REF **Weight Bearing**

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

Weight Bearing is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. The **Weight Bearing** software is used to rehabilitate static and dynamic pressure in terms of body weight distribution between the two lower limbs. It is also used to work on a patient's awareness of pressure by visualizing the value of pressure as a percentage of the body weight.

INDICATIONS

Rehabilitation of a patient's pressure distribution and balancing strategy according to body weight distribution.

CONTRAINDICATIONS

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

FOR USE BY

Healthcare professionals: Physiotherapists; Ergotherapists; Neuropsychologists; ENT doctors; Neurologists; PM&R physicians (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

Virtual Reality Immersion is a powerful tool, especially for optokinetic stimulation, optical flow, motorway simulations, dynamic SVV etc.

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

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

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 check the patient's tolerance to this type of stimulation.

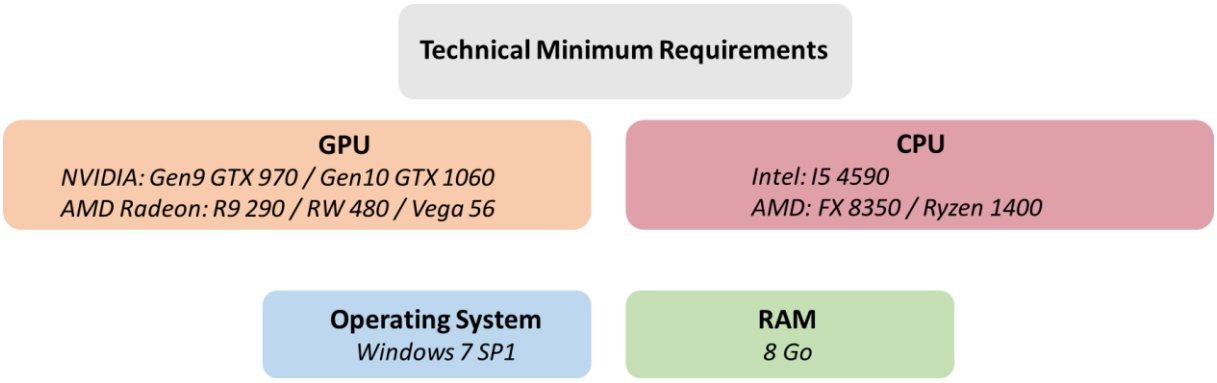
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

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)
- Posturography platforms (StaticVR)

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

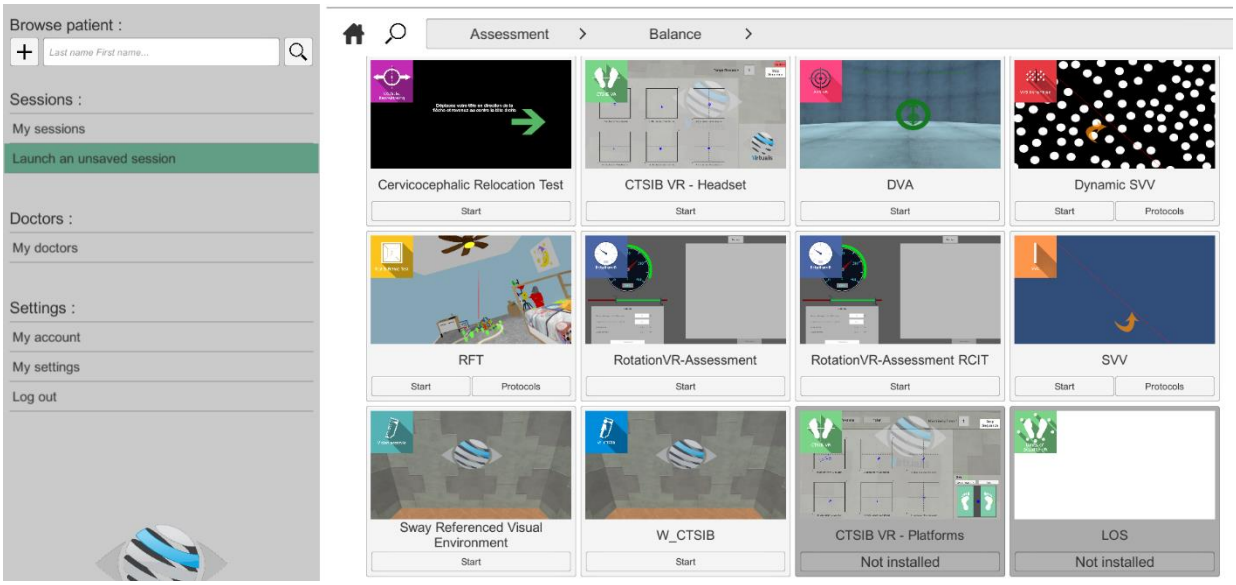


2. USE of PATIENT MANAGEMENT

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

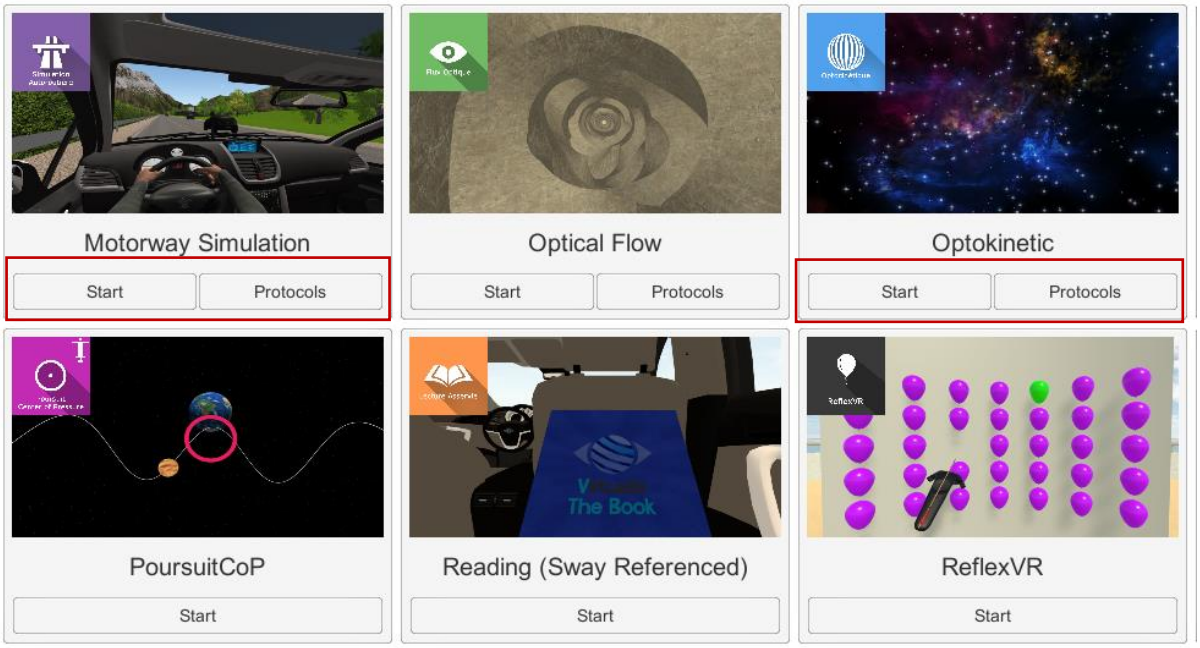
The softwares can be grouped according to criteria such as "Assessment" or "Rehabilitation" and then by pathology type: Neurology, Balance, Functional or Motion sickness.

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

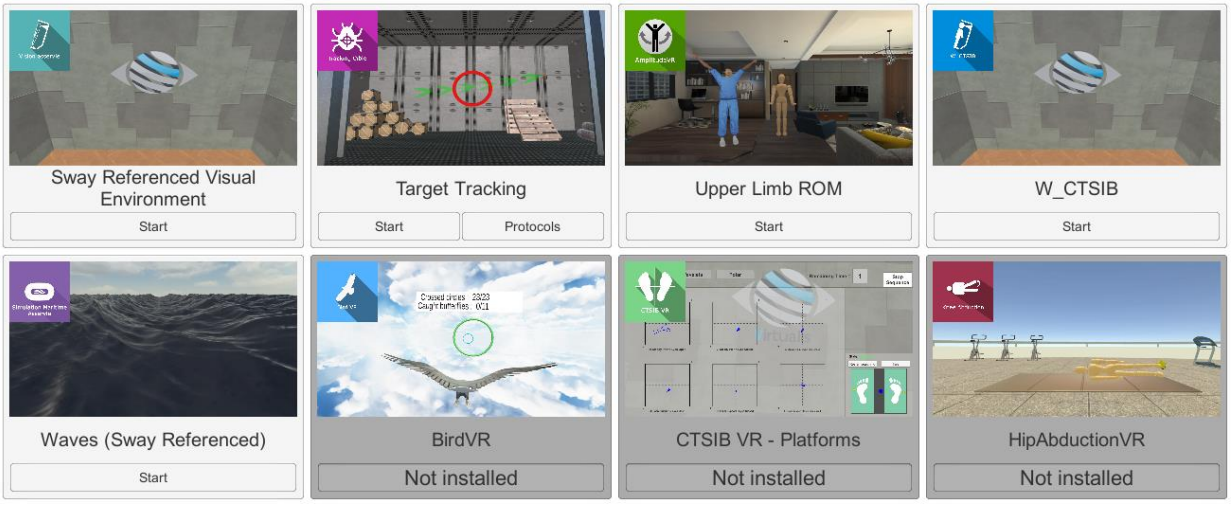


A number of softwares can be started either in ***manual mode***, by directly clicking the "Start" button, or in ***protocol mode*** by clicking the "Protocols" button.

The ***manual mode*** allows users to select settings for each environment. The ***protocol mode*** offers several sessions with different difficulty levels to test and gradually accustom patients to the VR environment.

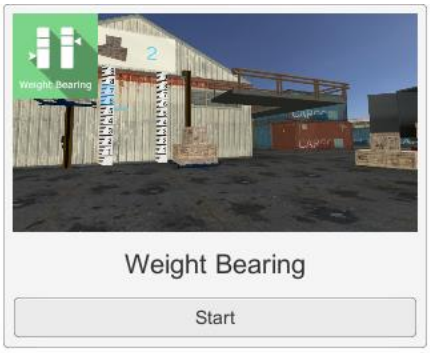


Softwares which are not included in your subscription package are grayed out. If you want to use them, please contact our sales department.



3. Weight Bearing

3.1. Start interface

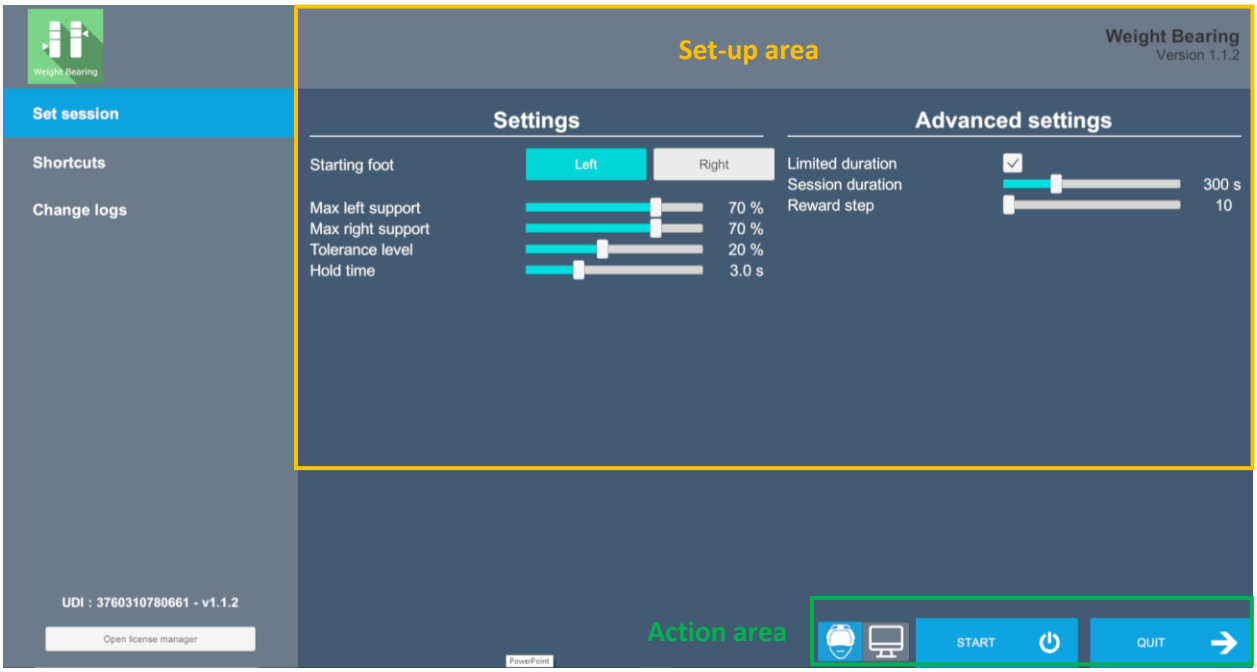


When launching the software in ***manual mode*** (Start button), it opens a launch interface consisting of a set up area and an action area (“start” and “quit” buttons).

The general Patient Management menu can be accessed from the start interface by simply clicking the "quit" button 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 has been pressed, the software is launched, taking into account the specified settings.



The selected environment launches in the headset, and you can see and track what is happening in your patients' headset using the software window.

3.2. Software field of application

Static and dynamic assessment of body weight distribution and transfer

3.3. Installing the patient

Patient standing on StaticVR force platform.

Positioning the patient on the platform:

- Center the patient's feet on the force platform.
- The medial malleolus of each foot should be directly centered on the horizontal line of the force platform.

Warning: It is recommended that all tests be performed with shoes removed, in order to get a standardized input of somatosensory system signals and to compare with the standard data set.

3.4. Session settings

To carry out this exercise, the patient, standing on the StaticVR platforms, must voluntarily transfer his body weight from one leg to the other. In doing so, he moves an arrow towards the targeted pressure weight.

When the target has been reached, the patient will see a wooden box rising from the ground towards a loading rail.

The patient's goal is to maintain his pressure, according to the intensity and duration defined by the user, in order for the box to rise from the ground and move towards a loading rail located at a height.

The software's variable settings are as follows:

Display mode

Two possibilities: Headset or Screen Mode

You can choose between "headset" or "screen" mode simply by clicking the corresponding icon; the selected icon switches to blue.

Headset mode: Instructions will be communicated to the patient visually through the virtual reality headset

Screen mode: Instructions will be communicated to the patient visually on an external screen. This mode requires a second screen connected to the computer

Warning: in this mode the headset should not be used and the patient should be facing the second screen

Max left and right support

This is used to select the maximum percentage of pressure for each leg, using the cursor.

Tolerance level

This is used to determine the degree of tolerance allowed with regard to the maximum pressure selected for each leg

Hold time

Time during which the patient must maintain the arrow in the right interval by transferring pressure on one of his legs

Session duration

This is used to select the duration of the exercise using the cursor, if the limited duration option has been activated

Reward step

This is used to select the number of pressures to carry out before visualizing a reward, using the cursor

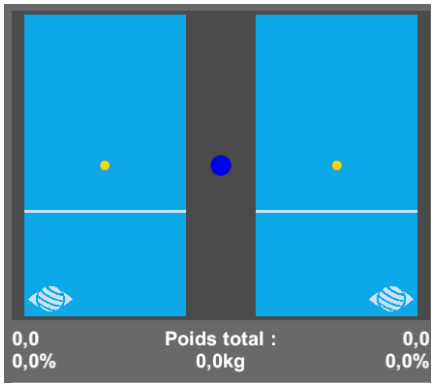
StaticVR settings

Raw data sent by the platforms

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

Blue dot: Overall 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 the data received

Decrease to reduce motion sensitivity

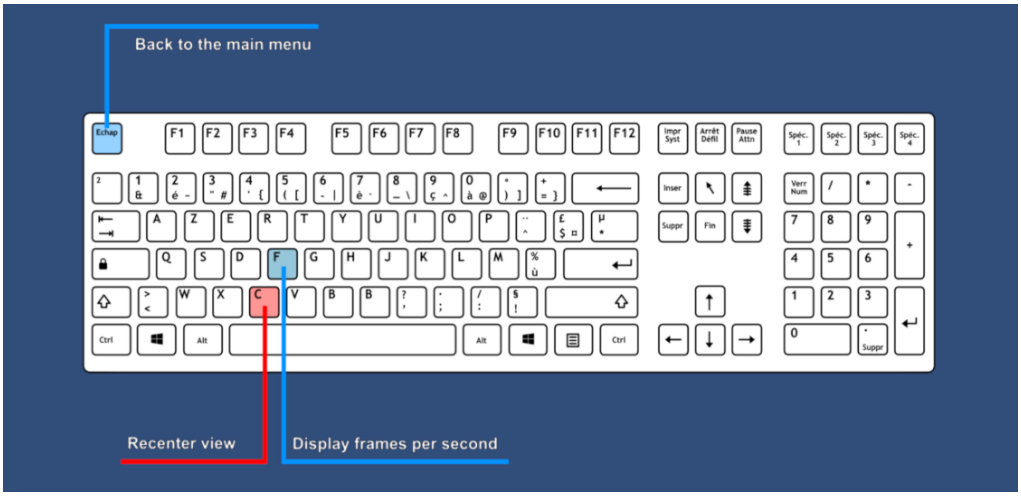
Score

At the end of the exercise, the user will get a score showing his achievement.

The parameters measured are: successful holds, hold attempts, holding score.

3.5. Shortcuts

Keyboard shortcuts are available in the software, by clicking the joystick icon in the upper right corner of the screen.



3.6. Data processing

Data retrieval and analysis is done using the Patient Management software.