



REF **HemiNeglect**

CE Class I Medical Device

User manual

Distribution mode

Available for direct download at
<http://virtualisvr.com/espace-client/>
Use under licence

 **VIRTUALIS**

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DESCRIPTION

HemiNeglect software is an immersive 3D simulation based on virtual reality technology, which allows a person to be immersed in an artificial digitally created world. **HemiNeglect** is software used to assess hemineglect in the context of adult cognitive disorders.

INDICATIONS

Assessment and quantification of hemineglect in pathologies affecting the central nervous system.

CONTRAINDICATIONS

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

FOR USE BY:

Healthcare professionals: Physiotherapists; Occupational Therapists; Neuropsychologists; Neurologists; PRM (Physical and Rehabilitation Medicine) Doctors, 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

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

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

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 make sure of patients' tolerance to this type of stimulation.

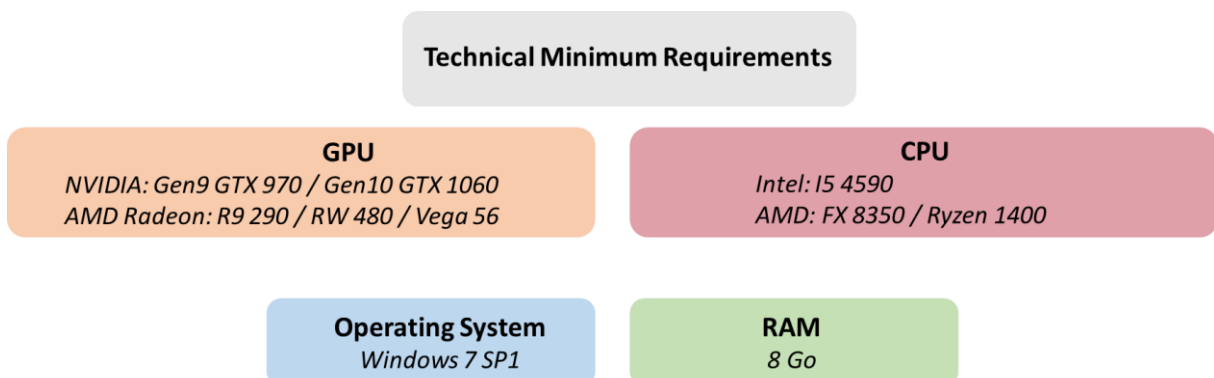
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

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)
- XBOX 360 Controllers
- USB HUB

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

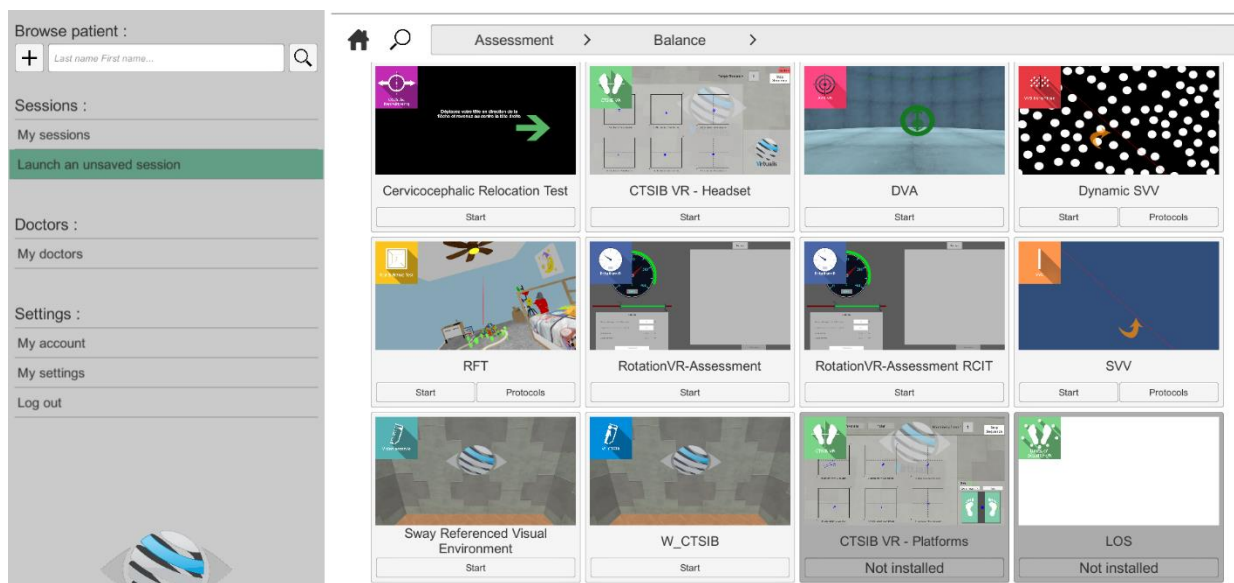


2. USE OF PATIENT MANAGEMENT

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

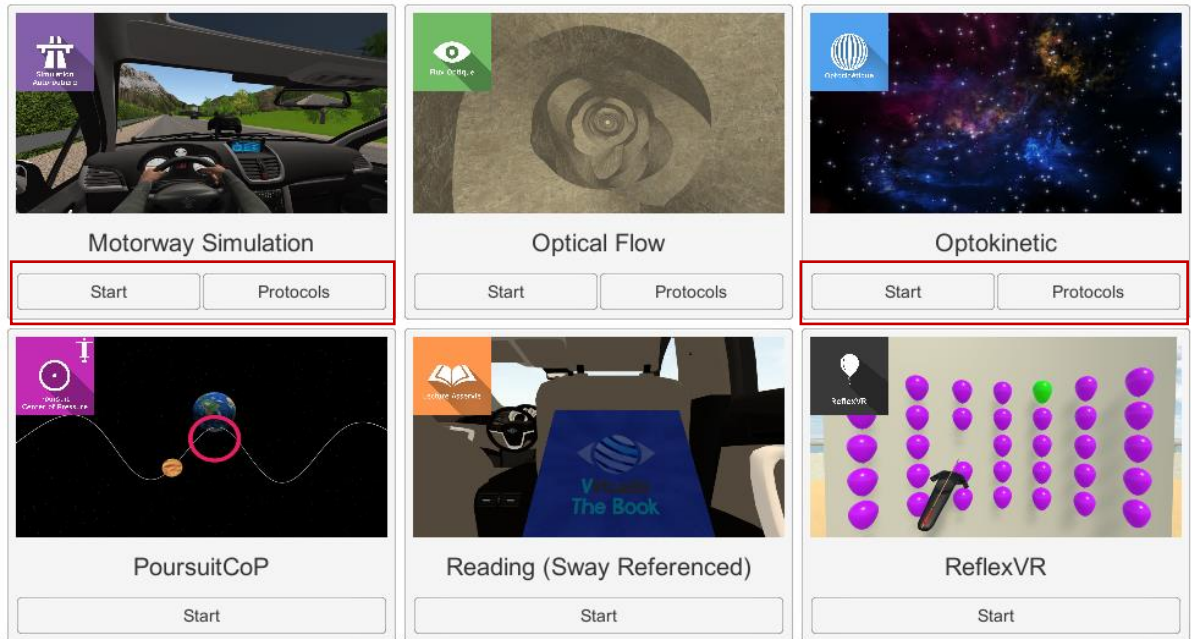
The software can be grouped according to criteria such as "Assessment" or "Re-education" and then by pathology type: Neurology, Balance, Functional or Travel sickness.

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

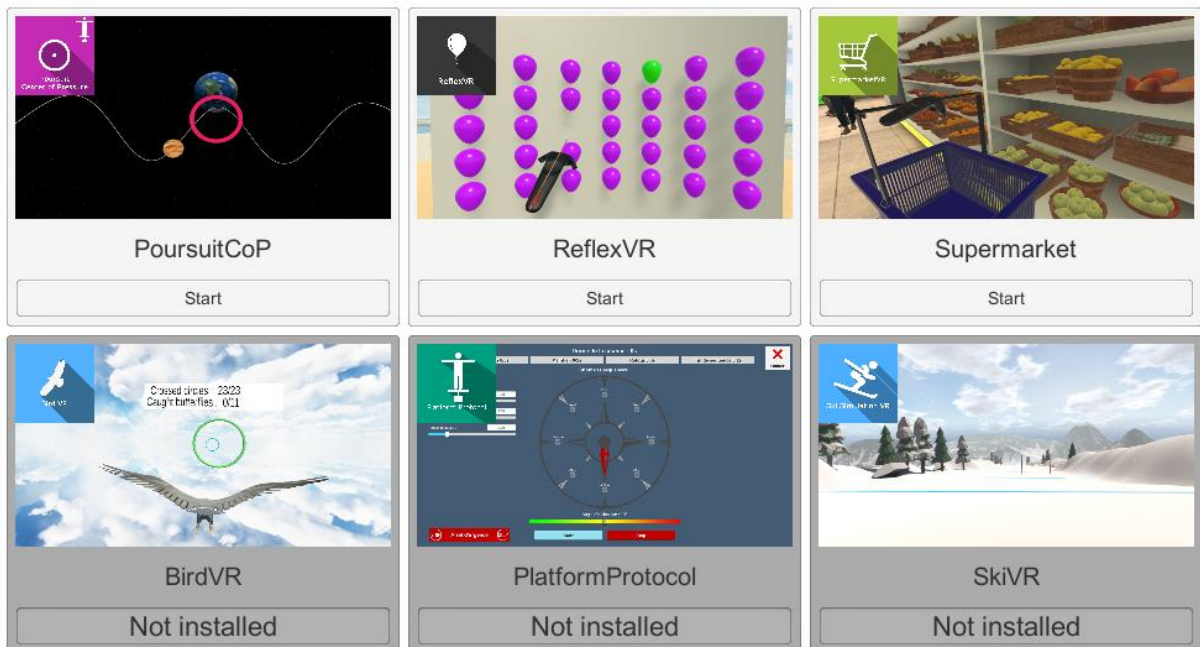


Some software can be started either in **manual mode**, by directly clicking the "Start" button, or in **protocol mode** by clicking the "protocols" button.

Manual mode allows users to choose the settings for each environment. **Protocol mode** offers several sessions with different difficulty levels to test and gradually accustom patients to the VR environment.

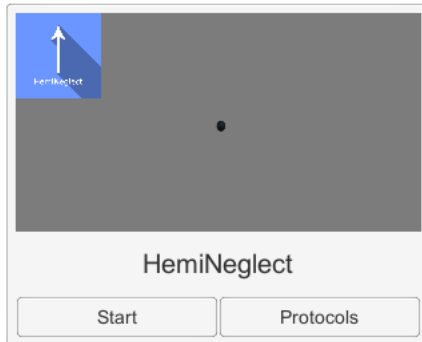


Software that is not part of your subscription package is greyed out. If you want to use it, please contact our sales department.



3. HemiNeglect

3.1. Start interface



To launch the HemiNeglect software from Patient Management you have two possibilities: **manual mode** ("Start" button) or **protocols**.

When the software is started in **manual mode**, the opening is made in a start interface consisting of a module selection menu on the left, a set up area on the right, and an action area at the bottom right.

Depending on the module selected in the left menu, the set up area shows the various possible settings/information.

It is possible to access the general Patient Management menu 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 module is launched by simply clicking the "Start" button in the action area.



Once this button is pressed, the module starts by taking into account the specified settings.

The Start/Quit buttons allow the environment to be played back or stopped entirely to adapt the experience to the patient's sensations.

When you start the HemiNeglect software from Patient Management in **protocol mode** you will arrive on a homepage from which you can find two protocols (for the left and right sides), each protocol can be used to take six measurements.



For each proposed protocol the different settings are already in place. Just validate the selected protocol to start the application.

Select a template		
Default settings	Enslavement	Yes
Protocol 6 controlled random L	Measure 1	35
Protocol 6 controlled random R	Measure 2	-20
	Measure 3	30
	Measure 4	20
	Measure 5	-35
	Measure 6	-30
	Number of measures	6
	Point size	4
	Vertical point position	0

Cancel Start

Once an environment has been selected, it launches in the headset, and you can see and track what is happening in your patients' headset from the software window.

3.2. Module field of application

This module is used to measure the Subjective Straight Ahead; one of the USN assessment and monitoring measurements.

Indications:

Hemineglect quantification using a measurement of the mean angle of deviation of a marker to be recentered by patients.

There are many different protocols in the literature

It is often recommended to take:

- at least 6 measurements (6 to 12)
- Variable initial angle, same tilts to the right and left in random order
- Alternating Sequence

3.3. Installing the patient

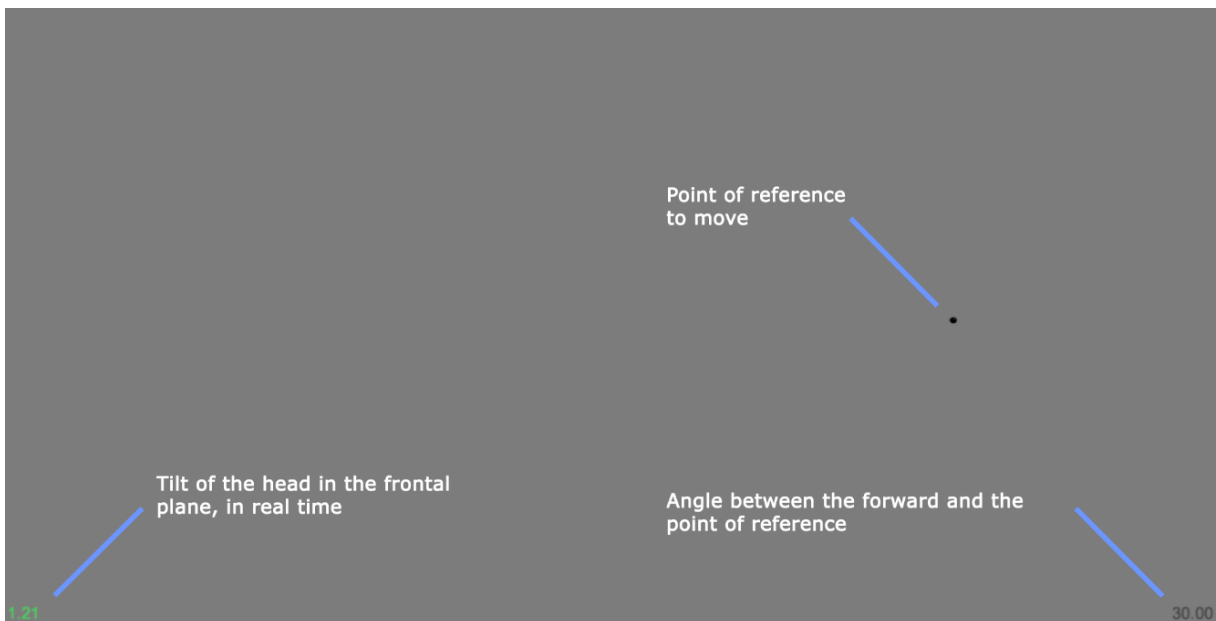
These are simple, limited numbers of tips drawn from the literature and from our personal experience

Use in a standing or sitting position, recenter at the start of the session.

It is therefore recommended to take the measurements using the following installation:

- Patient seated (preferably on an "upholstered" seat, a swivel chair is ideal)
- Feet on a footrest, not on the ground
- Joystick in hand to carry out the measurements themselves if possible. When it is not possible for patients to grip or handle the joystick, the therapist performs the recentering with patient guidance.

3.4. Session settings



The variable settings for this module are as follows:

Enslavement

ON: The image is coupled to the head movements. The point is as if "fixed" in front of patients and tilts with their own head tilts. The measured values are relative to the earth's vertical, without taking into account the tilt of the head. (Mode to be preferred in this assessment to avoid patient compensation)

OFF: The point is in "real conditions", as if it were floating in the room. It is therefore unaffected by the subjects' head movements.

Point size

The point diameter is adjustable by using the cursor with the mouse or keyboard. More accuracy is required if the point size is small.

Vertical point position

There are two choices: actual and perceived

Sequence

Number of measurements recorded during the session (maximum 24).

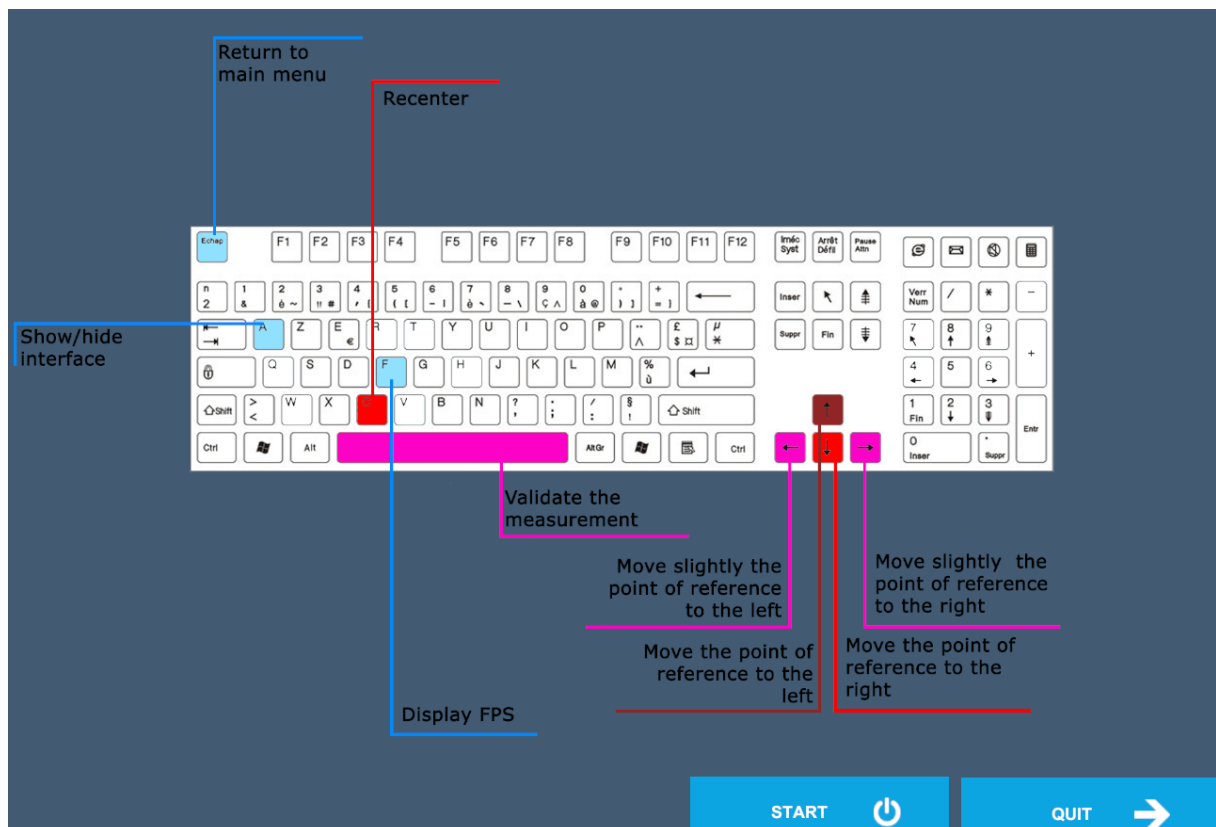
In manual mode the point starting angles must be entered by hand.

The selected values can be saved or the last values loaded by clicking the corresponding buttons.

3.5. Shortcuts

Keyboard shortcuts are available:

- on the "Shortcuts" tab available at the start interface level





3.6. Data processing

Data retrieval and analysis uses the Patient Management software.