

REF Spine Rotation VR

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

Spine Rotation VR software is an immersive 3D simulation based on virtual reality technology which allows a person to be immersed in an artificial digitally created world. **Spine Rotation VR** is rehabilitation software simulating trunk rotation activity initiated by scapulohumeral belt rotations. The software allows to work the upper limbs and the thoracolumbar spine in a fun environment - painting different objects with the left or right hand or with both hands at the same time in an artist's studio. Amplitude adjustment for each side (bending, extension, angle of rotation) is possible and adaptable in real time.

INDICATIONS

Active rehabilitation of the thoracolumbar spine

CONTRAINDICATIONS

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

FOR USE BY

Healthcare professionals: Physiotherapists; Ergotherapists; Neuropsychologists; ENT doctors; Neurologists; PMR doctors (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



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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)
- HTC VIVE Controllers
- HTC VIVE Trackers
- USB HUB

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



Technical Minimum Requirements

GPU

NVIDIA: Gen9 GTX 970 / Gen10 GTX 1060
 AMD Radeon: R9 290 / RW 480 / Vega 56

CPU

Intel: I5 4590
 AMD: FX 8350 / Ryzen 1400

Operating System

Windows 7 SP1

RAM

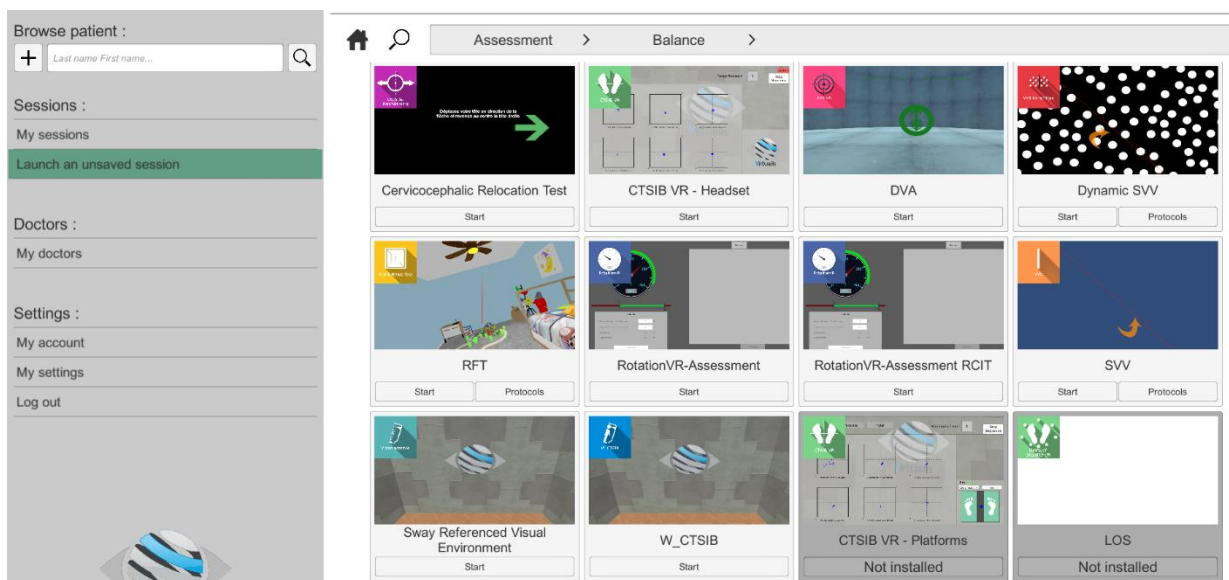
8 Go

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.

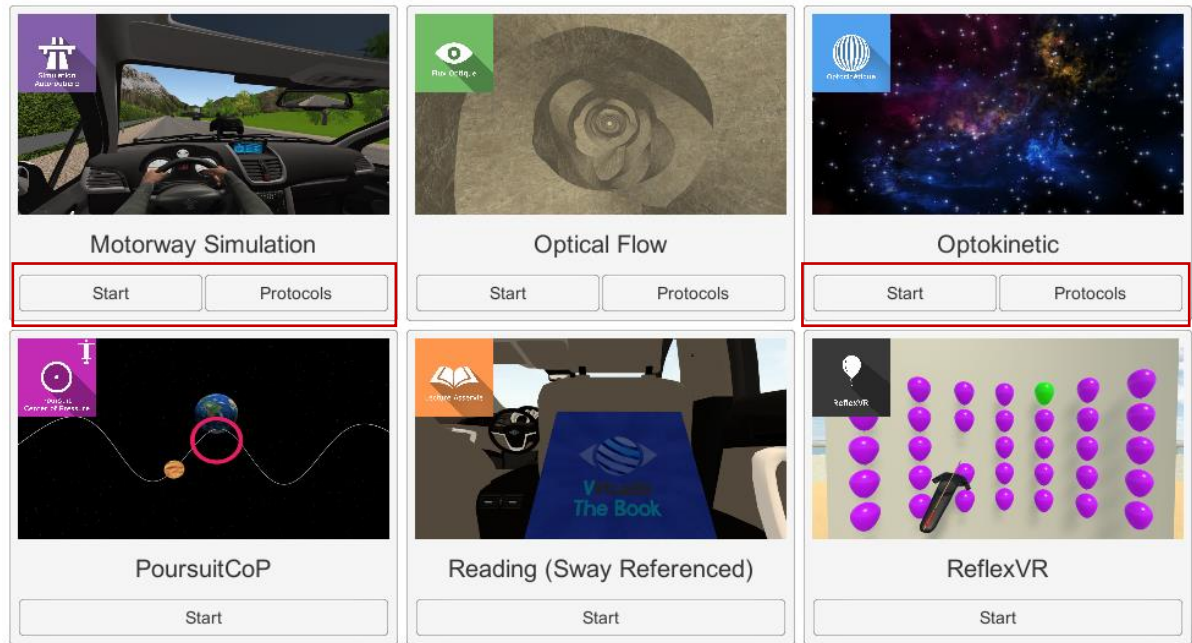
The software can be grouped according to criteria such as "Assessment" or "Re-education" and then by pathology type: Neurology, Balance, Functional, Motion Sickness or Fears - Phobias.

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

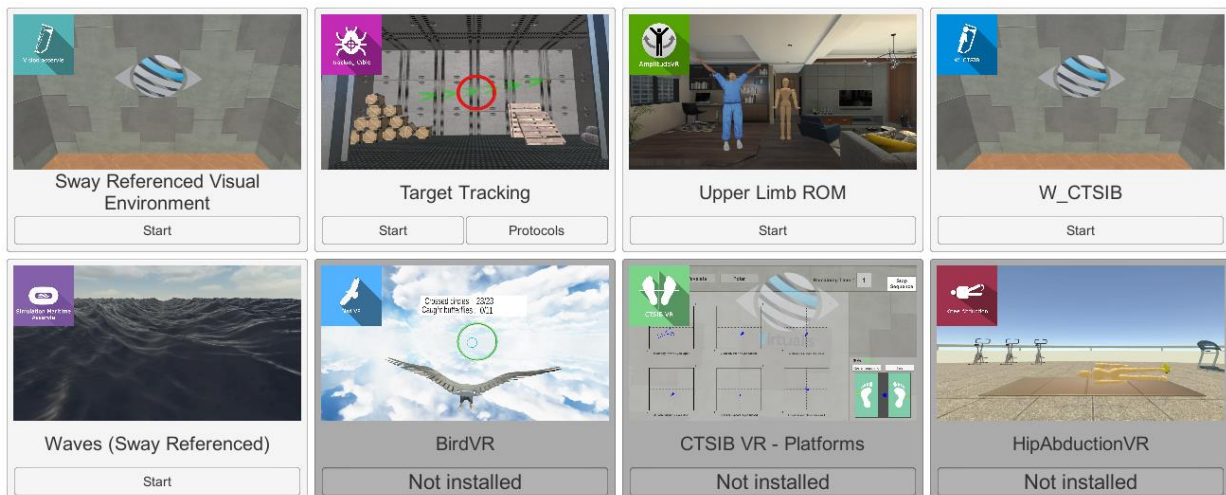


Some software can be started either in **manual mode**, by directly clicking the "Start" button, or in **protocol mode** by clicking the "Protocols" button.

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.

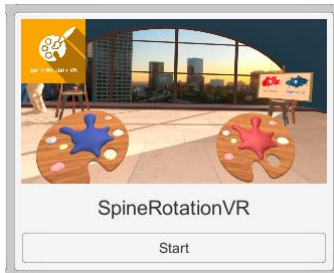


Software that is not part of your subscription package is grayed out. If you want to use it, please contact our sales department.



3. Spine Rotation VR

3.1. Start interface



When the software is started in **manual mode** ("Start" button), the opening is performed in 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.

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 software is launched by simply clicking the "start" button in the action area.



Once this button is pressed, the software starts by taking into account the specified settings. You also have the possibility to modify some settings when the software has been launched, using the mouse.

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. Software field of application

This software allows to work the upper limbs and the spine in the context of spinal and/or upper limb pathologies.

3.3. Installing the patient

The initial position depends on patients' abilities: standing or sitting.

Standing position, foot position at will: joined, apart, pointing out, etc.

3.4. Session settings



Settings		Session settings	
Mode	Two hands	Limited time	<input checked="" type="checkbox"/>
Reach	0,7 m	Session duration	120 s
Hold duration	2 s		
Left hand settings			
Palette horizontal position	90 °		
Palette vertical position	0 °		
Object horizontal position	0 °		
Object vertical position	0 °		
Right hand settings			
Palette horizontal position	-90 °		
Palette vertical position	0 °		
Object horizontal position	0 °		
Object vertical position	0 °		

The variable settings for this module are as follows:

Settings

Mode

There are three modes available for the exercise: two hands, right hand and left hand

The patient uses a blue brush for the right hand and a red brush for the left hand.

They must make rotational movements to get the right color paint and thus be able to paint the objects that appear.

Note: When there are gripping difficulties, the controller can be replaced by the tracker attached to a limb segment using the strap provided.



Reach

Palette-patient distance can be customized using the cursor.

Hold duration

The time during which the brush must remain dipped in the paint

Limited time

Used to define the session duration

Left hand settings

Horizontal / vertical palette position

Used to set the amplitude rotation sequences (angle, height) that the patient will carry out to reach the palette

Palette horizontal / vertical position

Used to set amplitude rotation sequences (angle, height) that the patient will carry out to paint the object

Right hand settings

Horizontal / vertical palette position

Use to set the amplitude rotation sequences (angle, height) that the patient will carry out to reach the palette

Palette horizontal / vertical position

Used to set amplitude rotation sequences (angle, height) that the patient will carry out to paint the object

Score

At the end of the exercise, users will get a score representing their success: the number of objects painted using the left and/or right hand.

3.5. Shortcuts

The "C" key on the keyboard is used to center the image.

3.6. Data processing

Data retrieval and analysis uses the Patient Management software.