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

BELLS TEST VR is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. **Bells Test VR** is an assessment software for hemineglect.

INDICATIONS

Assessment or rehabilitation in the context of hemineglect.

CONTRAINDICATIONS

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

FOR USE BY

Healthcare professionals: Physiotherapists; Ergotherapists; Neuropsychologists; Neurologists; PM&R physicians (Physical Medicine & 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 softwares, 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 rehabilitation must be undertaken progressively, especially in Virtual Reality where the stimulation is much more "powerful" than with traditional optokinetic stimulators.

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)

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.

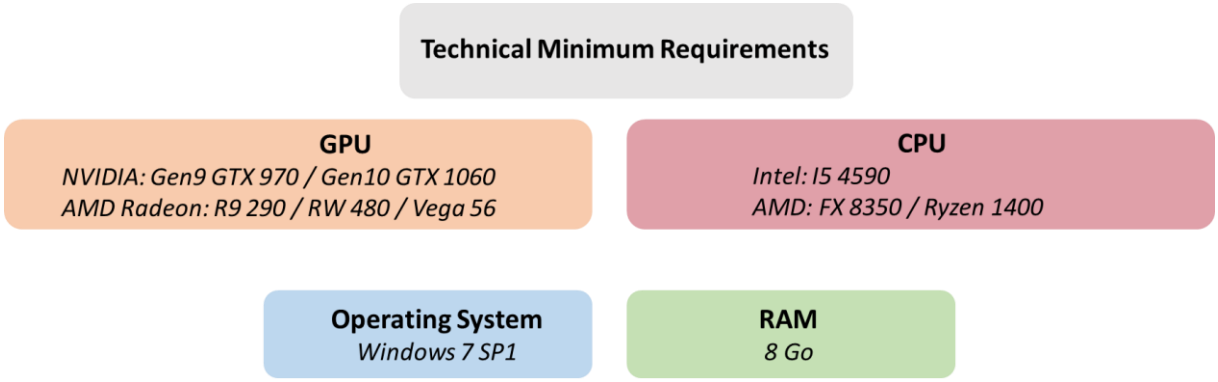
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

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)
- HTC VIVE Controller
- XBOX 360 Joysticks
- USB HUB

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

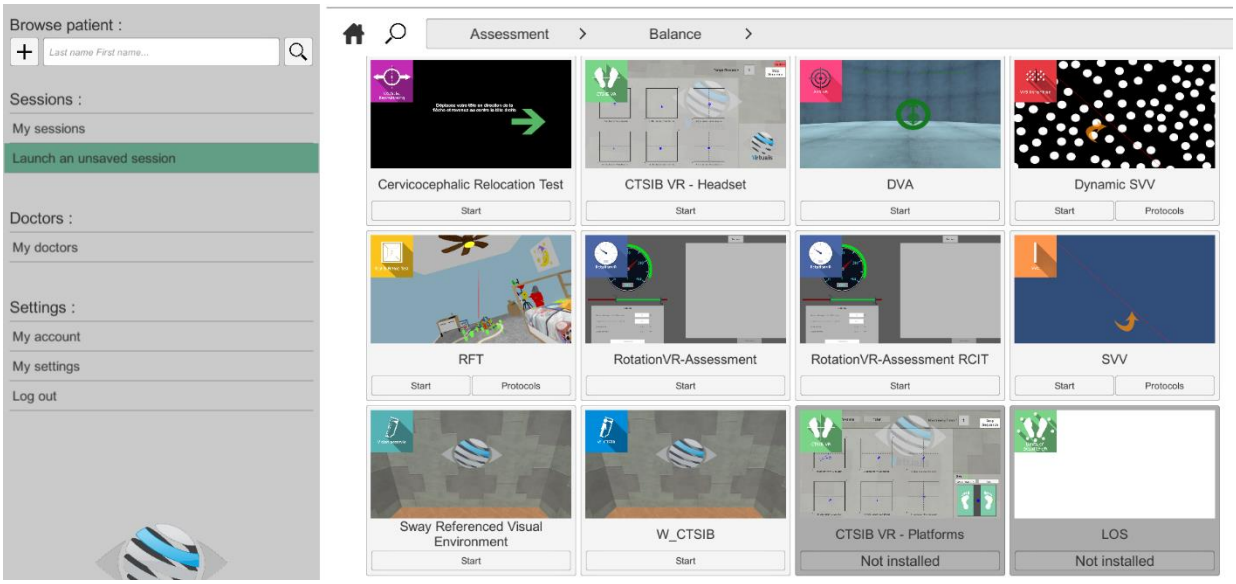


2. USE of PATIENT MANAGEMENT

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.

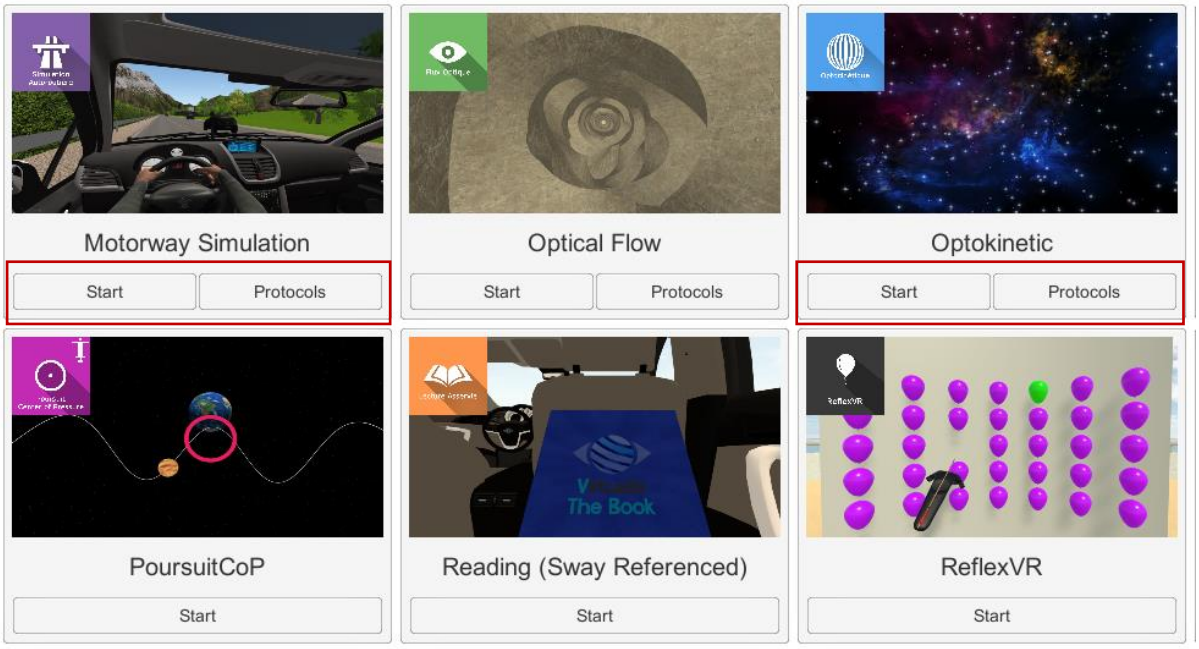
The softwares can be grouped according to criteria such as "Assessment" or "Rehabilitation" and then by pathology type: Neurology, Balance, Functional or Motion sickness.

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

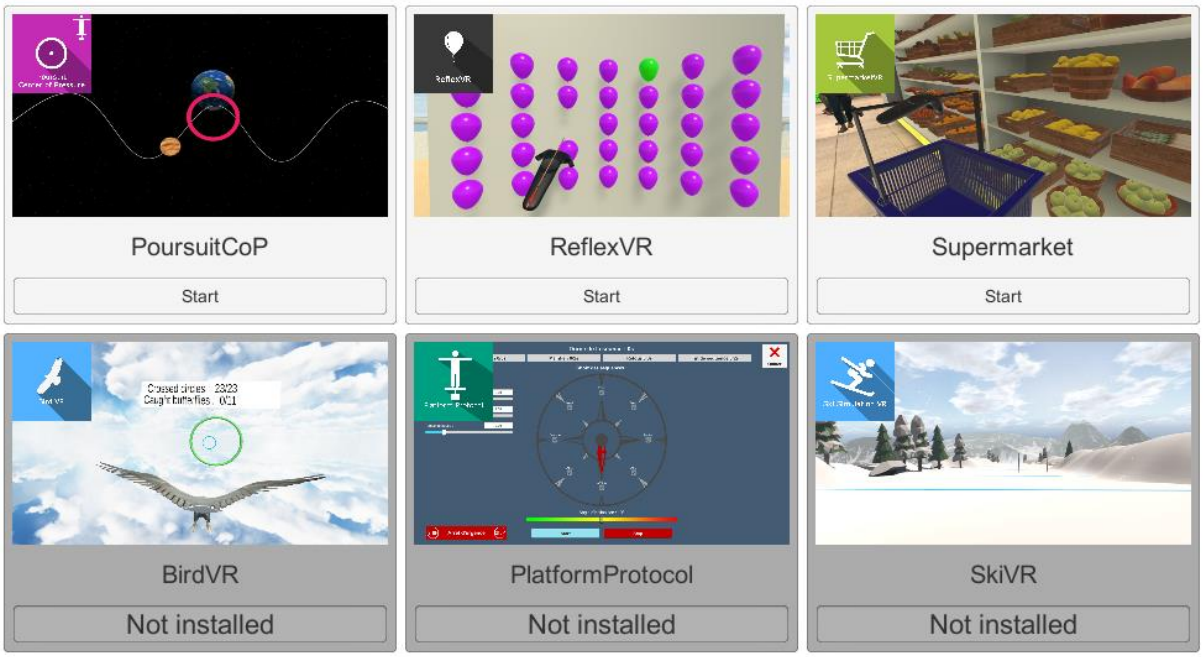


A number of softwares can be started either in ***manual mode***, by directly clicking the "Start" button, or in ***protocol mode*** by clicking the "Protocols" button.

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.

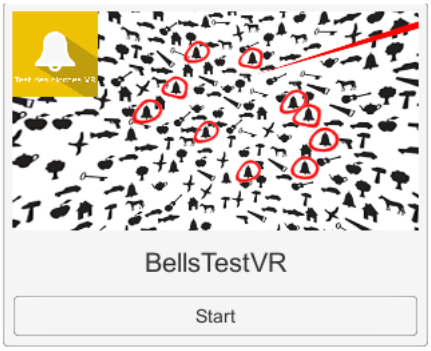


Softwares which are not included in your subscription package are grayed out. If you want to use them, please contact our sales department.



3. BELLS TEST VR

3.1. Start interface



When launching the software in ***manual mode*** from Patient Management ("Start" button), it opens a launch 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.

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. You can also modify a number of settings after the software has been launched, using the mouse.

The Start / Quit buttons are used to play or stop the environment entirely to adapt the experience to the patient's perception.

3.2. Software field of application

Assessment of a patient's exploration and visual discrimination skills as part of a unilateral spatial neglect assessment (USN).

3.3. Installing the patient

Sit patient down on a chair in a safe environment, without any risk of falling. Provide lateral support for patients who cannot sit up alone.

3.4. Session settings

The software's variable settings are as follows:

Settings

Distance

Sheet-to-examiner distance setting for variable scanning up to 180° using the cursor.

3D depth

This is used to set the 3D depth of objects

Vertical offset

This is used to shift the sheet up or down from the patient's visual center

Advanced settings

At the start of the session, advanced settings will not be available.

Objects size

This is used to set the dimension of objects

Objectives by column

This is used to set the number of bells for each column

Object density

This is used to set the quantity of distractors

Theme

3D objects

Activating this setting makes the objects appear in 3D with grayscale areas

Environment

Activating this setting makes a background appear on the screen, increasing the patient's distraction possibilities

Dynamic Environment

Activating this setting adds moving visual distractions to the patient's visual field

Icon pack

The practitioner can choose between 2 packs of symbols to carry out the session.

You can either perform a **Standardized Trial** or a **Random Trial**. Using a random trial during work sessions avoids the learning phenomenon when performing a standardized trial.

Advanced settings are only available when performing a Random Trial.

At the start of the session, refocus the virtual environment by pressing the "C" key on the keyboard once the patient is seated and wearing the virtual reality headset.

Score

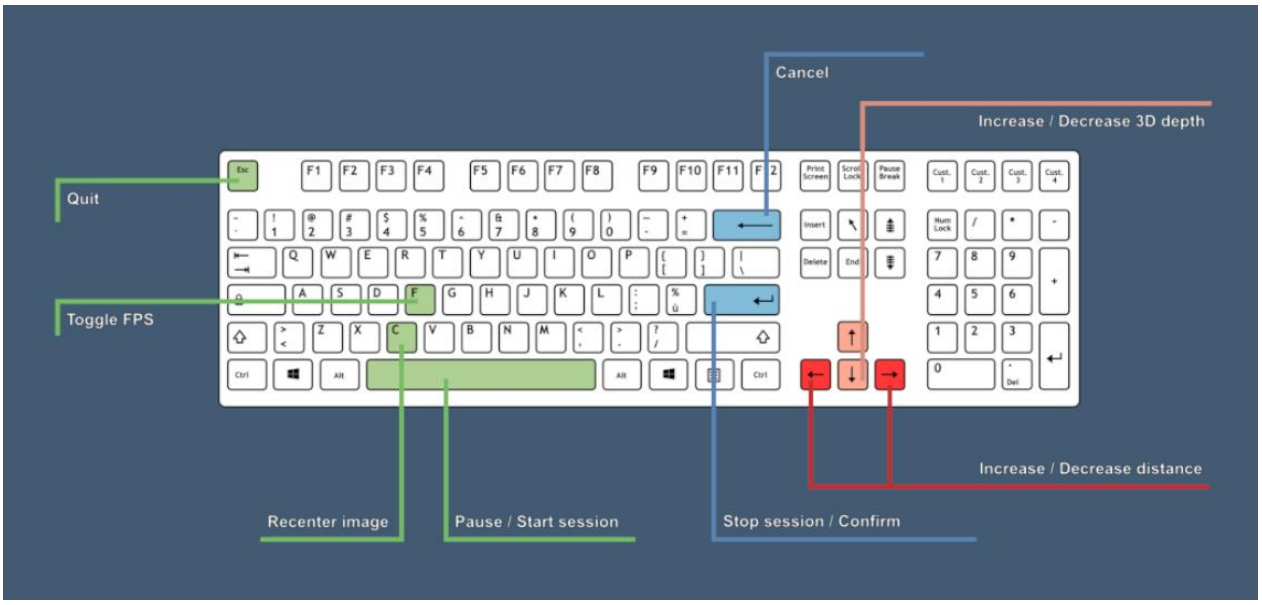
At the end of the exercise, the user can view detailed information summarizing the trial: patient's exploration strategy path, scores (number of bells aimed and/or missed, number of errors), average time between two bells aimed, total duration of the exercise, number of bells aimed per horizontal sector.

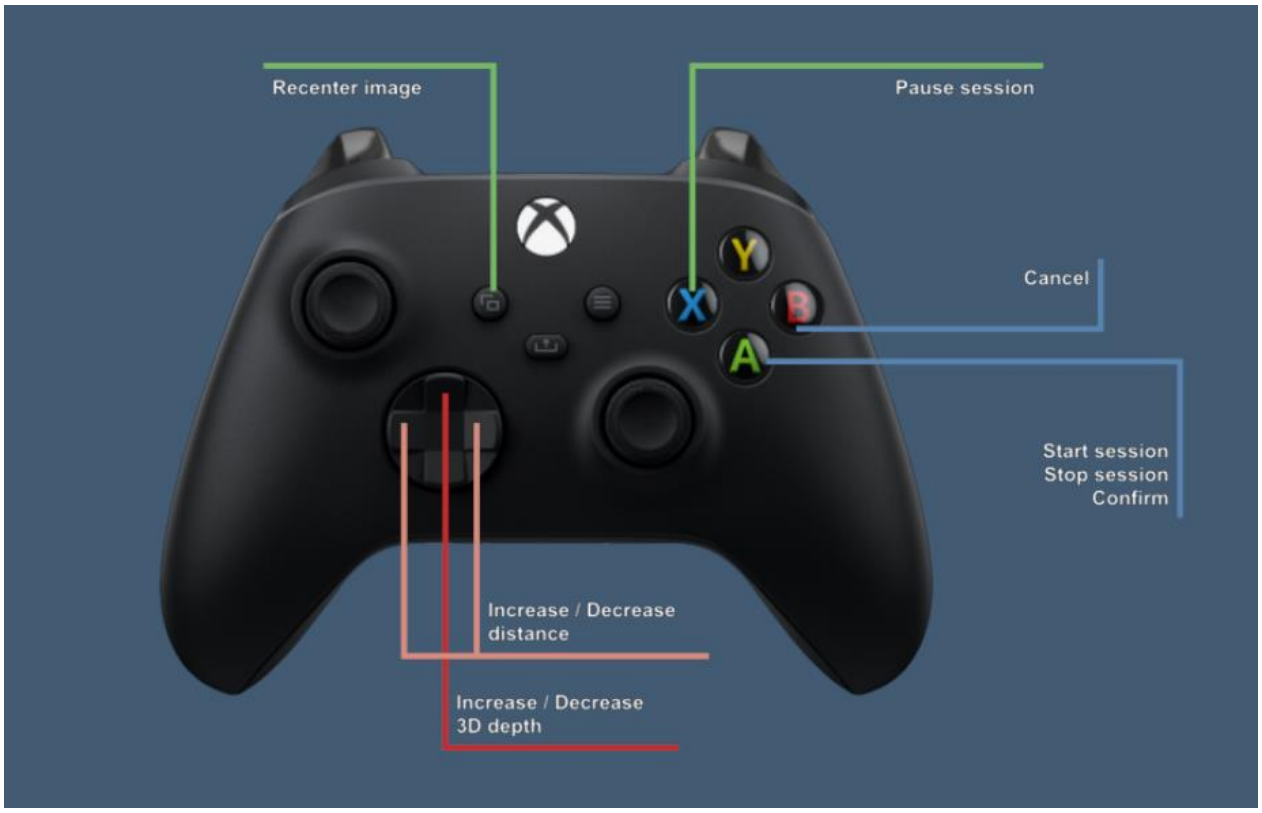
3.5. Shortcuts

Keyboard, joystick or controller shortcuts can be accessed in two ways:

- using the "Shortcuts" tab available in the launch interface
- in the software, by clicking the joystick icon in the upper right corner of the screen

Note: targeted objects can be selected / deselected using the controller





3.6. Data processing

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