



REF SHOULDERVR

CE Class I Medical Device

User manual

Distribution mode

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

 **VIRTUALIS**

Avenue de l'Europe - 34830 CLAPIERS - Tel. 09 80 80 92 91



DESCRIPTION

SHOULDERVR is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. **ShoulderVR** is a shoulder rehabilitation software.

INDICATIONS

Neurological or orthopedic impairments affecting the shoulder.

CONTRAINDICATIONS

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

FOR USE BY

Healthcare professionals: Physiotherapists; Occupational Therapists; 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 software, i.e. 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

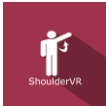
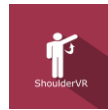


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1. GENERAL

1.1. Advice for use

These stimulations have the potential to cause certain disorders: Vasovagal syncope, epileptic seizures, migraines, etc.

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.

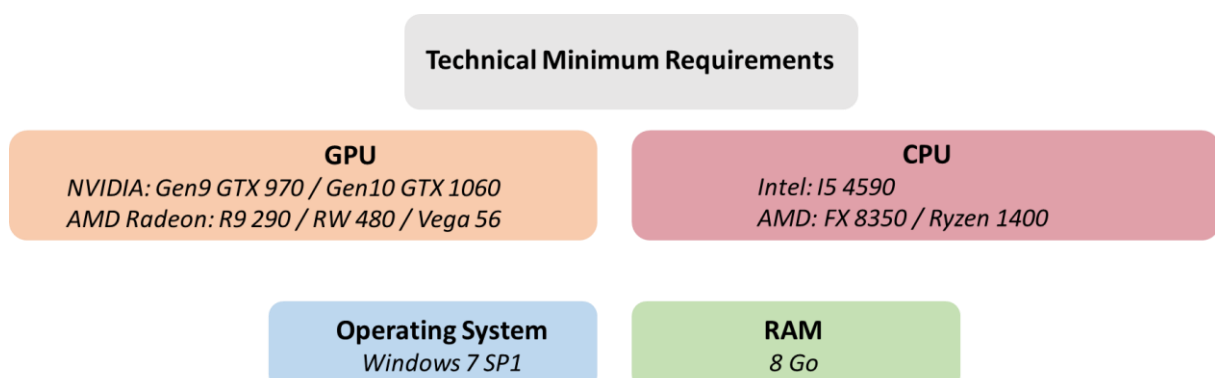
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

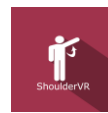
1.2. Hardware and minimum configuration requirements

Hardware required to use the system:

- VR Ready PC
- VR System: HTC VIVE, HTC VIVE Pro or compatible system
- Lighthouse bases (HTC VIVE tracking)
- HTC VIVE Controller
- HTC Vive Tracker

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



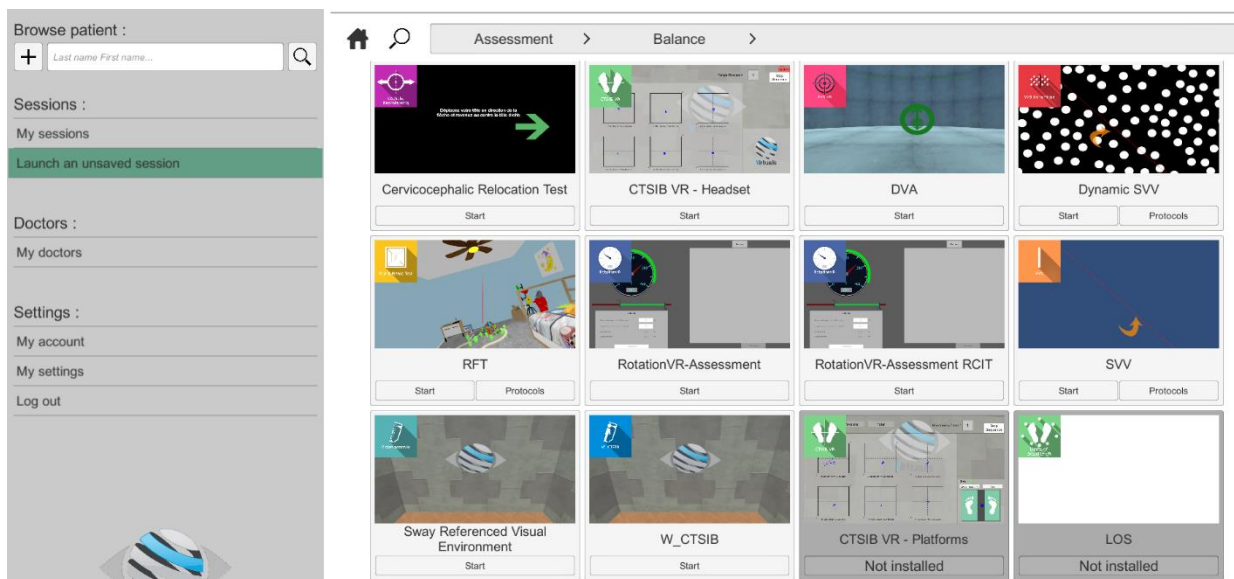


2. USE OF PATIENT MANAGEMENT

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.

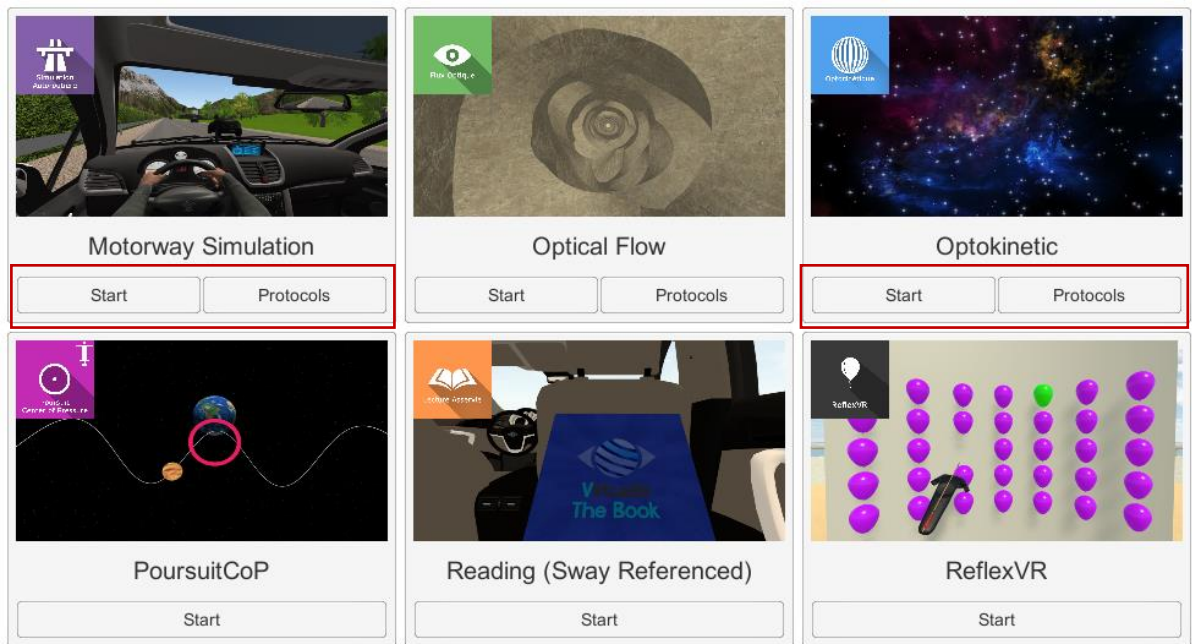
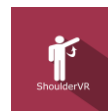
The software can be grouped according to criteria such as "Assessment" or "Re-education" and then by pathology type: Neurology, Balance, Functional or Travel sickness.

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

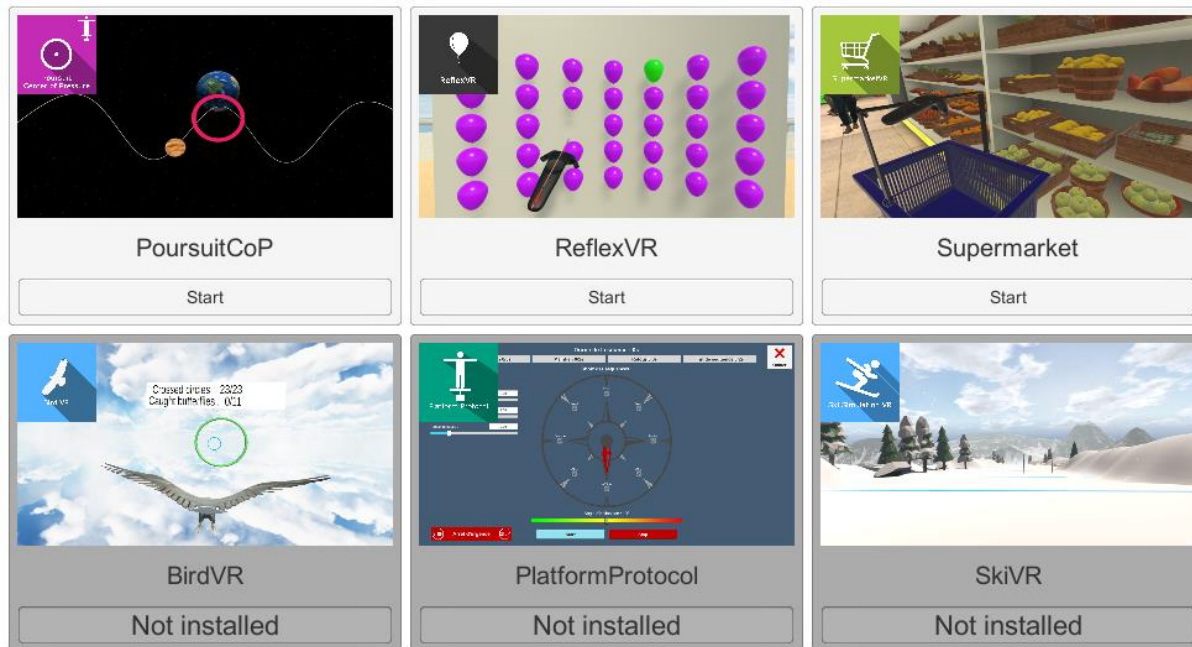


Some software can be started either in **manual mode**, by directly clicking the "Start" button, or in **protocol mode** by clicking the "Protocols" button.

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.

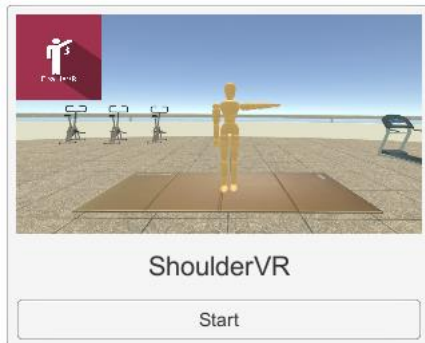


Software that is not part of your subscription package is greyed out. If you want to use it, please contact our sales department.



3. SHOULDERVR

3.1. Start interface



When starting the software in **manual mode** ("Start" button), 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. You can also modify some settings while the module is running, using the mouse or keyboard.

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

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 work on shoulder amplitudes.

3.3. Installing the patient

Standing / seated: shoulder work

3.4. Session settings



The variable settings for this module are as follows:

Shoulder to be re-educated

You can choose which shoulder to work on (right or left).

Targets settings

Targets can be set using the corresponding cursor.

Sequence validation:

The targets to be reached appear with a path to break down the movement; it is possible to force patients to validate the whole movement (full path) or only the targets at the ends of the path (via the drop-down menu).

Star size:

The larger the star size, the larger the collision zone.

Star spawn time:

Used to modulate the exercise sequence.

Star thickness:

The accuracy of the movement in the median axis depends on star thickness.

Sequence of movements to be carried out

The proposed movements are: Rest - Abduction; Rest - Anterior Elevation; Rest - Abduction - Elevation and Rest - Elevation - Abduction

Sequence

Used to choose the number of targets for each movement to force patients to maintain a position.

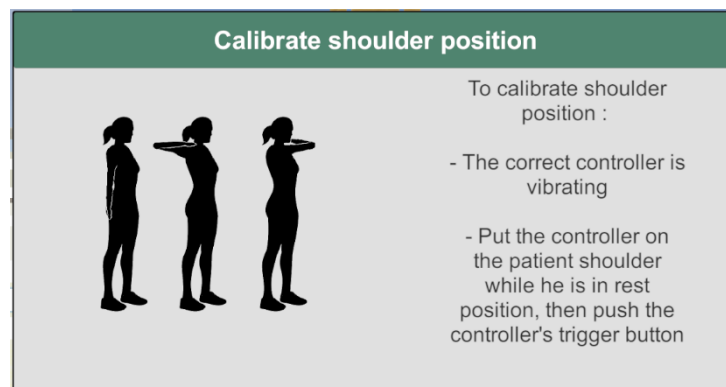
Calibrations:

At the beginning of the exercise, practitioners have the choice to keep Patient Management values or to recalibrate.

Before the calibration phase, patients must look forwards so that practitioners can recenter the view using the "C" key on the keyboard.

Shoulder Calibration:

- patients standing or seated in a resting position with the arm at the side of the body
- the HTC Vive Tracker is attached to the arm
- practitioners place the controller on the patients' shoulder (in the center) and press the trigger to calibrate (the controller to be used will vibrate slightly)



There are two possible methods for calibrating working angles:

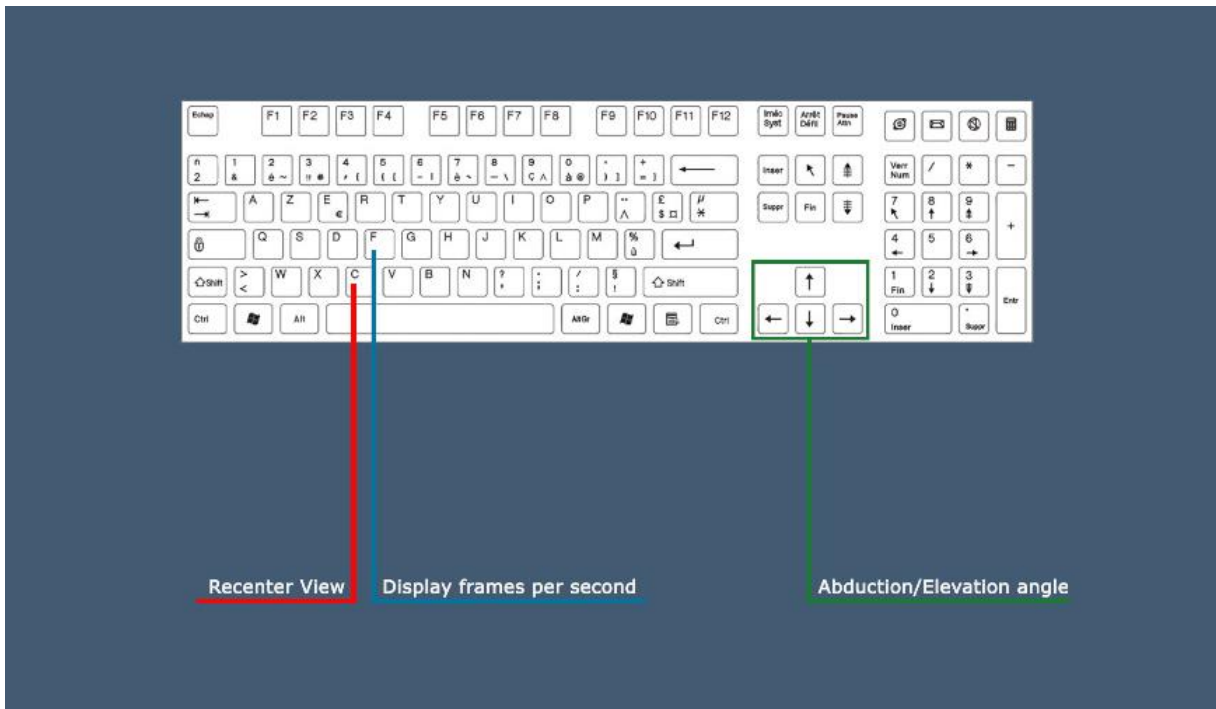
- enter the angle manually and press manual calibration or
- place patients in the working position and press the auto-calibration button

It is also possible to manually enter the working angle value during the exercise in the text field on the exercise scene.

At the end of the exercise, users will obtain results representing the maximum abduction and elevation angles achieved.

3.5. Shortcuts

Keyboard and controller shortcuts are accessible in the "Shortcuts" tab on the start interface.



3.6. Data processing

Data retrieval and analysis uses the Patient Management software.