REF **hCTSIB**

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

hCTSIB (**h**eadset - **C**linical **T**est of **S**ensory **I**nteraction on **B**alance) is an immersive 3D simulation software, based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. The **hCTSIB** software isolates and quantifies the efficiency of visual, vestibular and somatosensory systems in contributing to maintaining the subject's balance. Results include individualized scores per system, a composite score, statokinesiograms, and a visual dependency score.

INDICATIONS

Assessment of sensory interaction in balancing reactions.

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 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.

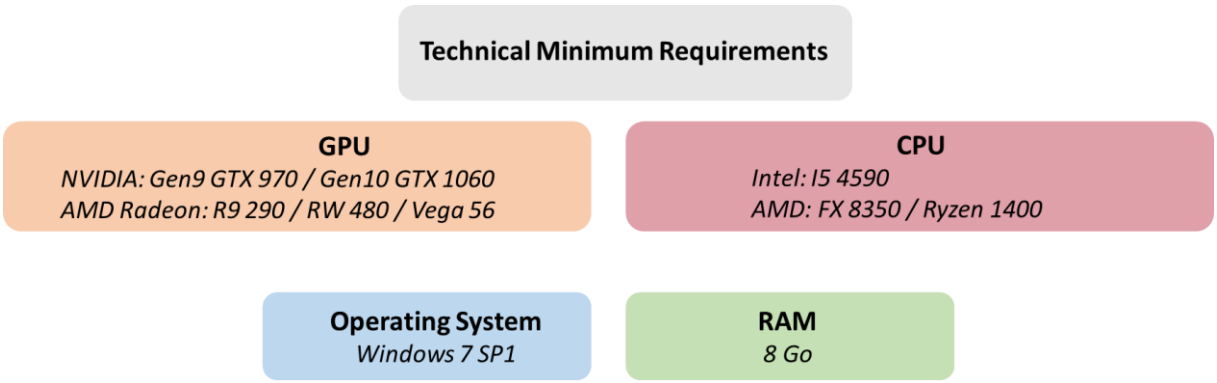
Virtualis declines any liability for any disorders suffered by patients during or after use of its software following inadequate stimulation with regards to the patient's state or aptitudes, or following inadequate patient securing means set up by the practitioner.

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)

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

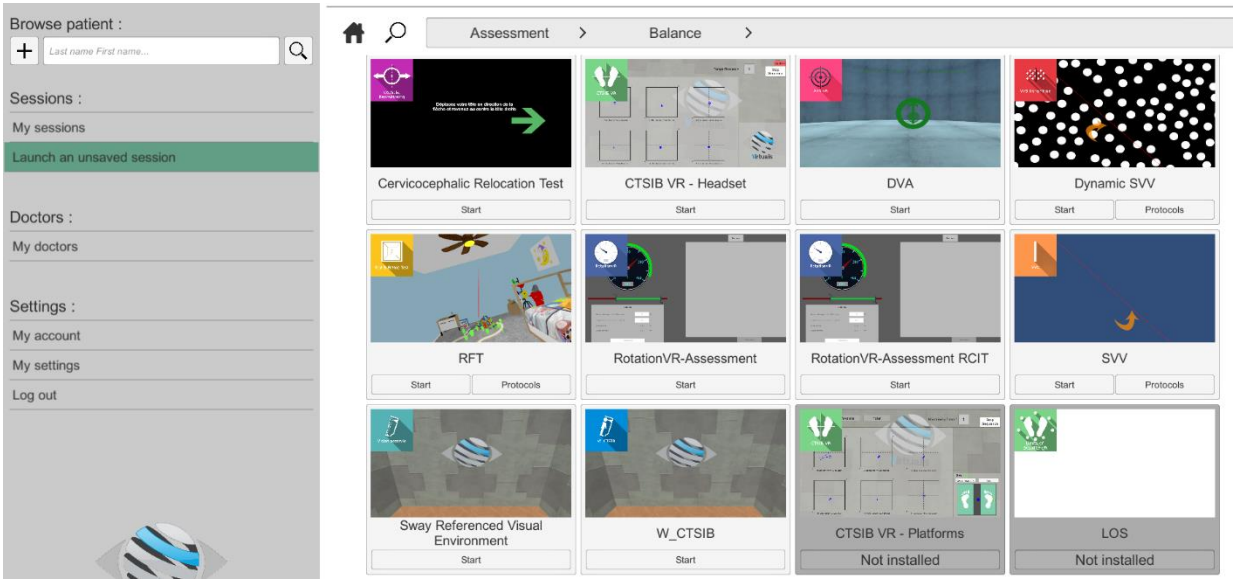


2. USE of PATIENT MANAGEMENT

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.

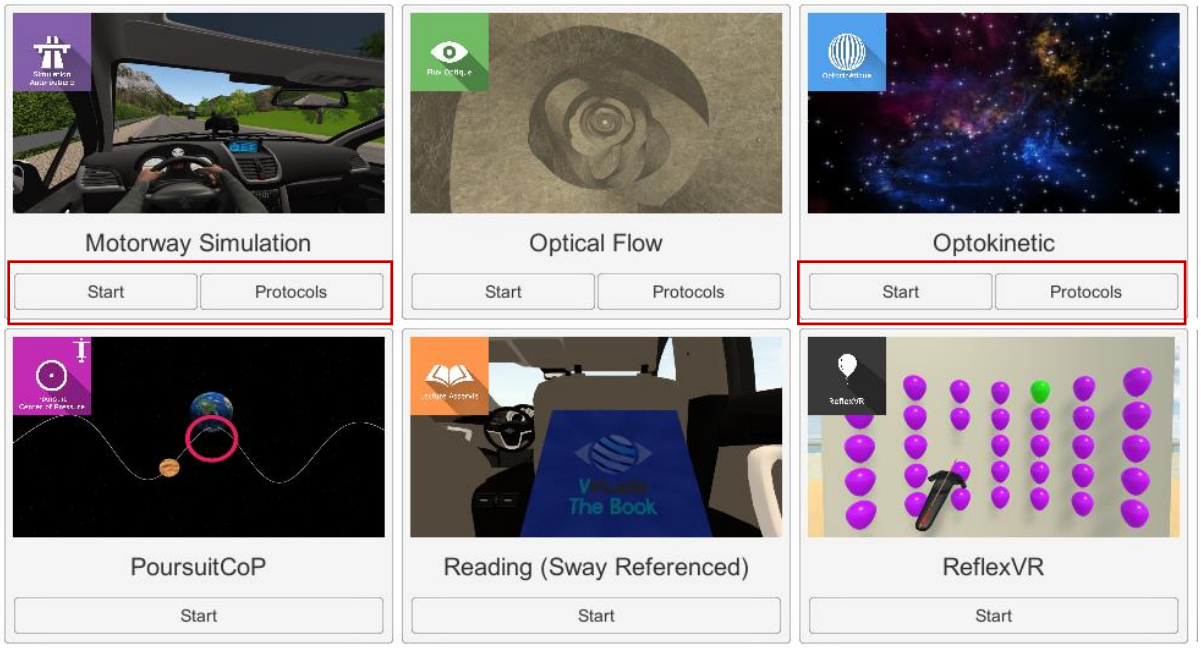
The softwares can be grouped according to criteria such as "Assessment" or "Rehabilitation" and then by pathology type: Neurology, Balance, Functional or Motion sickness.

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

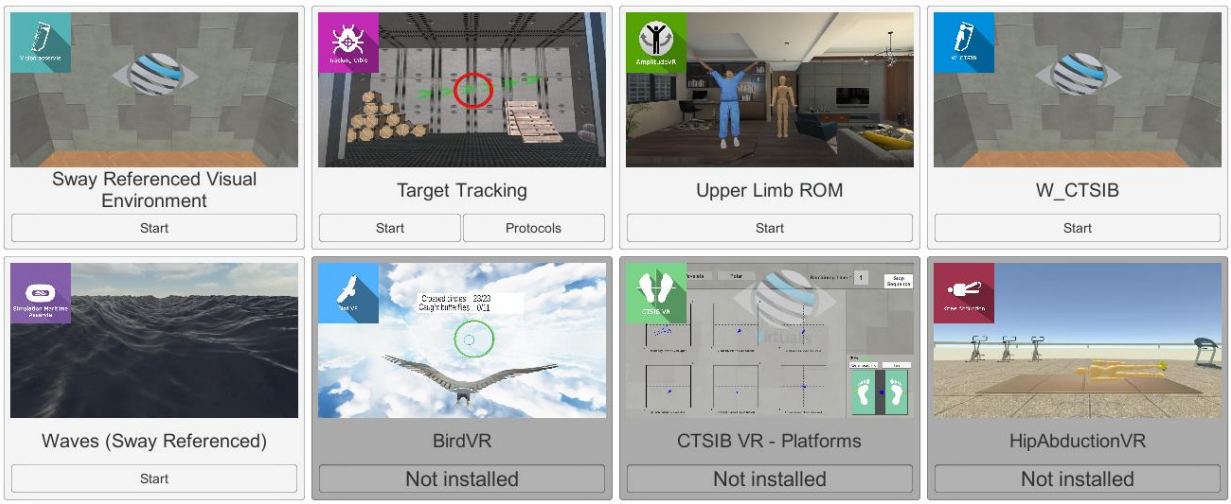


A number of softwares can be started either in ***manual mode***, by directly clicking the "Start" button, or in ***protocol mode*** by clicking the "Protocols" button.

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.

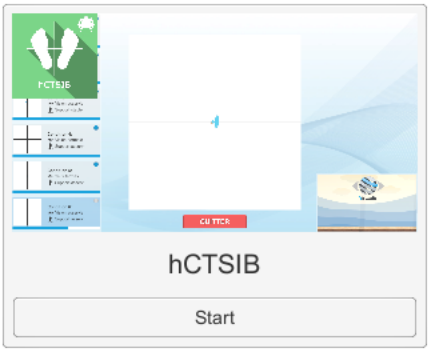


Softwares which are not included in your subscription package are grayed out. If you want to use them, please contact our sales department.



3. hCTSIB

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

VR adaptation of the CTSIB in which the computational system takes into account the head oscillations perceived by the headset rather than the variations of the center of pressure (CoP).

During the assessment, the system interprets the balance adaptation according to the information perceived by the eyes and the somesthesic and vestibular systems

A block of shape memory foam (type Airex) is required for conditions 4, 5 and 6 (see section 3.3.).

This is used to carry out a CTSIB in ideal conditions.

3.3. Installing the patient

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

The trial 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. It is recommended to use an Airex type foam block.

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 h-CTSIB 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 sequences in random order will be *Sequence 1* followed by *Sequence 2*.

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

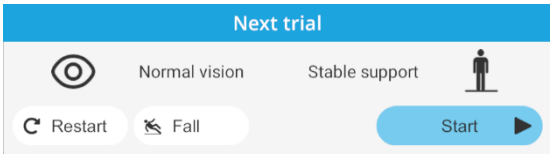
This information must be filled in for each patient and is required in order to analyze results.

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 trial, an orange light comes on and flashes; it turns blue once the recording has finished. The trial can be interrupted if the patient has fallen, using the button 

at the bottom of the screen.

At the end of each trial, 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 trial before moving on to the next trial.

Score

At the end of the exercise, results are shown in different forms: sensory analysis (somesthesia, vision, vestibular, visual dependence) compared to the standard, statokinesigrams, and movement amplitude.

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.