REF **Unilateral Stance**

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

Unilateral Stance is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. The **Unilateral Stance** software is used to assess and compare balance between the two lower limbs in unipedal position.

INDICATIONS

Comparative measure of proprioceptive efficiency and postural control during unilateral stance

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

Table of Contents

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.

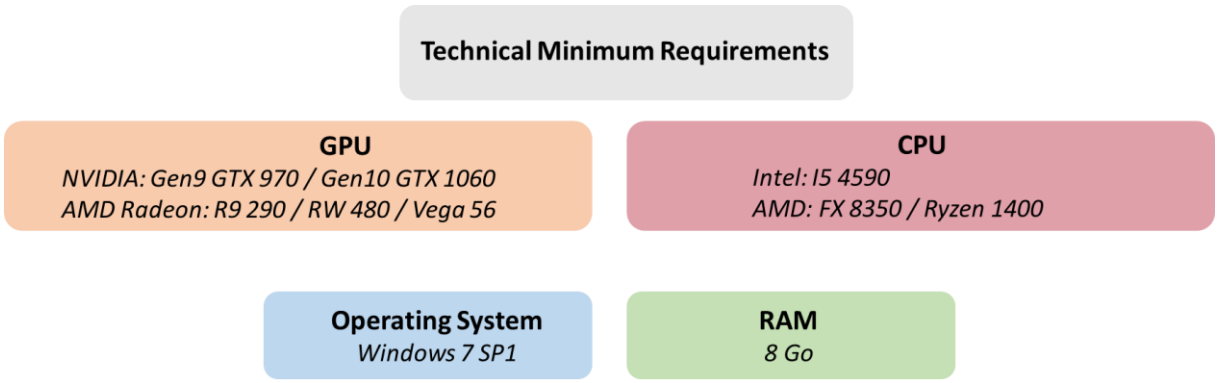
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

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 (Motion VR or Static VR)

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

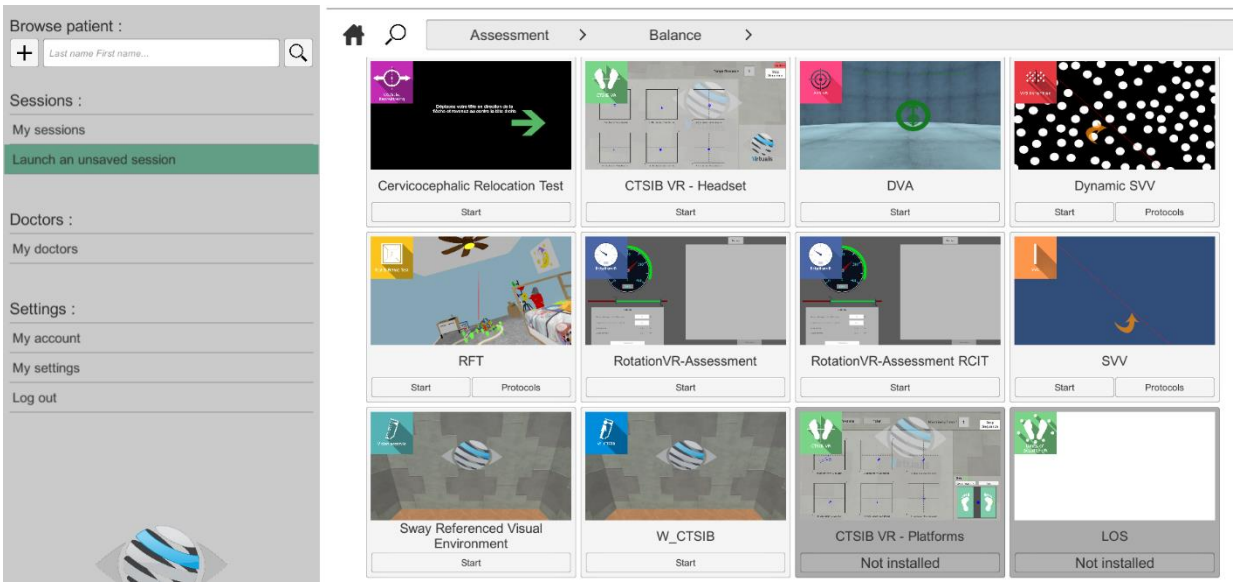


2. USE of PATIENT MANAGEMENT

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.

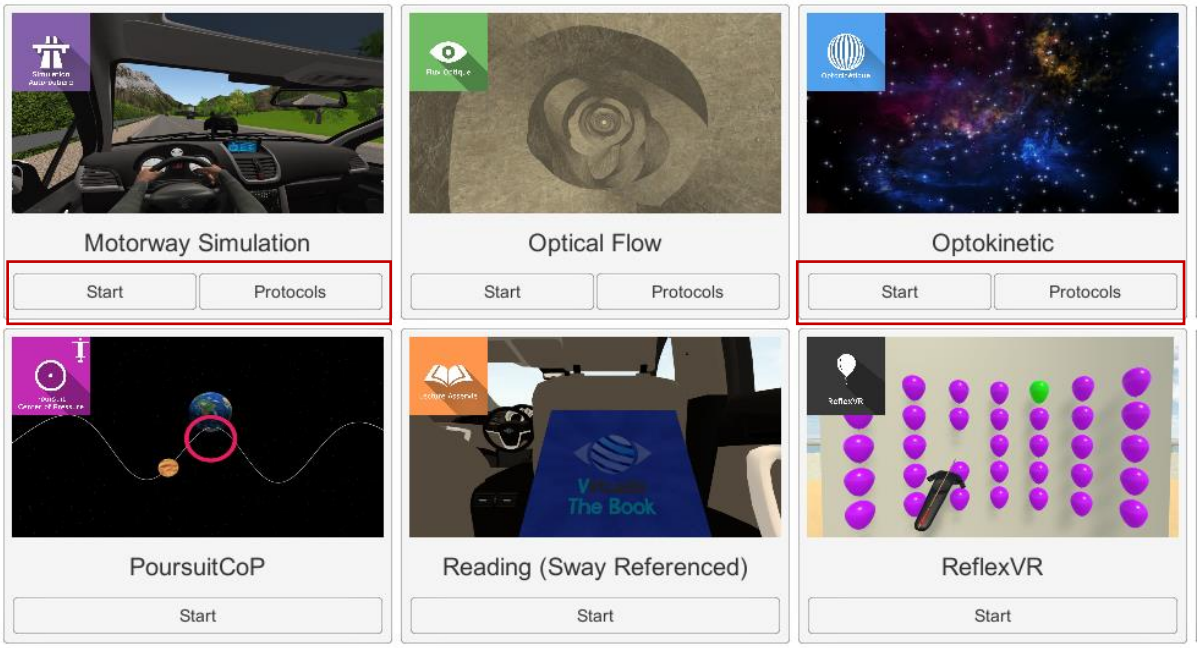
The softwares can be grouped according to criteria such as "Assessment" or "Rehabilitation" and then by pathology type: Neurology, Balance, Functional or Motion sickness.

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

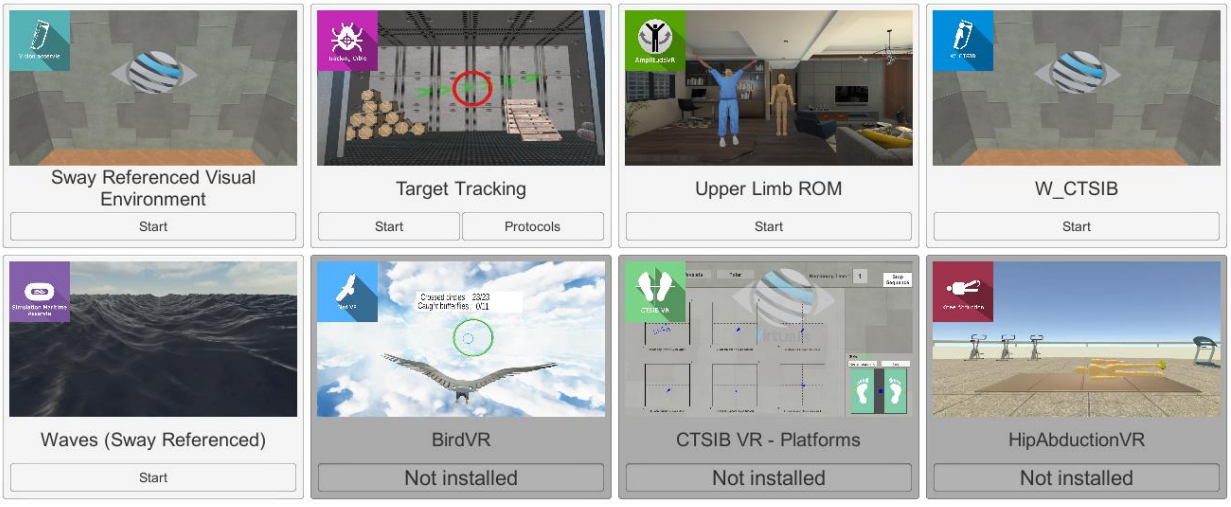


A number of softwares can be started either in ***manual mode***, by directly clicking the "Start" button, or in ***protocol mode*** by clicking the "Protocols" button.

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.

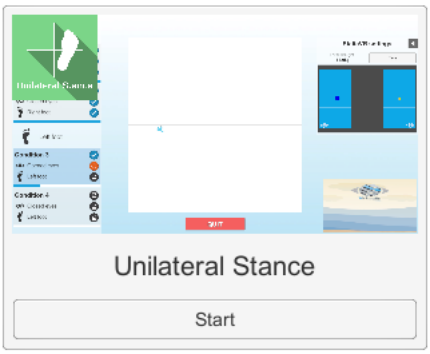


Softwares which are not included in your subscription package are grayed out. If you want to use them, please contact our sales department.



3. Unilateral Stance

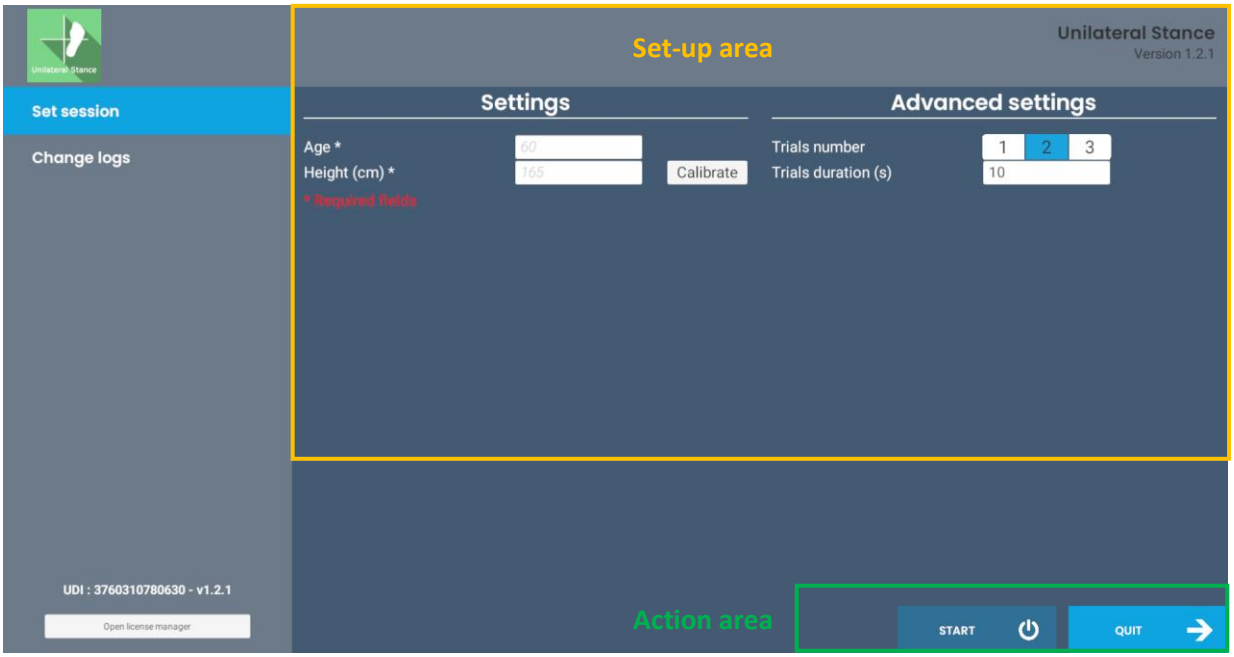
3.1. Start interface



When launching the software in ***manual mode*** (Start button), it opens a launch interface consisting of a set up area, and an action area at the bottom right.

The general Patient Management menu can be accessed 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 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 patient's headset using the software window.

3.2. Software field of application

Assessment of unipedal balance on static posturography platforms.

3.3. Installing the patient

The software requires the patient to be standing on the force platforms.

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.

The patient can choose to wear a VR mask in front of his eyes or not.

Recording of statokinesigrams during four successive unipedal stance sequences:

- Sequence 1: Standing on Right Foot / Eyes Open
- Sequence 2: Standing on Right Foot / Eyes Closed
- Sequence 3: Standing on Left Foot / Eyes Open
- Sequence 4: Standing on Left Foot / Eyes Closed

The patient is standing and places his hands on his waist. The weight-bearing foot is defined for each sequence. The other foot shall be lifted by bending the leg without it being in contact with the supporting leg.

When this unipedal position is adopted, the patient must try to maintain his balance as long as possible throughout the sequence, with eyes either open or closed, depending on the instructions given.

For each sequence, the patient can perform three attempts.

3.4. Session settings

The software's variable settings are as follows:

Patient age

Must be filled in for each patient

Patient height

Must be filled in for each patient.

Two possible modes: automatic detection through the headset by pressing the "calibrate" button or manually, by directly entering the required value in the appropriate field

Trial number

This is used to program the number of trials for each condition by selecting the required number. By default, the number of trials selected is 2 but it can be set from 1 to 3.

Trial duration

Time during which the patient must maintain his posture on one leg with his eyes open or closed.

This can be set by entering the required value in the appropriate box. The default value is 10 seconds per trial.

During the recording of each trial, an orange light comes on to indicate the trial is in progress; it turns blue once the recording has finished.

It is possible to indicate a fall during the recording of a trial by clicking the "fall" button on the software interface.

At the end of each trial, a window opens, giving the opportunity to indicate a fall and to move on to the next trial by clicking the corresponding buttons.

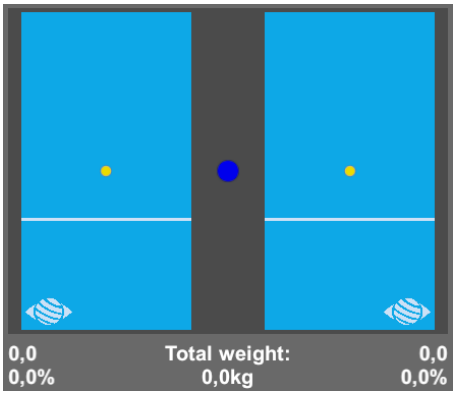
StaticVR settings

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, results are shown in various forms: statokinesigrams and sensory analysis (variation between left and right foot and eyes open or eyes closed).

There are other settings available, such as patient oscillation velocity, trial duration and falls.

3.5. Data processing

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