REF **AirRaceVR**

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

AirRaceVR is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. **AirRaceVR** is an active rehabilitation software (for the cervical and thoracolumbar spine) replicating an airplane ride simulation between pylons. It is controlled through the patient's active movements, achieved by tilting the cervical or lumbar spine or by moving the center of pressure. The movement's amplitudes as well as their speed can be configured by the user.

INDICATIONS

Active rehabilitation of the cervical and thoracolumbar spine and body weight transfer

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.

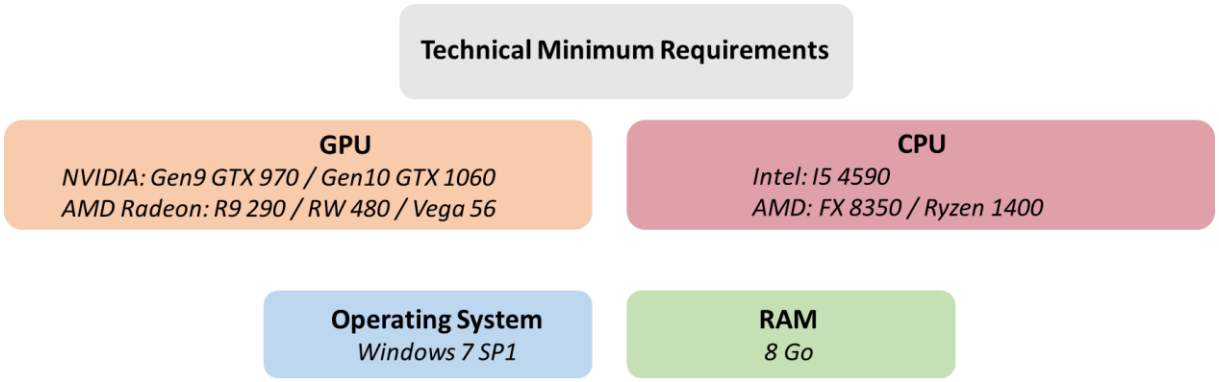
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

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)
- HTC VIVE Trackers
- Static platform (StaticVR)
- USB HUB

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

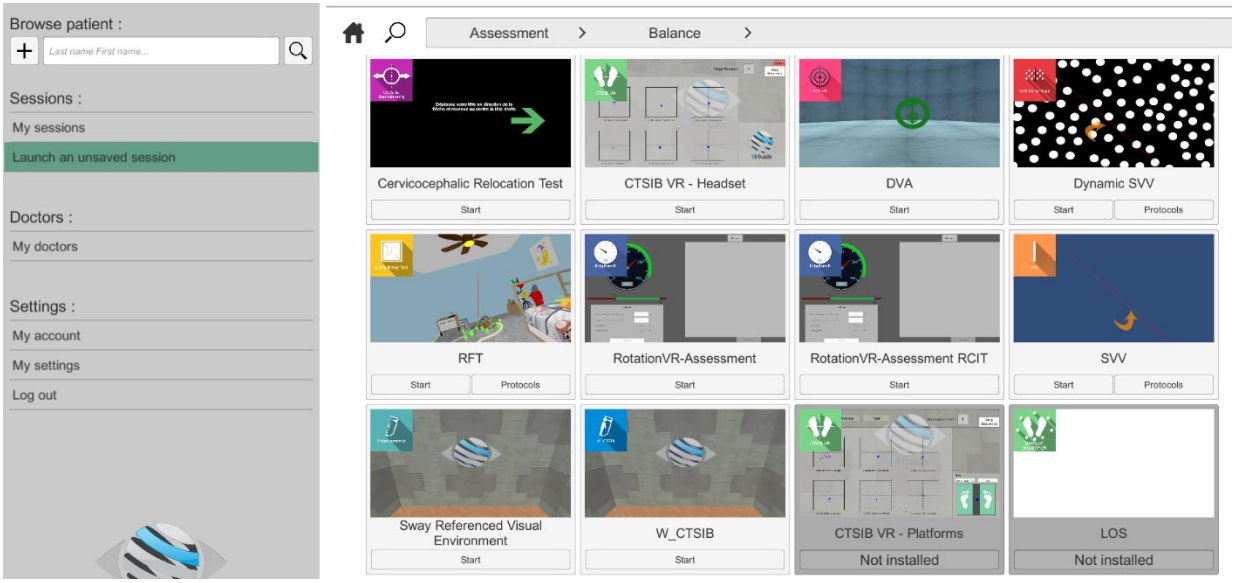


2. USE OF PATIENT MANAGEMENT

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.

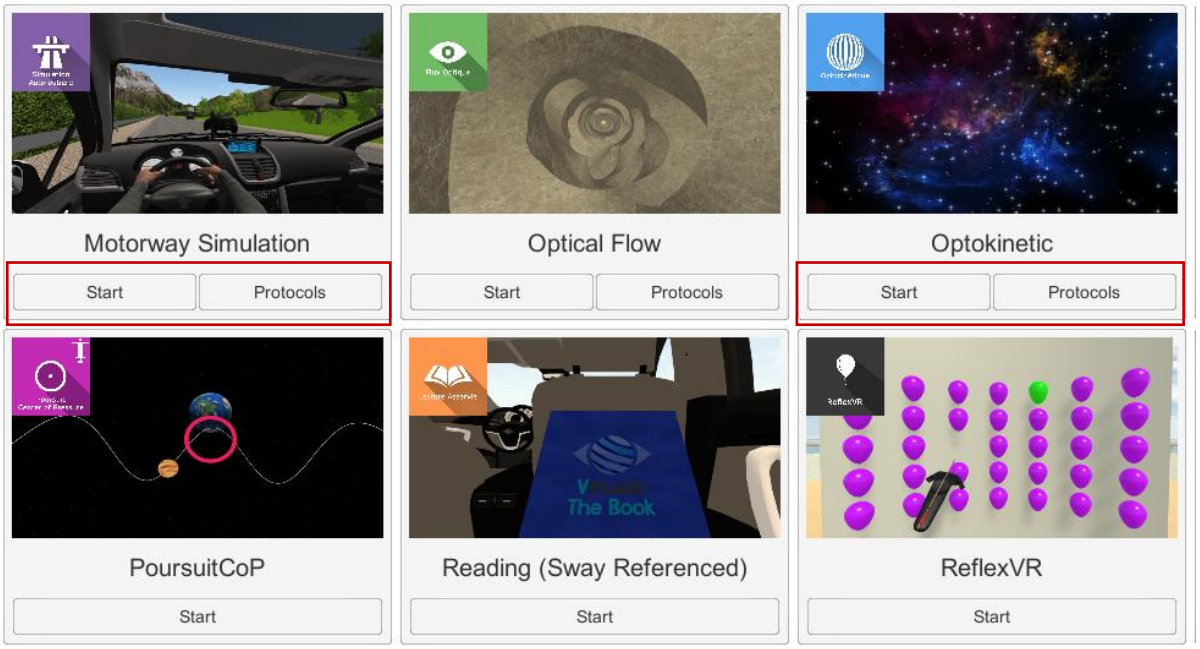
The software can be grouped according to criteria such as "Assessment" or "Re-education" and then by pathology type: Neurology, Balance, Functional, Motion Sickness or Fears - Phobias.

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

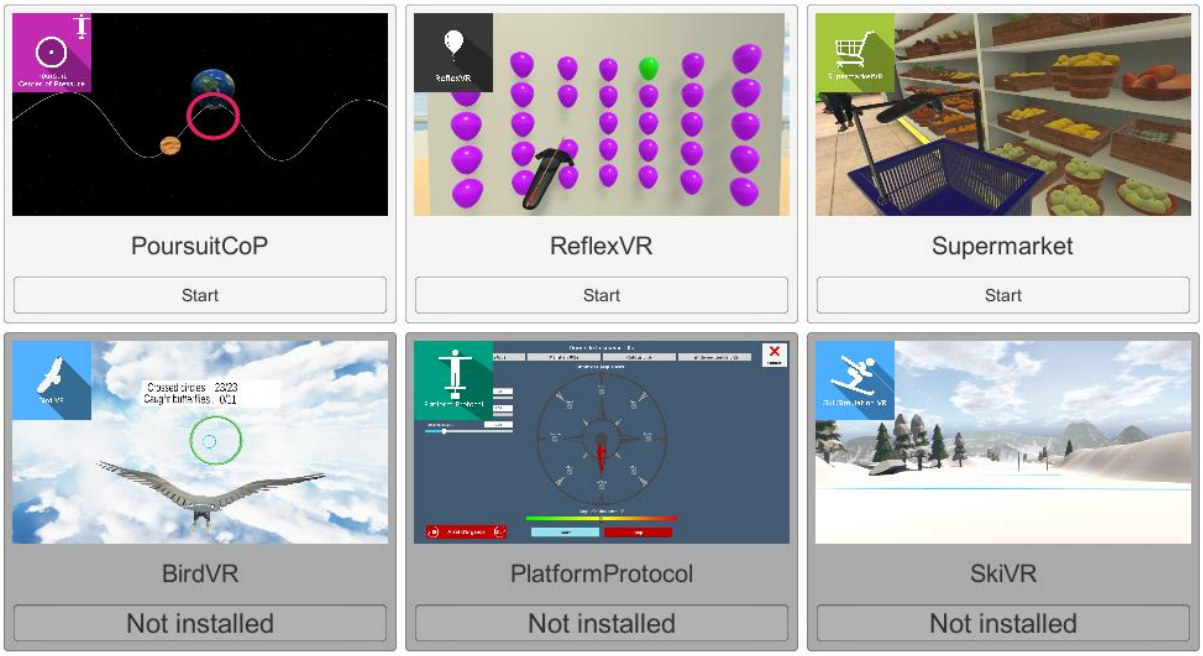


Some software can be started either in ***manual mode***, by directly clicking the "Start" button, or in ***protocol mode*** by clicking the "Protocols" button.

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. AirRaceVR

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 general Patient Management menu from 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

This software allows patients to carry out active inclinations of the spine as well as active displacements of his center of pressure.

3.3. Installing the patient

For working on the spine alone and using the headset or tracker as a motion capture tool:

The patient can be seated or standing.

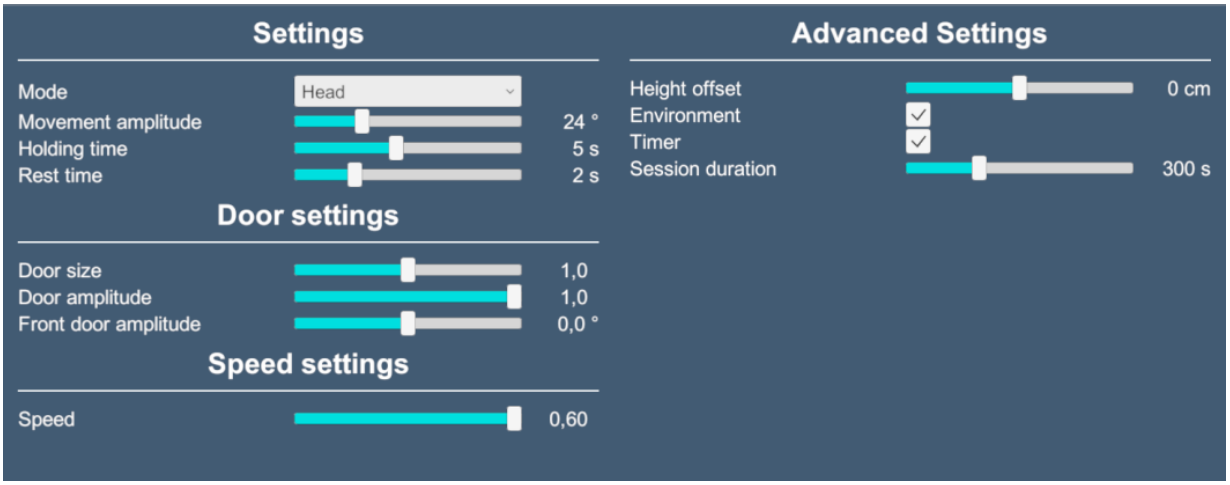
Standing position; foot position at will: joined, apart, pointing out, etc.

Seated: When working in a seated position with the back supported, the system will only be able to take into account cervical inclinations.

For the work of displacement of the center of pressure:

The exercise will be performed with the patient in a standing position, feet on the StaticVR posturography platforms. In order to allow a better perception of the supports, the patient's feet will be bare foot. The feet are parallel and the bimaleolar line aligned with the horizontal white line printed on the top of the platforms.

3.4. Session settings



The variable settings for this module are as follows:

Settings

How to carry out the exercise:

With headset, trackers or CoP (StaticVR)

The aircraft will move according to the tilting movement perceived by the headset or the tracker (head and back mode).

Head mode measures head movements from the headset tilts.

Back mode measures the tracker's movements.

The use of a tracker at the pectoral level makes it possible to only measure thoracic or lumbar inclinations.

If the back is not fixed by a support then the patient can carry out cervical, thoracic and lumbar inclinations.

If the back is supported, then head mode will be selected to record the cervical inclinations.

StaticVR mode (CoP): the plane will move according to the intensity of the displacement of the patient's center of pressure perceived by the StaticVR platforms.

Movement amplitude

Determines the amount of movement required to achieve maximum movement of the aircraft in the virtual environment.

Can be modulated using the cursor

Holding time

Corresponds to the holding time required of the patient in the maximum amplitude position defined for the proper performance of the exercise. The good achievement is objectified by the passage of the aircraft between two pairs of consecutive pylons.

Rest time

Corresponds to the holding time requested from the patient in the neutral position. The good achievement is objectified by the passage of the plane between two pairs of consecutive pylons.

Patient’s height

This parameter is only displayed when the **CoP mode** is selected.

Can be entered manually or automatically by pressing the "calibrate" button once the headset is placed on the patient's head.

Note: For a more accurate calibration, please place the patient standing up with the VR headset correctly positioned onto the head. The feet should be on the floor and the patient should look straight forward.

Door settings

Door size

Used to increase door size to make the exercise easier.

Door Amplitude

Used to change the angle of inclination required to pass through doors.

Front door amplitude

Allows the movement to be carried out along a receding or reentrant path in relation to the passage of the first door.

Speed settings

The target movement speed can be set using the cursor.

Advanced settings

Height offset

Used to adjust the aircraft observation angle

Environment

Possibility to carry out the exercise by removing or not visual elements of the decor by checking the corresponding box

Timer

Used to define the session duration

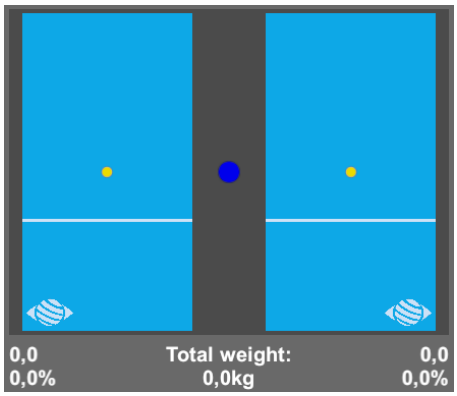
StaticVR settings

Raw data sent by the platforms

Yellow dots: Center of Pressure (COP) of each foot

Blue dot: Global Center of Pressure (COP)

The weight distribution for each foot is displayed



Smoothed data & settings:

Tare

Platform reset (must be carried out when empty)

Smoothing

Smoothing force applied to the data

Sensitivity

Multiplier applied to received data

Decrease to reduce motion sensitivity

Score

At the end of the exercise, users will get a score representing their accuracy (number of doors passed through).

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.