



REF SOT

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

SOT (Sensory Organization Test) is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. The **SOT** software uses dynamic force platform technology to isolate and quantify the sensory system's contribution to balance. Results are generated as individual balance score, composite score, sensory analysis results, strategy selection by sensory condition, center of gravity at the beginning of each test, wavelets and polar views.

INDICATIONS

Sensory Organization Test on dynamic force platforms

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..... 4
 - 1.1. Advice for use..... 4
 - 1.2. Hardware and minimum configuration requirements..... 4
- 2. USE of PATIENT MANAGEMENT 5
- 3. SOT..... 7
 - 3.1. Start interface..... 7
 - 3.2. Software field of application 8
 - 3.3. Installing the patient 8
 - 3.4. Session settings 9
 - 3.5. Data processing 12



1. GENERAL

1.1. Advice for use

Virtual Reality immersion is a powerful stimulation tool. This type of rehabilitation should be approached progressively and should consider the subject's tolerance, particularly during stimuli that may cause sensory conflicts or with patients with visual or balance disorders.

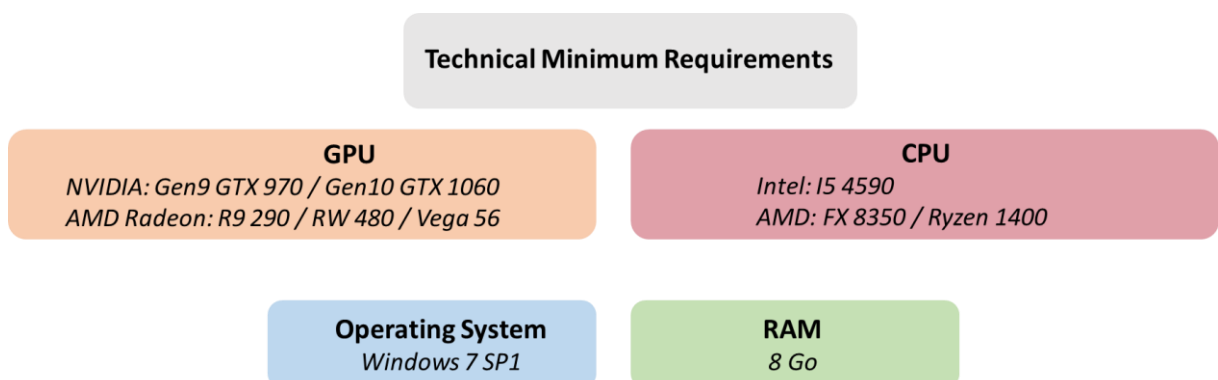
Virtualis declines any liability for any disorders suffered by patients during or after use of its software following inadequate stimulation with regards to the patient's state or aptitudes, or following inadequate patient securing means set up by the practitioner.

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)
- Dynamic posturography platform (Motion VR)

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

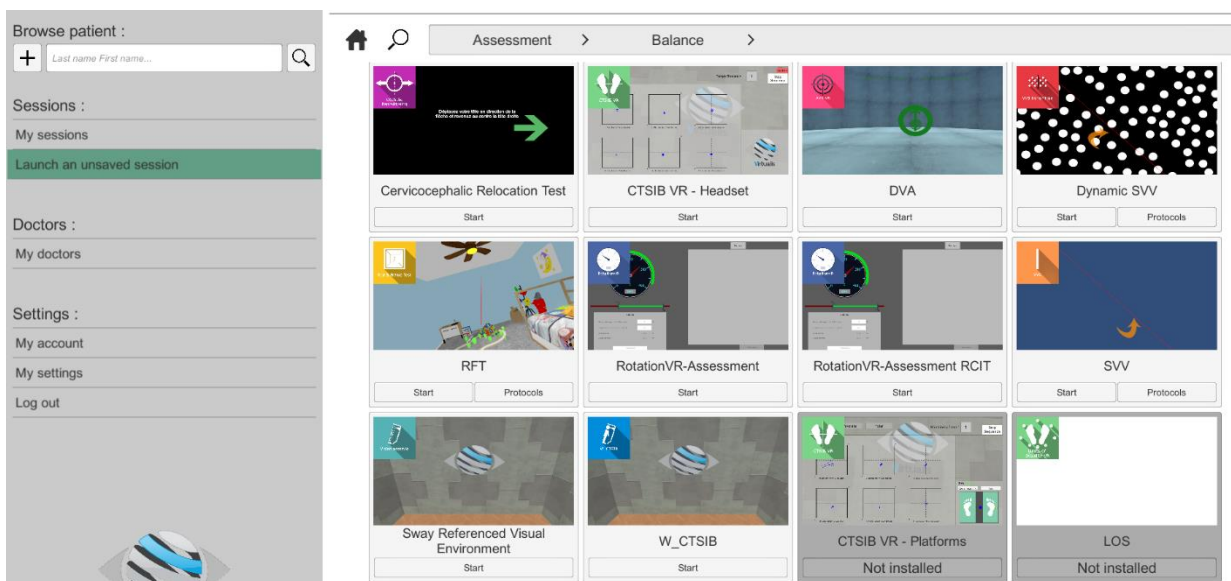


2. USE of PATIENT MANAGEMENT

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.

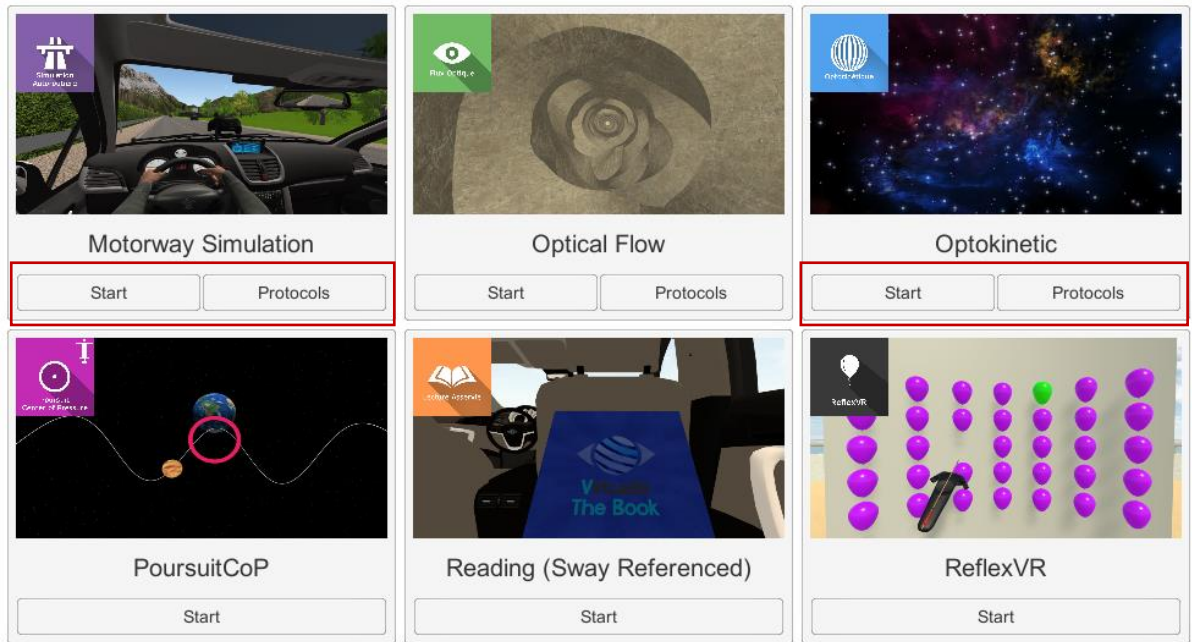
The softwares can be grouped according to criteria such as "Assessment" or "Rehabilitation" and then by pathology type: Neurology, Balance, Functional or Motion sickness.

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

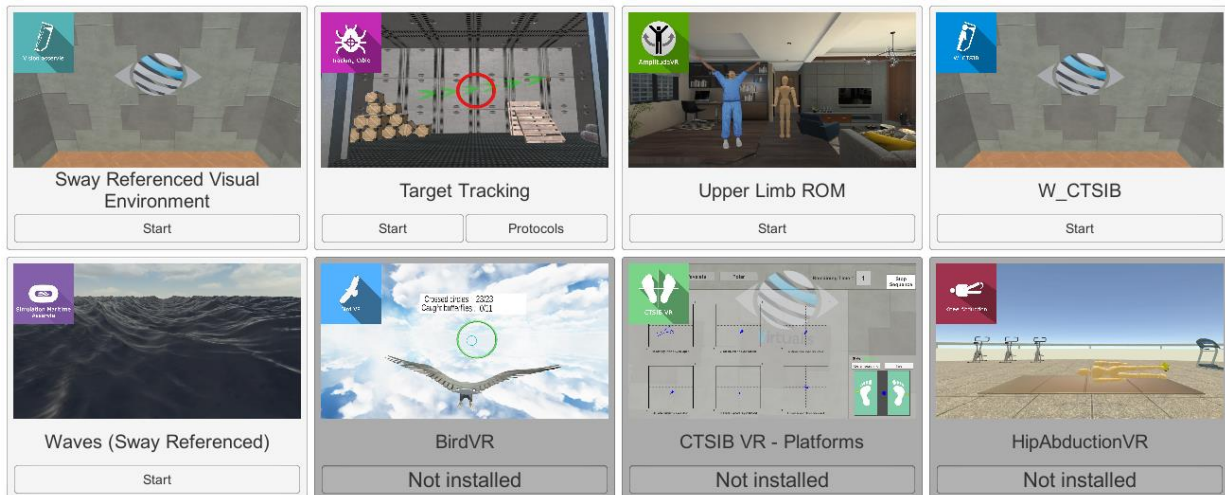


A number of softwares can be started either in **manual mode**, by directly clicking the "Start" button, or in **protocol mode** by clicking the "Protocols" button.

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.



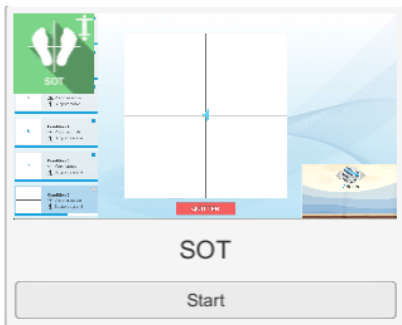
Softwares which are not included in your subscription package are grayed out. If you want to use them, please contact our sales department.





3. SOT

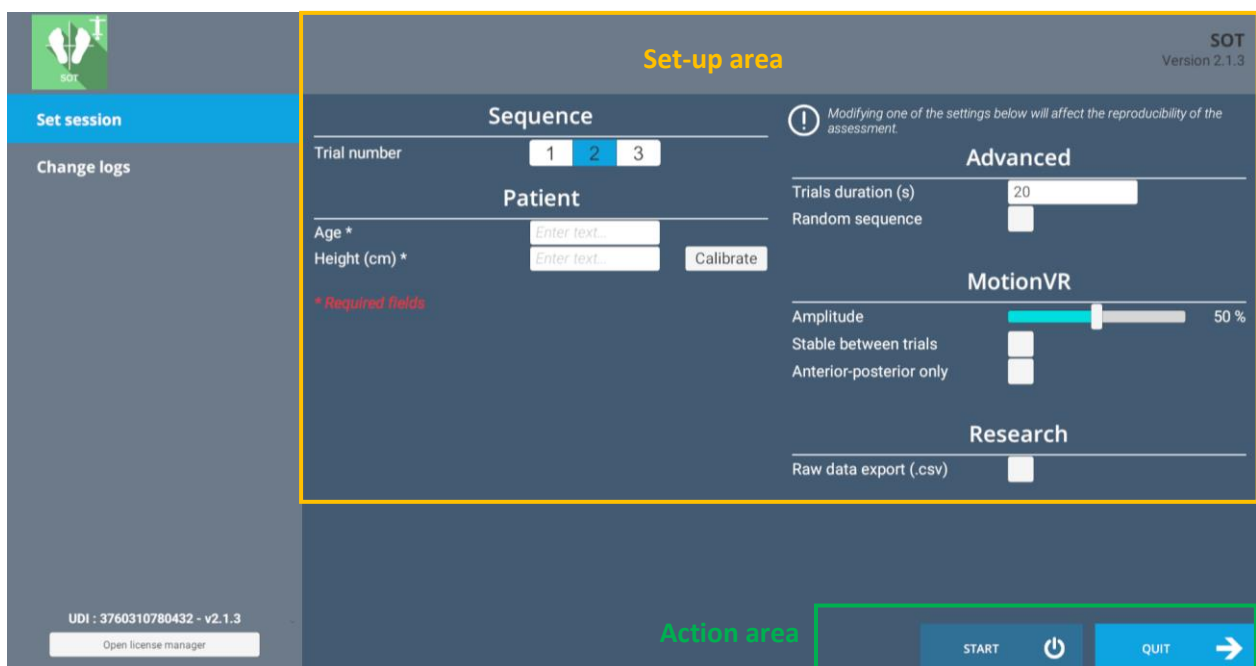
3.1. Start interface



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 balance on a dynamic posturography platform.

Carrying out the sensory organization test (SOT) with VR tools.

3.3. Installing the patient

During the test, the patient is asked to stand still during 6 recording and data analysis sequences while being subjected to various sensory disturbances.

The test starts with the patient standing on a stable floor. The first sequences will be performed with the patient standing on a stable floor, then the next 3 on an unstable floor (instability is created by random platform movements)

Patient standing with feet on the force platform (immobile) for conditions 1 to 3.

Patient standing with feet on force platform in an unstable environment for conditions 4-6.

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. The outer edge of the foot should be aligned with the antero-posterior lines.



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.

VR headset placed in front of the eyes.

Characteristics of the sensory stimuli during the 6 sequences:

- Sequence 1: Stable Ground / Eyes Open
- Sequence 2: Stable Ground / Eyes Closed
- Sequence 3: Stable Ground / Sway-referenced Vision
- Sequence 4: Unstable ground / Eyes open
- Sequence 5: Unstable ground / Eyes closed
- Sequence 6: Unstable Ground / Sway-referenced Vision



3.4. Session settings

The software's variable settings are as follows:

Sequence

A sequence coincides with an analysis phase during which the patient will be asked to stand still with the same sensory stimulation conditions.

There are 6 sequences in the SOT test.

Trial number

This is used to program the number of trials for each sequence 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

Trial duration can be set to a fixed time by entering the required value. The default value is 20 seconds per trial.

Random sequence

This setting, which can be activated by checking the appropriate box, is used to make sequences follow one another randomly.

Note: the first two conditions in random order will be *Sequence 1* followed by *Sequence 2*.

MotionVR amplitude

The value of the platform movement amplitude is set using the cursor; by default, the amplitude value is 50%.

Stable between tests

The practitioner must manually activate MotionVR from sequence 4 onwards to allow the patient to stabilize.

If this option is activated, the platform stops after each test in horizontal position.

Note: The practitioner must manually activate MotionVR at the beginning of each test on unstable ground.

Antero-posterior only

This setting can be activated by checking the appropriate box, resulting in the platform moving exclusively along the antero-posterior axis.

Data export (.csv)

This setting can be activated by checking the appropriate box, creating a .csv file on the desktop at the end of the report, which includes raw data from the headset, the StaticVR, the MotionVR and a tracker

Patient age


This information must be filled in for each patient. This value is used to compare the test results with a base of patients of the same age group.



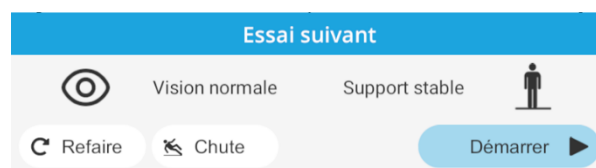
Patient height

This information must be filled in for each patient and is required in order to analyze results.

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

During the recording of each test, an orange light comes on and flashes; it turns blue once the recording has finished. The test can be interrupted if the patient has fallen, using the  **Fall** button at the bottom of the screen.

At the end of each test, a window of this type opens (here for condition 1)



giving the healthcare professional the opportunity to indicate a fall if applicable or to restart the test before moving on to the next test.

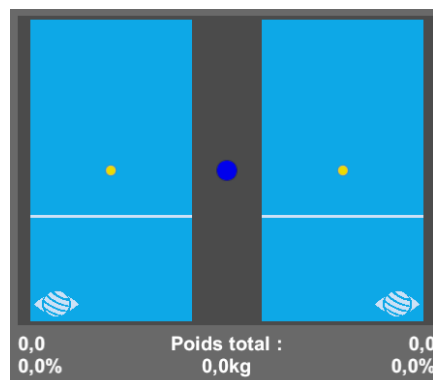
StaticVR settings

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

MotionVR settings



If you press the emergency stop button, the platform will freeze in its current position.



A window opens and the following message appears



**Warning:**

Stopping the software or changing the window may cause the platform to reset to the default position and cause movement that could be dangerous for the patient. It is therefore advisable not to touch the computer again until you have secured the patient when the emergency stop is triggered.

Score

At the end of the exercise, results are shown in various forms: sensory analysis (somesthesia, vision, vestibular, visual dependence) compared to the standard, statokinesigrams, movement amplitude, wavelets, polars, hip-ankle strategy, average center of gravity.

3.5. Data processing

Results are analyzed at the end of the test and are displayed at the end of data processing. Analysis data can be retrieved using the Patient Management software.