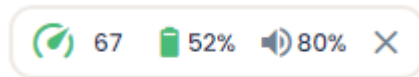
3. After being paired, you will see the **Visor**: This provides information about what the patient is viewing on the device. If you have activated the high-quality viewer in the configurations of your platform, you will see a reproduction of the environment equal to that seen by the patient. Here you will also be able to control the audio volume that you hear.

Rev: 01| Last update: Initial release | Product UDI: 07290016986167
Software Version: VRBehavior VRET-910 ("Expose") V 1.0   **Page 22 of 37**

XRHealth

4.   Here you have the Main actions:

• Restart: This button restarts the environment that is playing at the current moment in the visor.

• Play / Pause: This allows you to start and pause the environment playback during the session.

• Center view: If the patient is not seeing the environment from the correct starting point of view, then use this button to correct the position of the avatar/environment. Before clicking "Center View" tell your patient to look straight ahead in a comfortable position.

5.   Right under the Visor, you will see the **Elements of interaction** with the device. These buttons will allow you to communicate with the patient directly on the device, allowing you to maintain the immersion within the scene at the same time that you communicate with the patient. You can **send messages to the device**, by writing a message, and sending it to the patient's device. And **Ask for subjective anxiety** sending a subjective anxiety question, the patient will be able to choose on a scale from 1 to 10 their level of discomfort. Both elements are registered at the end of session reports.
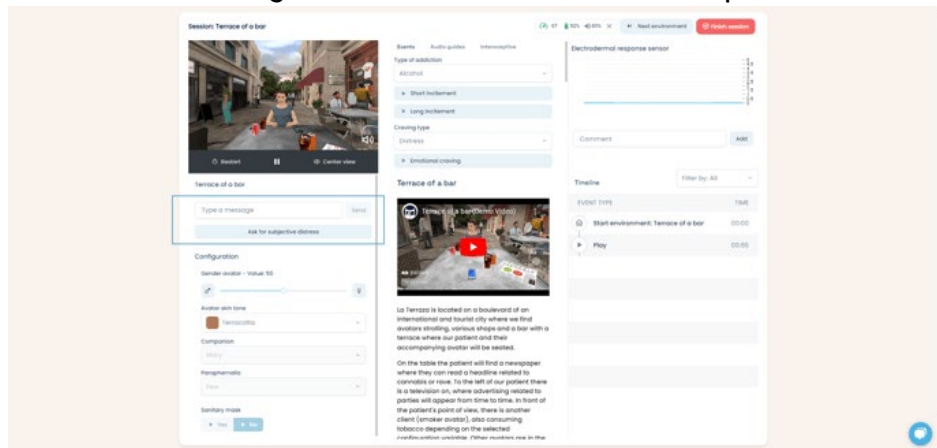
6.   The **Configuration variables** determine which elements will be present in the scene, regulating the exposure the patient faces. These variables **can be changed before launching the environment (pressing play), or only after pressing** <u>Restart</u> **on the visor**.

7.   Not all environments will have configuration variables, the presence or absence of configuration variables, as well as their use, will be explained in the environment user manual.

Rev: 01| Last update: Initial release | Product UDI: 07290016986167
Software Version: VRBehavior VRET-910 ("Expose") V 1.0   **Page 23 of 37**

🐸 **XR**Health
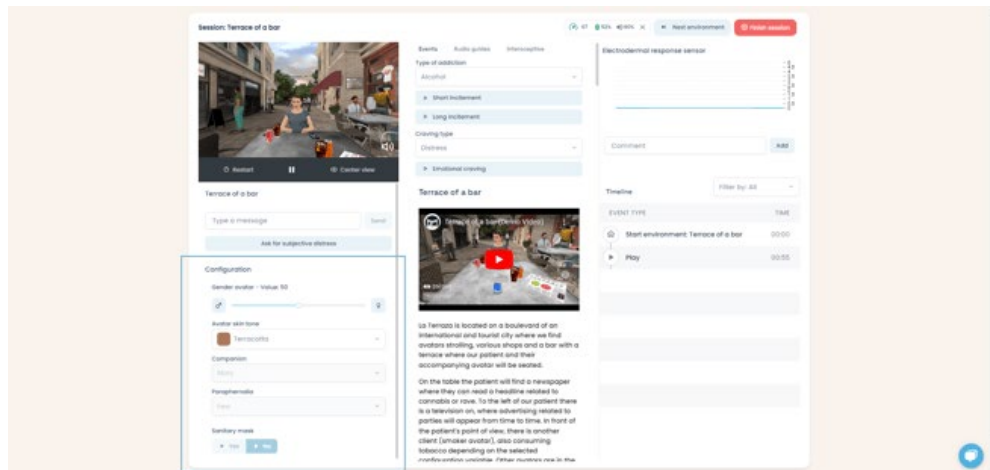
8. The **Event variables** section contains the variables that interact with the scene during the playback time.

- **Events tab**: Contains a list of events specific to the environment being used. It may be the case that some environments do not have events. You will find this information in the user manual for the environment.

- **To be able to launch an event, the scene must be playing**. You will find a 'Play' button under the viewfinder of the platform, this button will play the scene once the patient has the scene loaded in the headset.
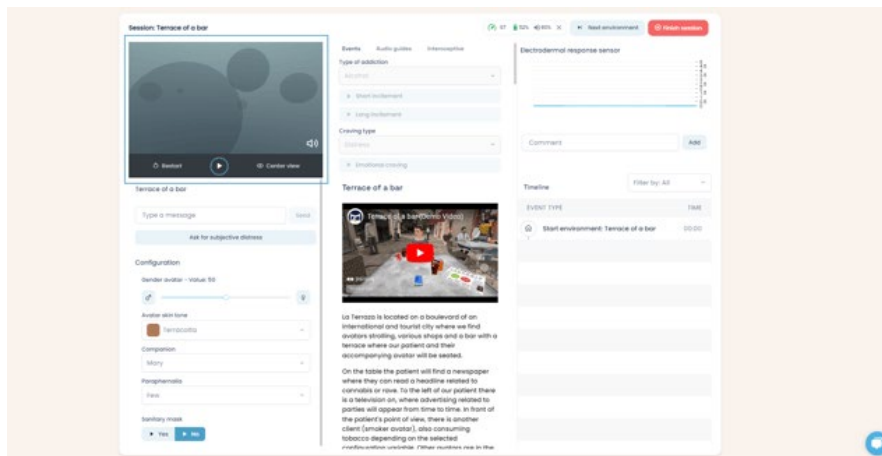
9. Under the Events you have the **Environment manual**: The manuals have information about the environment you have chosen to use during the session. They include:

- **Sample video**: This shows a preview of the environment

- **Description**: Provides both descriptive and clinical information about the environment.

Rev: 01| Last update: Initial release | Product UDI: 07290016986167
Software Version: VRBehavior VRET-910 ("Expose") V 1.0   **Page 24 of 37**

XRHealth

- **Configuration variables**: A list of variables that affect the elements that will appear, as well as the level of exposure that will be present in the environment.
- **Event variables**: A list of variables that allow you to advance in the reproduction of the environment, passing from one point to another, as well as activating or deactivating specific events that can increase or reduce exposure.
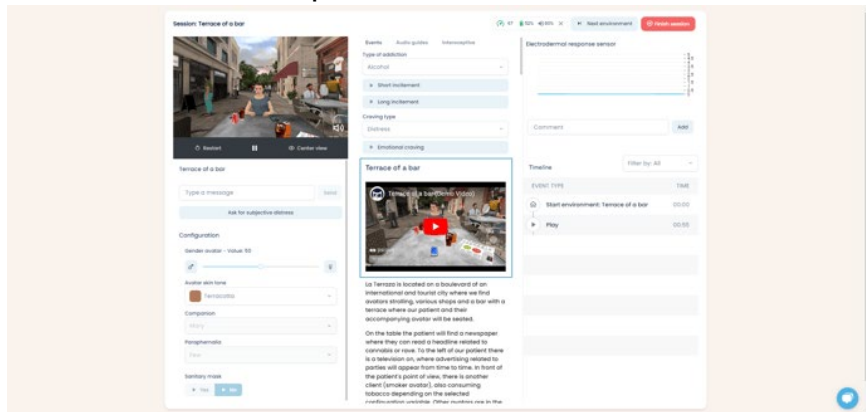

10. You can change the scene and end a session with the two buttons in the upper right area of the web platform.
    - **Next environment**: This allows you to reproduce another scene during the session, in case we want to expose the patient to several exposure environments, or an exposure environment followed by a relaxation environment to reduce activation and compare their behavior.
    - **Finish session**: As its name indicates, it ends the current session and shows us the report generated throughout the entire session with the information collected in the timeline of the control page.

XRHealth
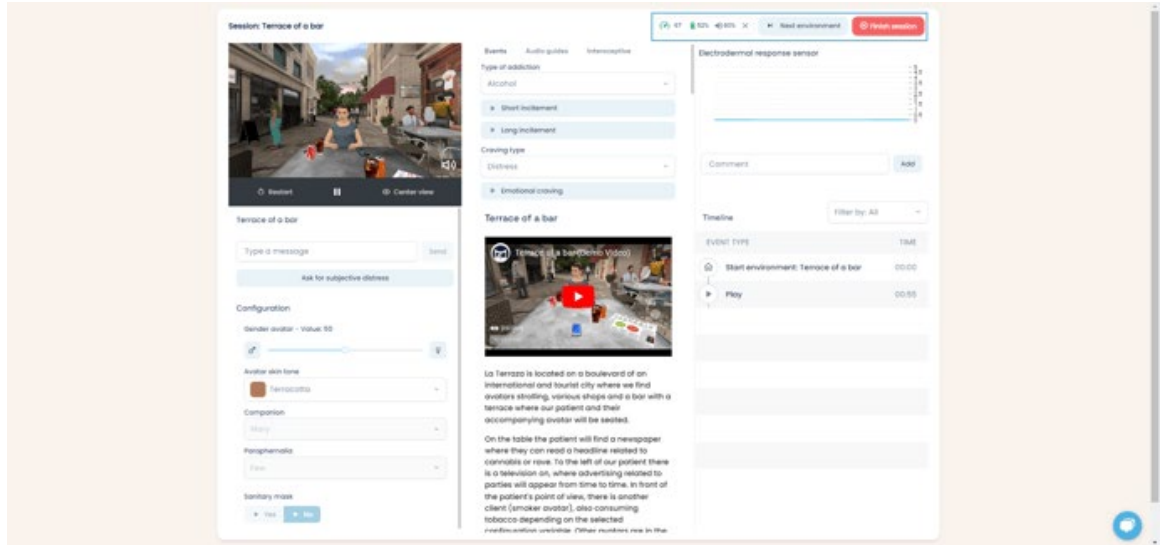
Patient's profile and report

1. All patients information is anonymized. If any account is closed the patient's information can not be recovered due to data inscription and privacy policies, unless the account is reactivated.

2. Required fields when creating the profile:

   - On the Patients section, you can create a patient profile by clicking on **New Patient**.
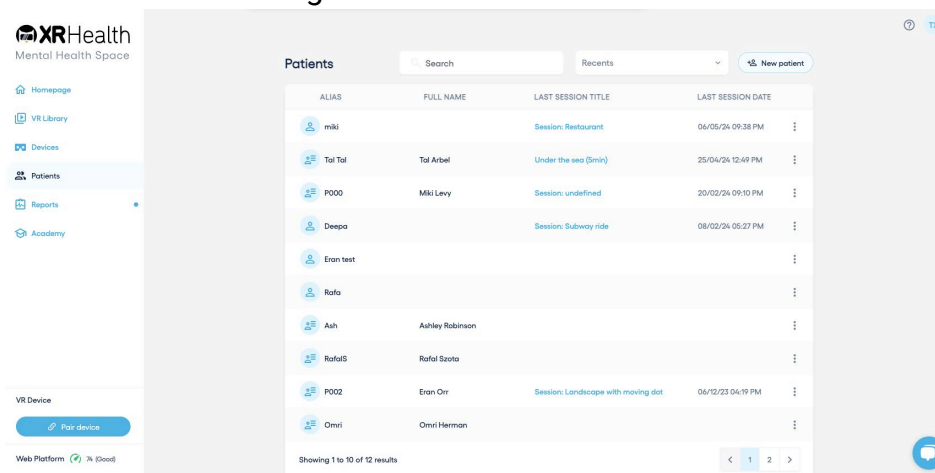
   - Select Add personal data now and inside fill in the required information highlighted in red: First name, last name and email address.

   - Register the information by clicking on Create.

XRHealth

- You can add extra information such as Personal data, Clinical data and associate the reports to the patient's profile.

Create new patient

Patient Alias

Pt.1

Avoid using personal data in the Alias. (Min. 3 characters)

Add personal data now?

Let's start with the mandatory fields:

First name*   Last name*

This field is required   This field is required

Email address*

This field is required

An email will be sent to your patient notifying them that you have created a personal profile

ⓘ To ensure security, and maintain regulatory compliance, all patient's personal data will be encrypted and stored in a separate server.

Cancel   Create

Rev: 01| Last update: Initial release | Product UDI: 07290016986167
Software Version: VRBehavior VRET-910 ("Expose") V 1.0   **Page 27 of 37**

XRHealth

3. **What the patient should expect:** We send an email to the patient informing them a profile has been created by you. That is the only communication the patients receive from our part.

4. What to do if your patient doesn't have an email address

You can do the session without a profile, and **(1) name the Report through keywords** to be able to find it later or you can create the patient's profile through an **(2) Alias** without having to fill in the personal data.

Rev: 01| Last update: Initial release | Product UDI: 07290016986167
Software Version: VRBehavior VRET-910 ("Expose") V 1.0   **Page 28 of 37**

XRHealth

You can unlink the patient's profile to remove it. Once it's removed you won't be able to create a new profile with the same email address.

5. Children's profile

You can do the session without a profile, and **(1) name the Report through keywords** to be able to find it later or you can create the patient's.

* The information of minors should be entered according to the guidelines of your country.

6. How to associate an existing report to a patients profile:
    - Go to the Reports section
    - Choose the Report you need to associate and click on Edit Report
    - Choose the Patient you want to associate the report to.
    - Save the change. You will find the report in the patient's profile.
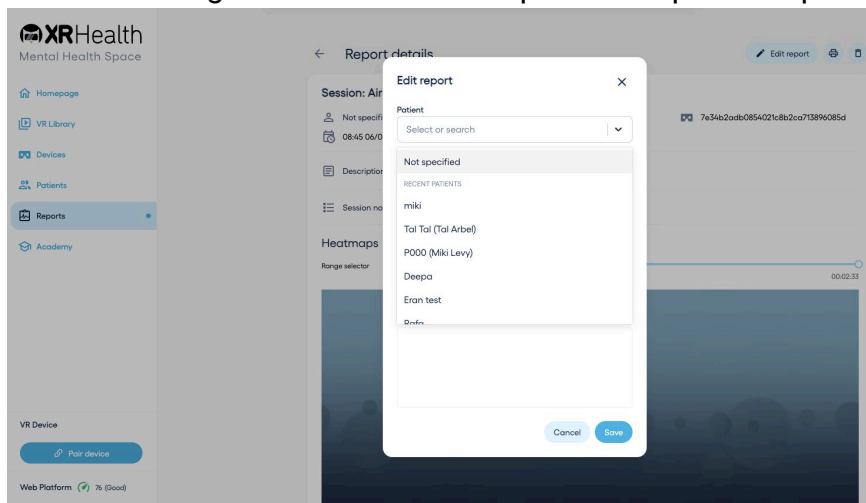

7. How to download reports:
- Once you are inside the report you wish to download, click on the print button:
- A new window will appear, where you need to choose **Save as PDF**, and then click on the Save button.
- You will have the option to choose where in your computer you want to download it.
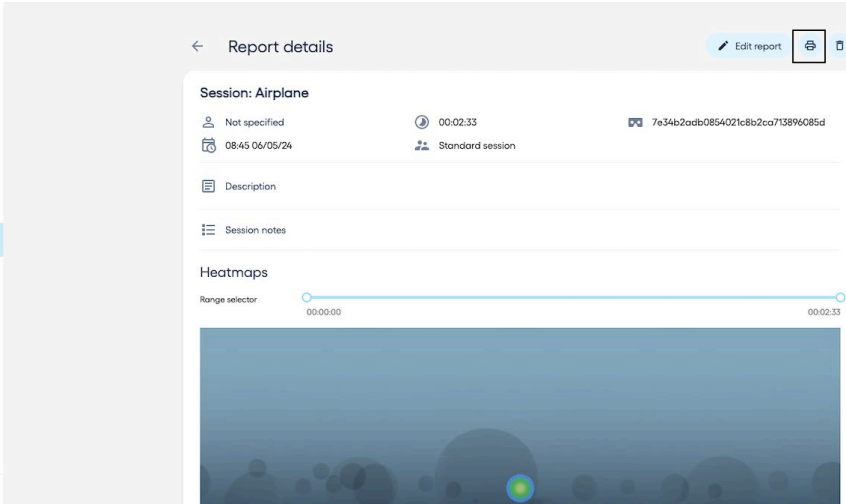
Heatmaps

1. Heatmaps are graphic representations in which the most visited areas of a virtual scene are differentiated by means of a color code. These representations are based on thermography. To interpret the color of the maps, you can consider them to represent:

   - **Red**: high attention
   - **Green**: some attention
   - **Blue**: low attention
   - **No color**: not explored/no attention
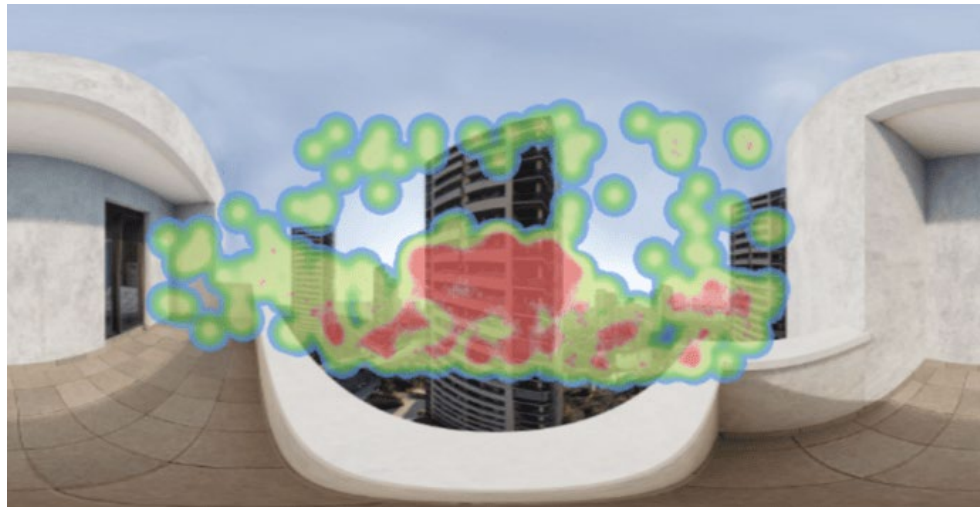
2. Expose's Heatmaps are meant to portray the orientation of the patient's head inside virtual reality scenes. Using this method

Rev: 01| Last update: Initial release | Product UDI: 07290016986167
Software Version: VRBehavior VRET-910 ("Expose") V 1.0   **Page 32 of 37**

XRHealth

provides information on the user's behavior while detecting which items inside of the scene are those most observed by the user.

3. In initial evaluations
    - HMs are a tool to provide information for the initial pre-intervention assessment.
    - HMs will provide us with baseline information on user behavior in interaction with the virtual environment.

4. Intervention
    - They are a behavioral measure complementary to self-reported subjective measures and physiological measures.
    - To establish therapeutic objectives and hypotheses and contrast them with the information provided by the HM.
    - Compare the PHMs between sessions.

5. Location of heatmaps on XRHealth platform:
    The heatmaps are found within the sessions reports, at the bottom of the report.

Rev: 01| Last update: Initial release | Product UDI: 07290016986167
Software Version: VRBehavior VRET-910 ("Expose") V 1.0   **Page 33 of 37**

XRHealth

6. Range Selector: The final representation of a heatmap provides us with knowledge about how the patient behaved during a certain range of time. This time range may consist of an entire session or part of one. If you would like to filter the data to show only the information from a specific moment in the session or exposure, you can use the range selector bar to adjust the time frame that is being represented in the heatmap data. This can be particularly useful to evaluate your patient's reaction to particular stimuli or events.

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

Rev: 01| Last update: Initial release | Product UDI: 07290016986167
Software Version: VRBehavior VRET-910 ("Expose") V 1.0   Page 36 of 37

XRHealth

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 Wi-Fi 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 does not help – Reboot headset
  ❖ Last option – Uninstall and Re-install application

**These Instructions for Use (IFU) is also available as a hard copy. If you are interested in printed copy of this IFU, please send a request to the customer support and it will be printed and delivered within 30 days.

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