



REF **RelaxationVR**

CE Class I Medical Device

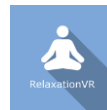
User manual

Distribution mode

Available for direct download at
<http://virtualisvr.com/espace-client/>
Use under license

 **VIRTUALIS**

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DESCRIPTION

RelaxationVR software is an immersive 3D simulation based on virtual reality technology which allows a person to be immersed in an artificial digitally created world. The **RelaxationVR** software is used to immerse the patient in ecological environments conducive to relaxation.

INDICATIONS

Immersion of the patient in an ecological environment conducive to relaxation during treatments such as hypnosis or massage or for algesic patients.

CONTRAINDICATIONS

Epileptic patients, children under 15 years of age, pregnant women

FOR USE BY

Healthcare professionals: Physiotherapists; Ergotherapists; Neuropsychologists; ENT doctors; Neurologists; PMR doctors (physical medicine and rehabilitation), etc.

Research Centers: CNRS, CHU, INSERM, etc.

WARNINGS AND CAUTIONS

During sessions, stay close to the patient in order to anticipate any loss of balance or discomfort caused by the use of virtual reality.

Define a working area of about 3m² to allow for risk-free movements.

Take a 10 to 15 minute break every 30 minutes of use.

Potential adverse effects are those due to the use of Virtual Reality, namely vomiting, malaise, dizziness, syncope.

The accessories required to use the software may emit radio waves that can interfere with the operation of nearby electronic devices. If you have a pacemaker or other implanted medical device, do not use the product until you have taken advice from your doctor or the manufacturer of your medical device.

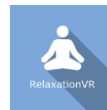


Any serious incident should be notified in writing to qualite@virtualisvr.com



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1. GENERAL

1.1. Advice for use

This type of re-education must be undertaken progressively, especially in Virtual Reality where the stimulation is much more "powerful" than the traditional optokinetic stimulators.

These stimulations have the potential to cause certain disorders: Vasovagal syncope, epileptic seizures, migraines, etc. (Despite a test phase on more than 2000 patients. Similarly to previous generation optokinetics, caution is required)

The contraindications are identical: Mainly epilepsy and migraines.

As postural reactions can be spectacular, it is VERY STRONGLY advised to place patients in a safe environment and to stay close to them throughout the session.

It is also recommended to increase the duration and intensity of the stimulation very gradually, after an initial short session to make sure of patients' tolerance to this type of stimulation.

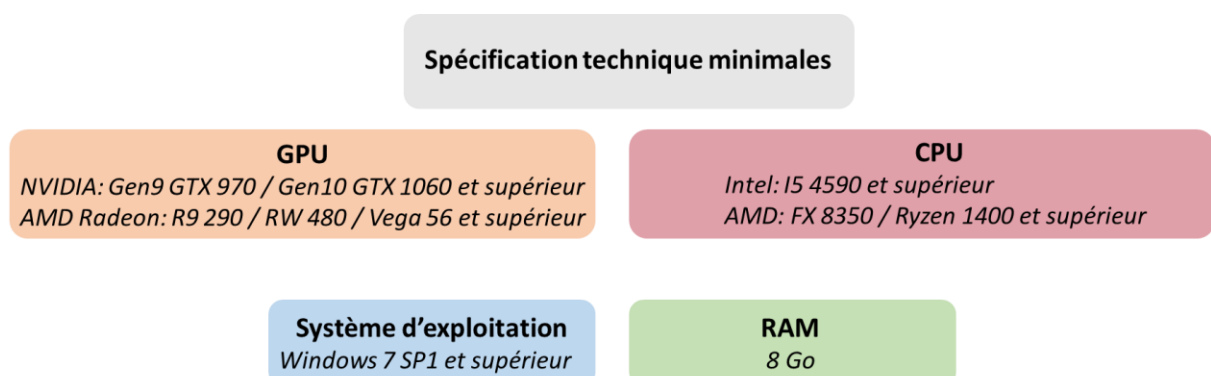
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

1.2. Hardware and minimum configuration requirements

Hardware required to use the system:

- VR Ready PC
- VR System: HTC VIVE, HTC VIVE Pro or compatible system
- Lighthouse bases (HTC VIVE tracking)
- USB HUB

In order to install and use our virtual reality applications, we recommend a configuration equal to or higher than the system requirements:

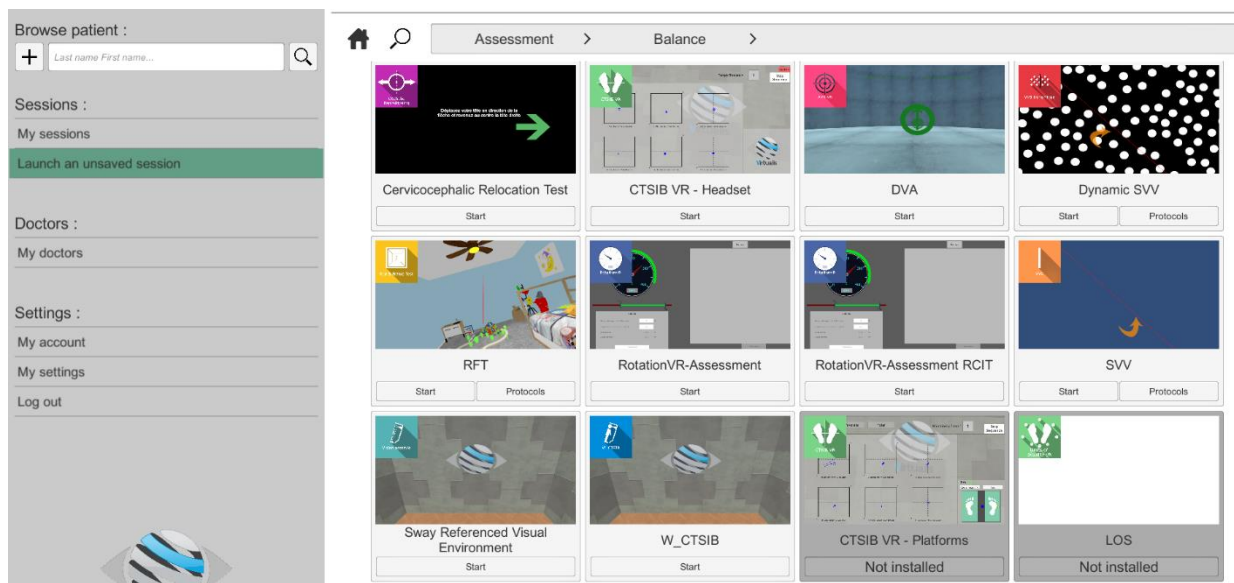


2. USE OF PATIENT MANAGEMENT

Once connected to the Patient Management software, you arrive on the home page. It is from this home page that you will be able to start your VR software as well as the other Patient Management functions.

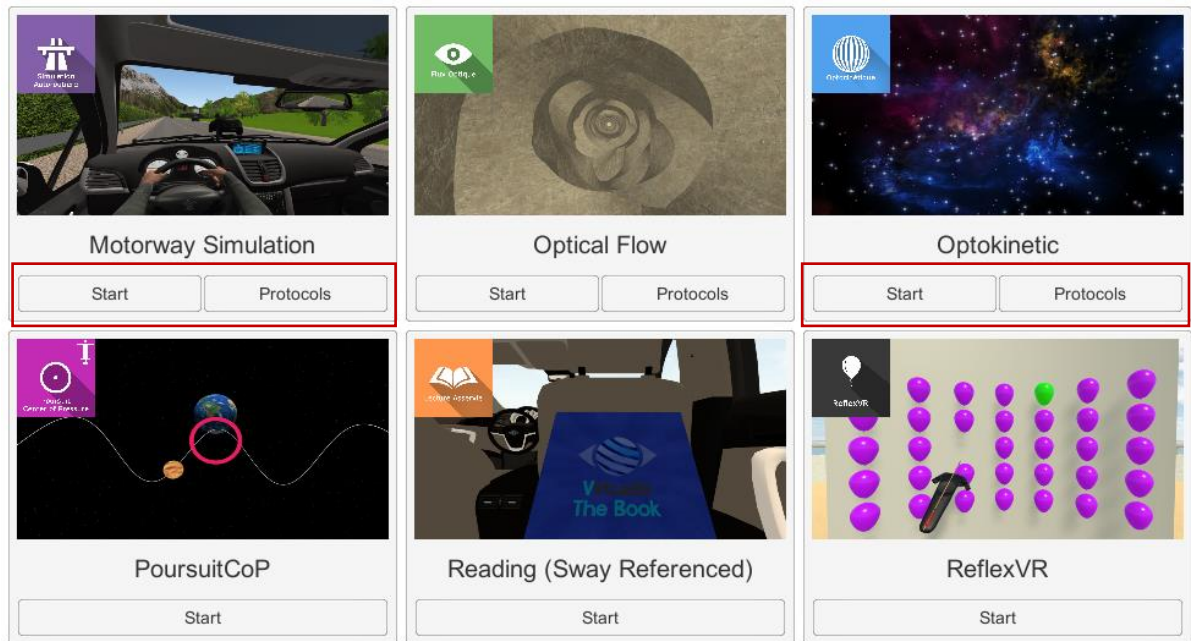
The software can be grouped according to criteria such as "Assessment" or "Re-education" and then by pathology type: Neurology, Balance, Functional or Motion sickness.

You can start or switch from one software to another from the home page by clicking the corresponding "Start" or "Protocols" button.

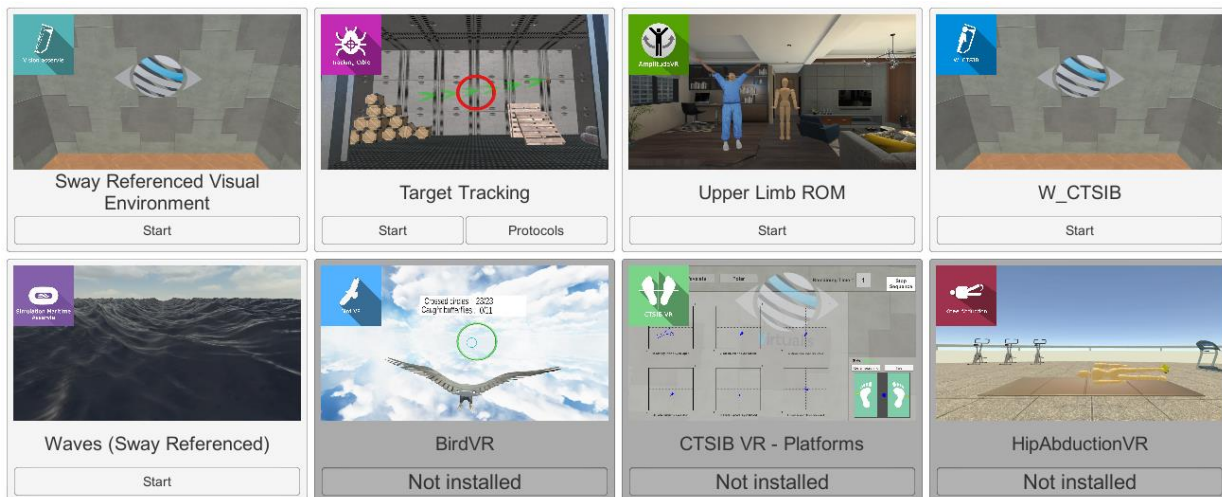


Some software can be started either in **manual mode**, by directly clicking the "Start" button, or in **protocol mode** by clicking the "Protocols" button.

Manual mode allows users to choose the settings for each environment. **Protocol mode** offers several sessions with different difficulty levels to test and gradually accustom patients to the VR environment.



Software that is not part of your subscription package is grayed out. If you want to use it, please contact our sales department.



3. RelaxationVR

3.1. Start interface

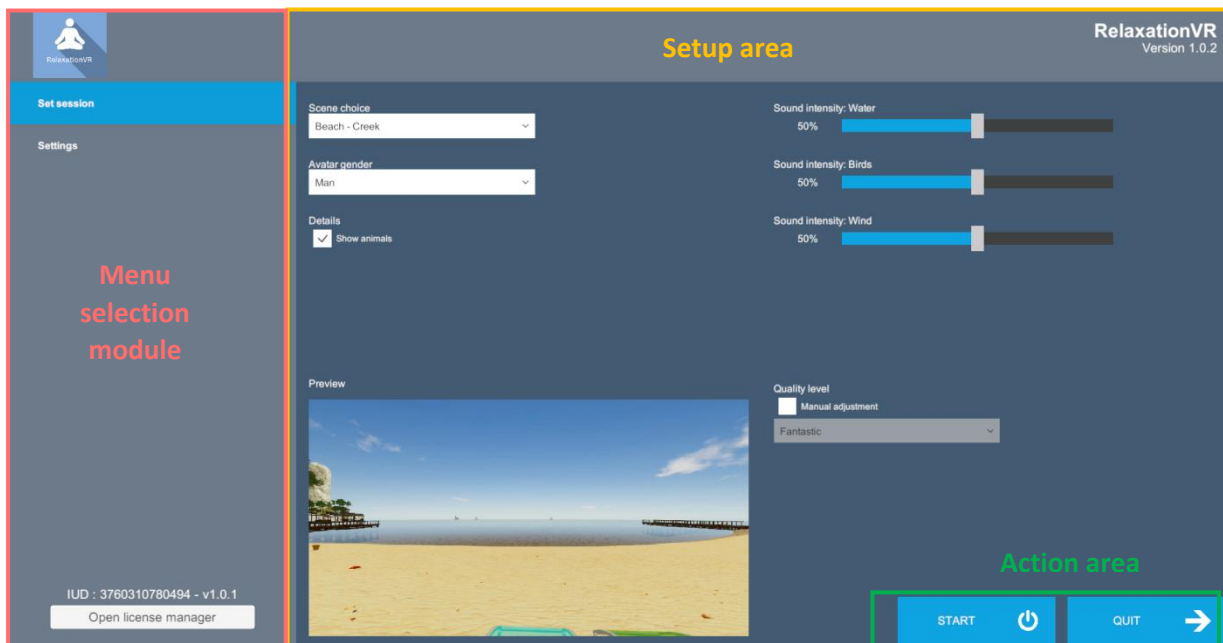
When starting the software in **manual mode** ("Start" button), the opening is made in a start interface, consisting of a module selection menu on the left, a set up area on the right, and an action area at the bottom right.

Depending on the module selected in the left menu, the set up area shows the various possible settings/information.

It is possible to access the Gestio main menu

It is possible to access the start interface by simply clicking the "quit" button located in the action area, or by pressing the "escape" key on the keyboard.

The software is launched by simply clicking the "start" button in the action area.



Once this button is pressed, the software starts by taking into account the specified settings. You also have the possibility to modify some settings when the software has been launched, using the mouse.

The Start/Quit buttons allow the environment to be played back or stopped entirely to adapt the experience to the patient's sensations.

Once an environment has been selected, it launches in the headset, and you can see and track what is happening in your patients' headset from the software window.

3.2. Software field of application

Any treatment that requires cutting the patient off from their real environment.

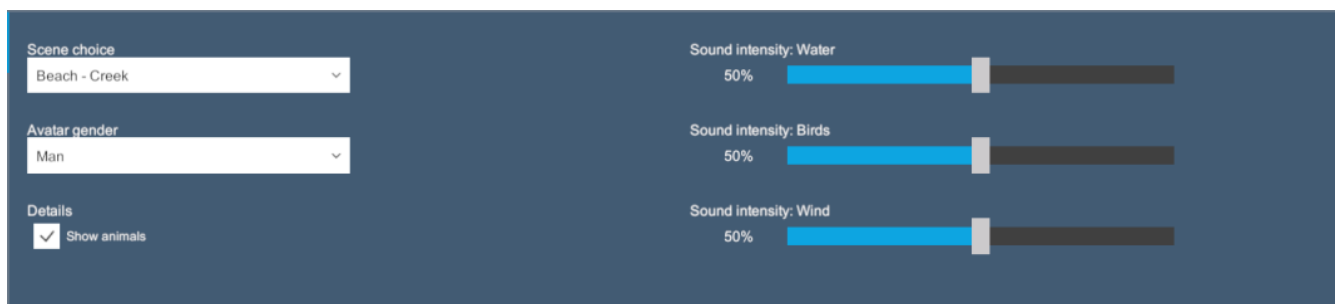
3.3. Installing the patient

Depending on the environment, the patient will be represented by an avatar in a sitting or lying position. It is advisable to install the patient in the same position as the avatar if there is to be coherence between the visual rendering of the environment and the real position of the patient.

Beach: semi-recumbent position, or even lying down.

Pines and Fir trees: sitting position.

3.4. Session settings



The variable settings for this module are as follows:

Scene choice

Several environments are possible: beach-creek; pine forest; fir forest

Avatar:

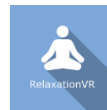
Female, male or none

Show animals:

This option can be enabled by checking the corresponding box

Sound intensity of water, birds and wind

Used to set the environment parameters using the cursor



3.5. Shortcuts

The "C" key on the keyboard is used to center the image.

3.6. Data processing

Data retrieval and analysis uses the Patient Management software.