



REF **LOS**

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

LOS (Limits of Stability) is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. The **LOS** software uses the Static VR or MotionVR platforms to measure and quantify the movement of the patient's center of pressure (CoP). During this test, the patient voluntarily moves it in 8 directions. He must move his CoP as quickly as possible toward the designated target until the maximum position in which he can hold his balance, and maintain that position until instructed to return to the center.

INDICATIONS

Assessment of balance performance on static posturography platforms in all pathologies requiring assessment of the patient's balance.

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 (Static VR or MotionVR)

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



Technical Minimum Requirements

GPU

NVIDIA: Gen9 GTX 970 / Gen10 GTX 1060
AMD Radeon: R9 290 / RW 480 / Vega 56

CPU

Intel: I5 4590
AMD: FX 8350 / Ryzen 1400

Operating System

Windows 7 SP1

RAM

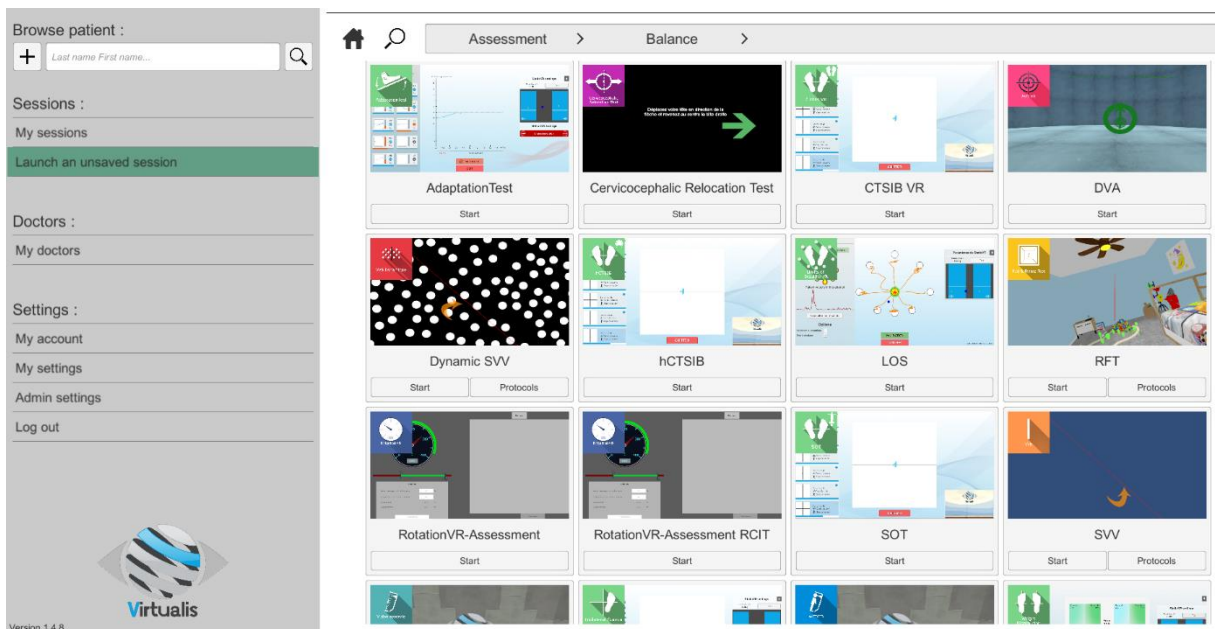
8 Go

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.

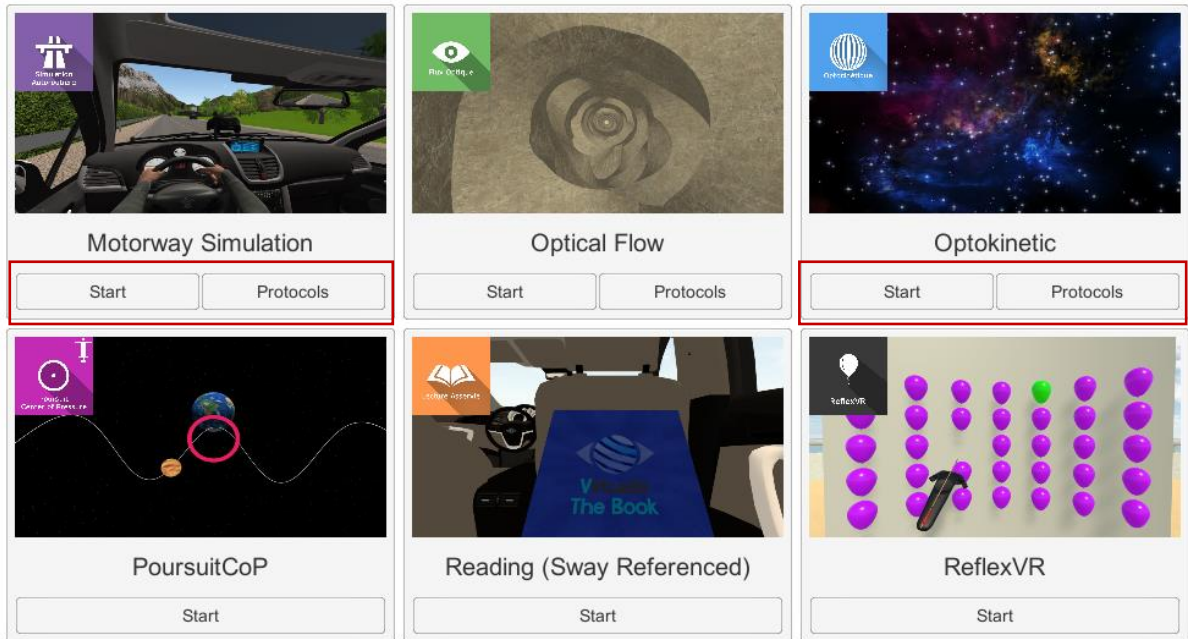
You can start or switch from one software to another from the home page by clicking the corresponding "Start" or "Protocols" button.



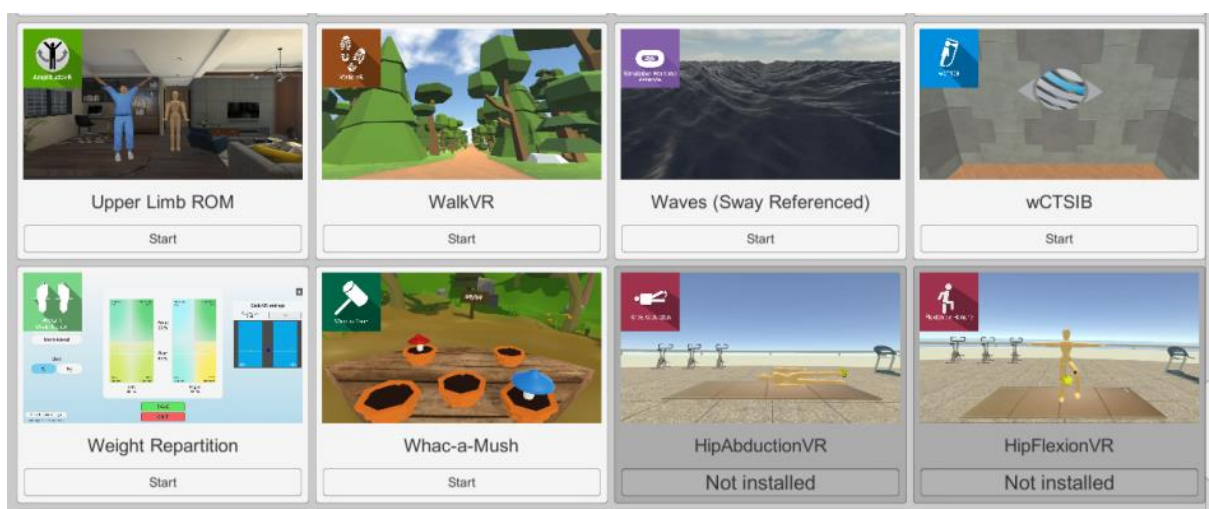


A number of softwares can be started either in **manual mode**, by directly clicking the "Start" button, or in **protocol mode** by clicking the "Protocols" button.

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.



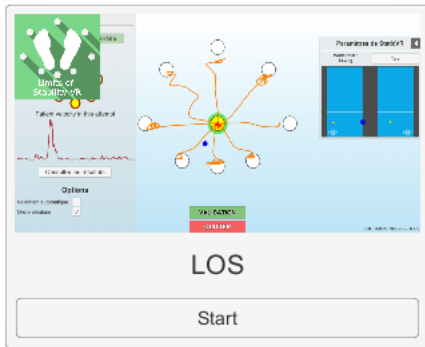
Softwares which are not included in your subscription package are grayed out. If you want to use them, please contact our sales department.





3. LOS

3.1. Start interface

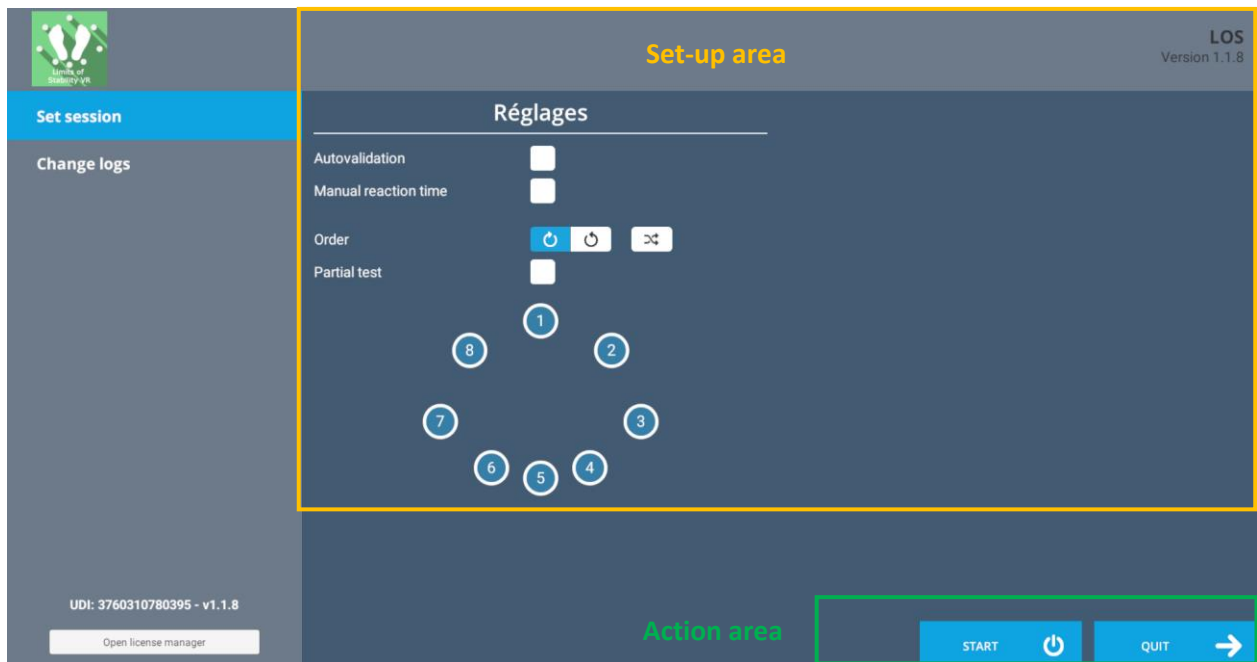


When launching the software in **manual mode** (Start button), it opens a launch interface consisting of a set up area and an action area (“start” and “quit” buttons).

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 patient’s headset using the software window.



3.2. Software field of application

Software used to measure a person's limits of stability by giving an angle measurement of the tilt cone.

3.3. Installing the patient

Patient standing on Static VR 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.

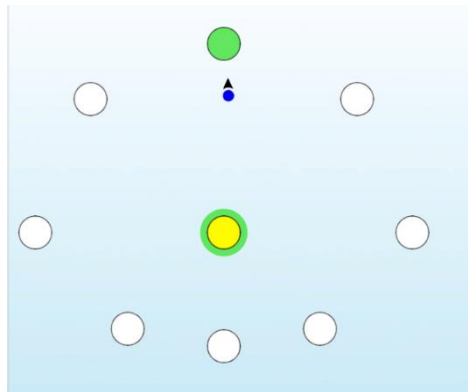
3.4. Session settings

To perform this test, the patient, standing on the platform, must move his center of pressure by leaning successively towards a target, in the eight directions (front, front-right, right, back-right, back, back-left, left, front-left) in a clockwise, anticlockwise or random way.

The direction to be followed is indicated by an arrow. The patient must intentionally shift his center of gravity, i.e. tilt his body in a given direction without losing balance, walking, or seeking help. Once the target has been reached, the position will have to be maintained until instructed to return to the center.

Between each movement, the patient must return to the center.

If the "partial test" option has been activated, the healthcare professional can manually select the targets to be worked on and the direction in which the tests are carried out.



By drawing the movements of the center of pressure, you will be able to calculate the patient's stability limits in all 8 directions.

The software's variable settings are as follows:

Autovalidation

Activating this setting is used to validate each test automatically

Manual reaction time

Activating this setting is used to manually select the reaction time recorded when calculating the assessment (if the system is not able to automatically detect the reaction time).

Order

This is used to select the direction in which the tests are carried out: clockwise, anticlockwise or random, by simply clicking the corresponding icon

The healthcare professional can restart each test ("restart" button) before moving on to the next direction.

Partial test

This is used to manually select the directions that will be tested and the direction in which the targets will be aimed during the successive sequences.

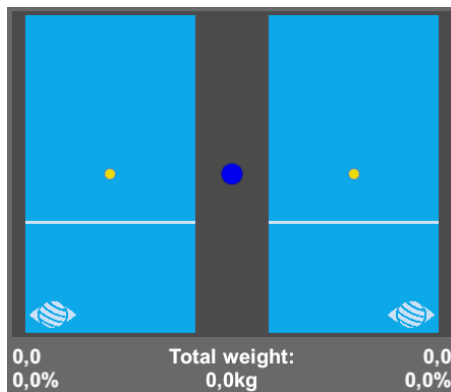
StaticVR settings

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 different forms: table, detailed and composite graph, statokinesigrams and ellipses compared to the standard.

Parameters measured are: reaction time, average velocity, directional control, initial excursion and maximum excursion.

3.5. Data processing

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