

REF SpineVR

CE Class I Medical Device

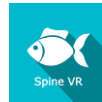
User manual

Distribution mode

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

 **VIRTUALIS**

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DESCRIPTION

SpineVR software is an immersive 3D simulation based on virtual reality technology which allows a person to be immersed in an artificial digitally created world. The software simulates an underwater environment that allows active rehabilitation of the spine and lower limbs by shrimp fishing.

INDICATIONS

Active rehabilitation of the lower limbs and the 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.

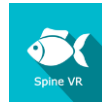


Any serious incident should be notified in writing to qualite@virtualisvr.com



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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)
- USB HUB

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



Spécification technique minimales

GPU

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

CPU

Intel: I5 4590 et supérieur
AMD: FX 8350 / Ryzen 1400 et supérieur

Système d'exploitation

Windows 7 SP1 et supérieur

RAM

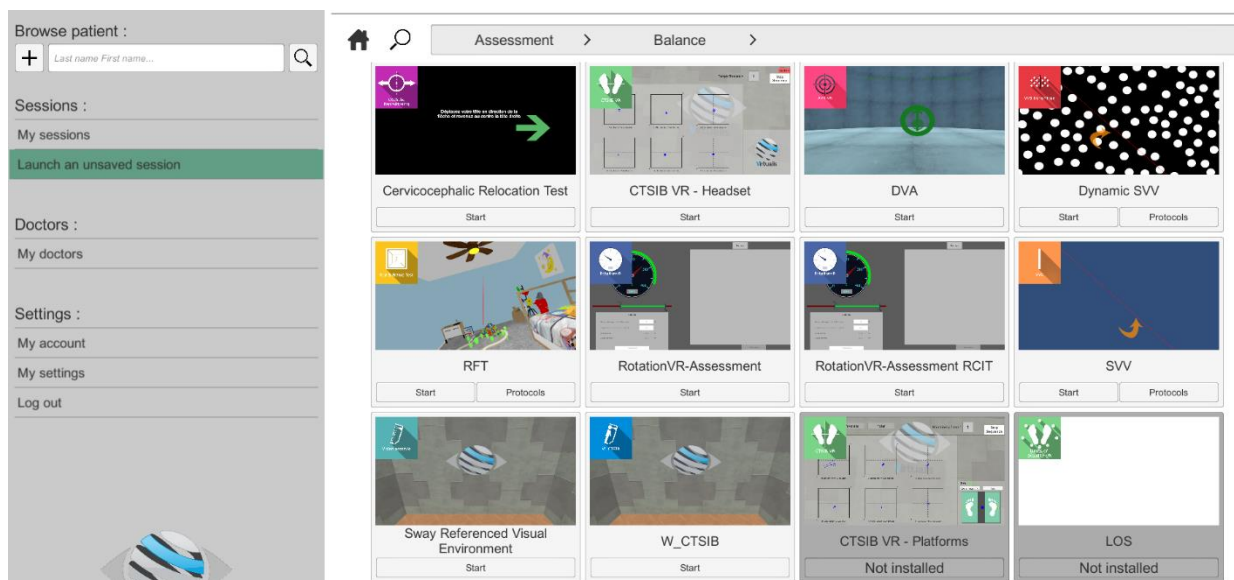
8 Go

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.

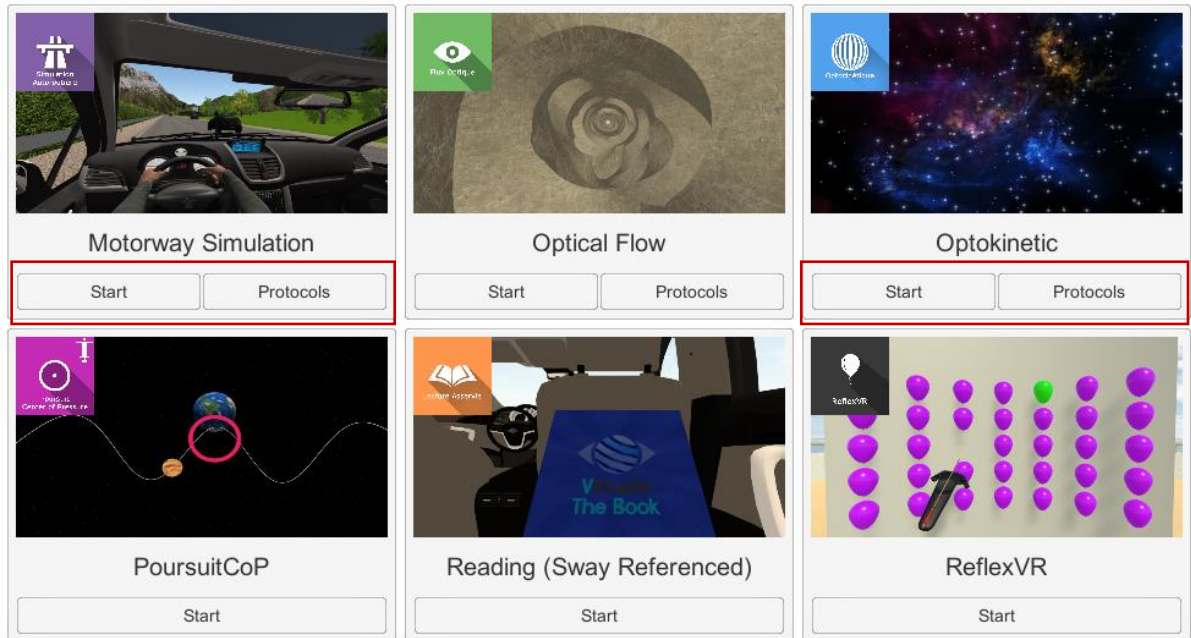
The software can be grouped according to criteria such as "Assessment" or "Re-education" and then by pathology type: Neurology, Balance, Functional, Motion Sickness or Fears - Phobias.

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

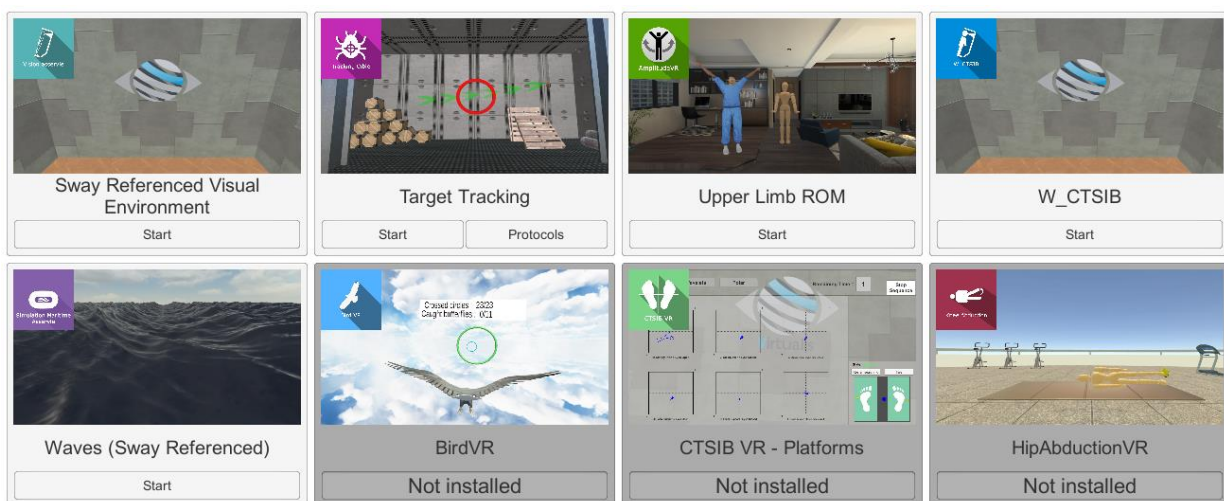


Some software can be started either in **manual mode**, by directly clicking the "Start" button, or in **protocol mode** by clicking the "Protocols" button.

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. SpineVR

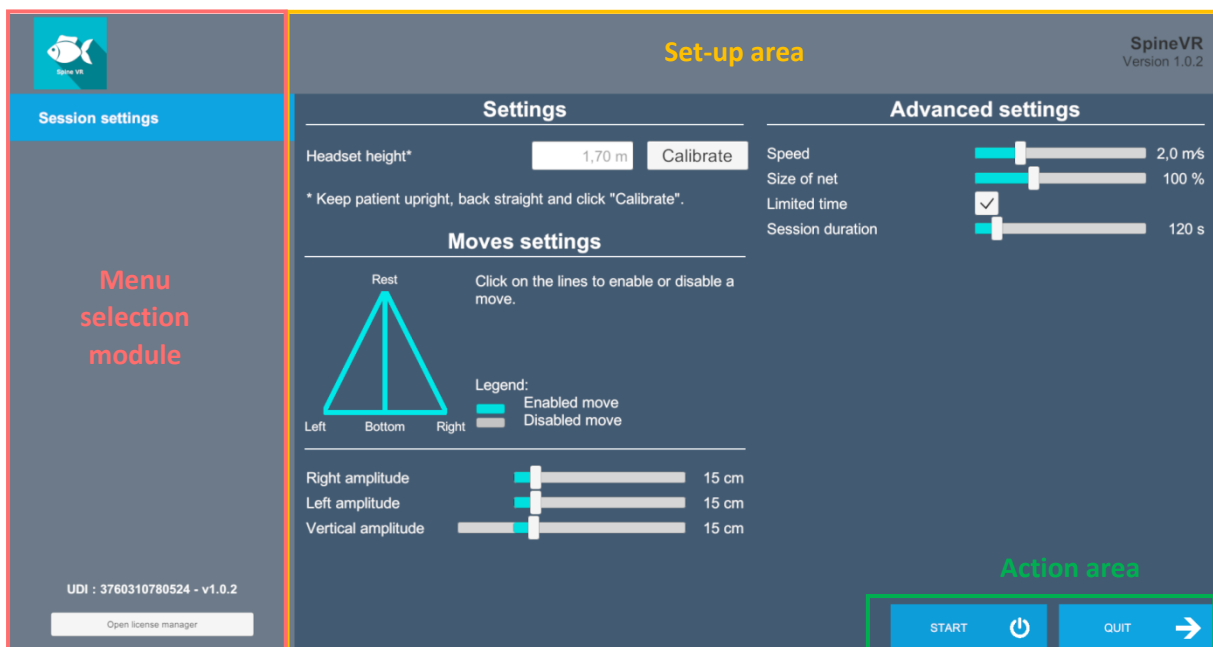
3.1. Start interface

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.

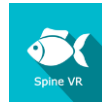
The software is launched by simply clicking the "start" button in the action area.



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 the active rehabilitation of the spine and lower limbs by simulating shrimp fishing.

The patient will move the headset worn on the head in space carrying out bend/extension/linear movements of the spine and lower limbs in order to catch shrimps in a virtual net.

3.3. Installing the patient

Standing or seated.

When standing: position of the feet depending on the movement to be carried out: joined, spread out.

3.4. Session settings

Settings

Headset height*

* Keep patient upright, back straight and click "Calibrate".

Advanced settings

Speed 2,0 m/s

Size of net 100 %

Limited time

Moves settings

Click on the lines to enable or disable a move.

Rest

Left Bottom Right

Legend:

- Enabled move
- Disabled move

Right amplitude 80 cm

Left amplitude 40 cm

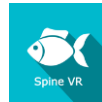
Vertical amplitude 20 cm

The variable settings for this module are as follows:

Settings

Headset height:

Calibration is used to determine the height of the headset from the ground, which will serve as a reference for the patient's rest position but also as a reference position from which the upper and lower movement limits will be determined. To adjust the headset height, keep the patient upright with their back straight and click the "calibration" button.



Moves settings:

Several movements are possible from the rest position: up - down - left - right.

To enable the movement(s) to be carried out, click the corresponding line(s). The enabled movement appears in blue.

To disable a movement, simply click on the line corresponding to the movement; it then appears grayed out.

Right, left, vertical amplitude:

The amplitudes for the selected movements can be customized using the cursor. This makes it possible to define the maximum movement amplitudes to be carried out but also to vary the difficulty of the exercise.

The vertical amplitude is the variation in height from the rest position. A positive value will cause a downward movement while a negative value will cause an upward movement.

Speed:

Shrimp movement speed can be set using the cursor.

Size of net

Used to increase the net size to make the exercise easier

Limited time

Used to define the session duration

Score

At the end of the exercise, users will get a score representing their success: the number of shrimps caught, the number of missed shrimps.

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.