REF **MIRROR LOWER LIMB**

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

Mirror Lower Limb is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. The **Mirror Lower Limb** software deals with sensory and motor disorders of the lower limb, deafferentation pain, CRPS and other types of chronic pain.

INDICATIONS

Neuromotor rehabilitation, rehabilitation of hemiplegia, chronic pain, CRPS, phantom limb pain.

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.

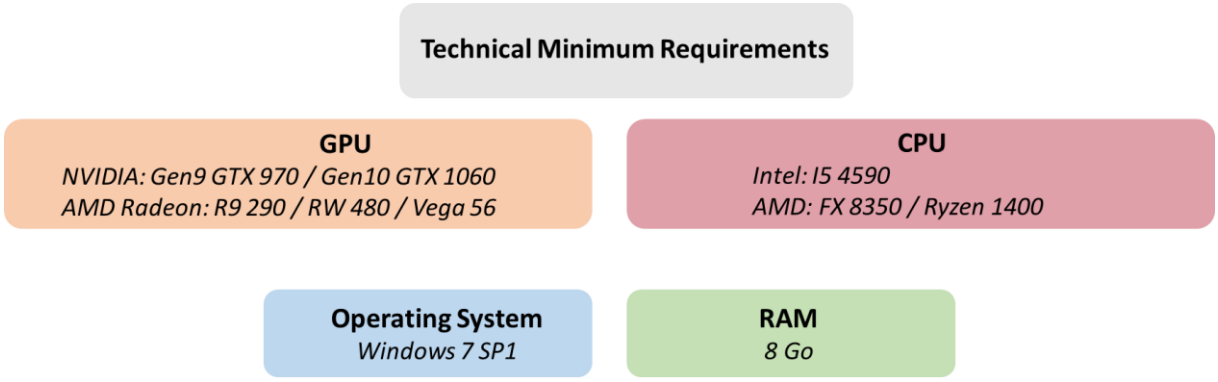
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

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
- 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 following system requirements:

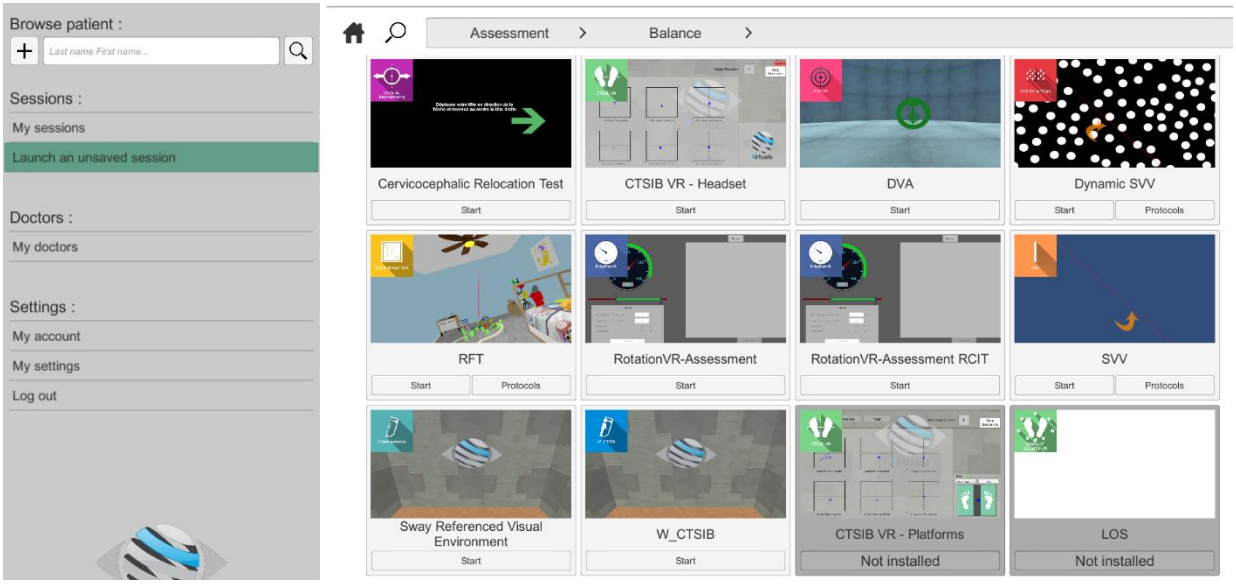


2. USE of PATIENT MANAGEMENT

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.

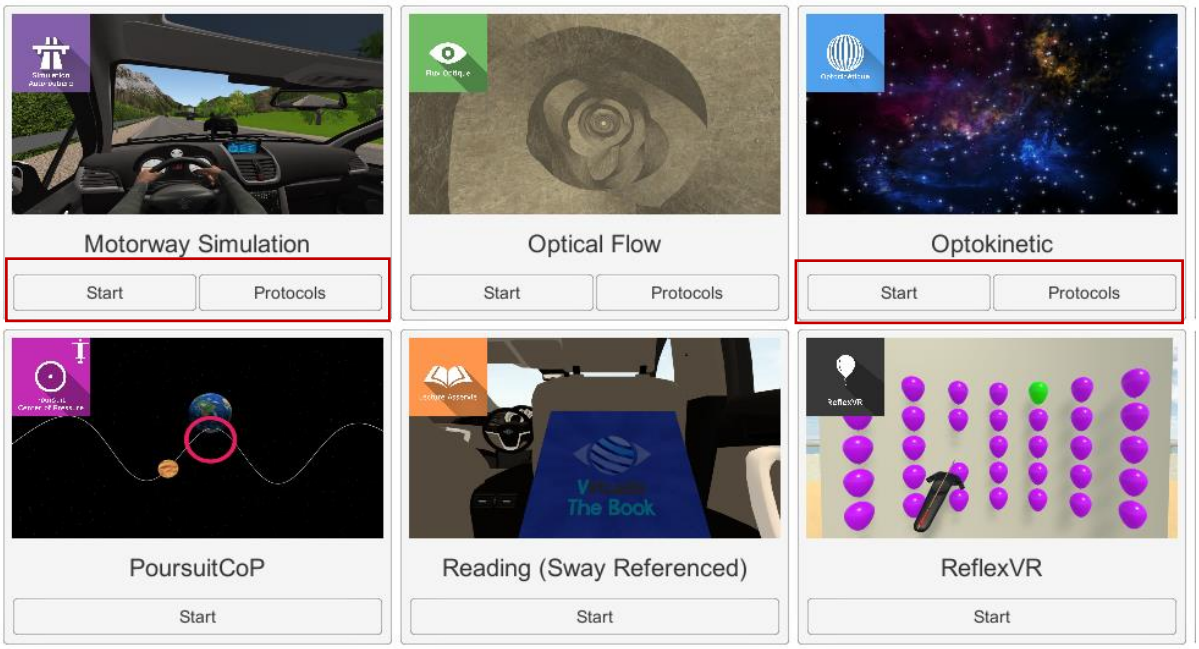
The softwares can be grouped according to criteria such as "Assessment" or "Rehabilitation" and then by pathology type: Neurology, Balance, Functional or Motion sickness.

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

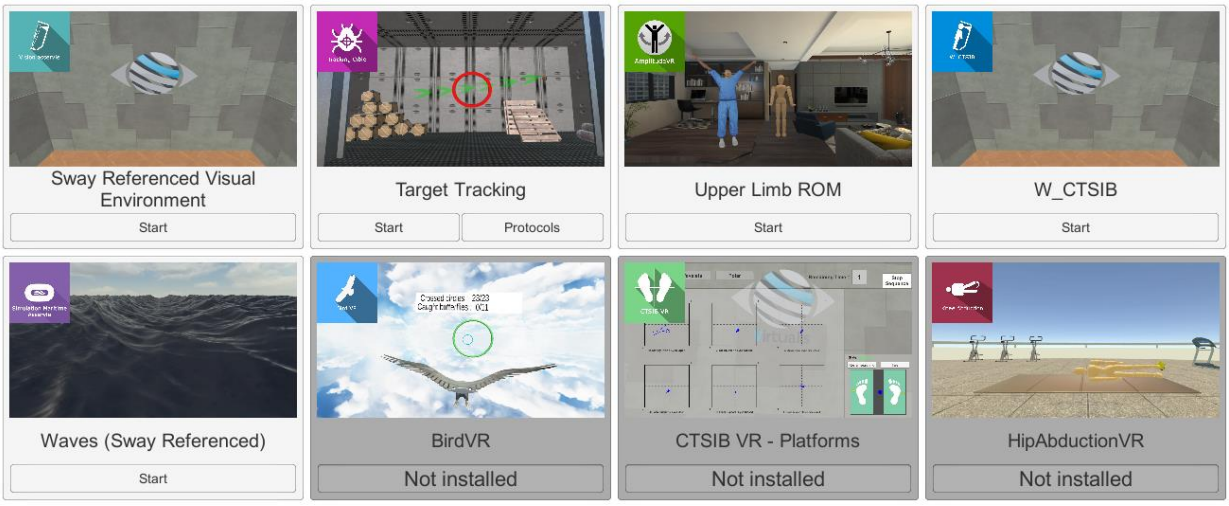


A number of softwares can be started either in ***manual mode***, by directly clicking the "Start" button, or in ***protocol mode*** by clicking the "Protocols" button.

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.

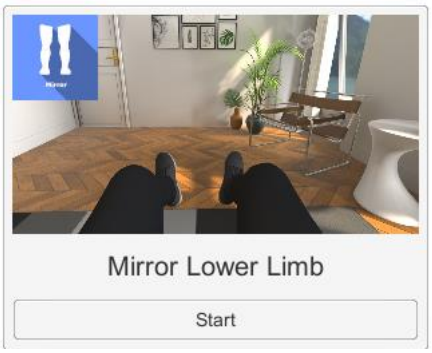


Softwares which are not included in your subscription package are grayed out. If you want to use them, please contact our sales department.



3. MIRROR LOWER LIMB

3.1. Start interface

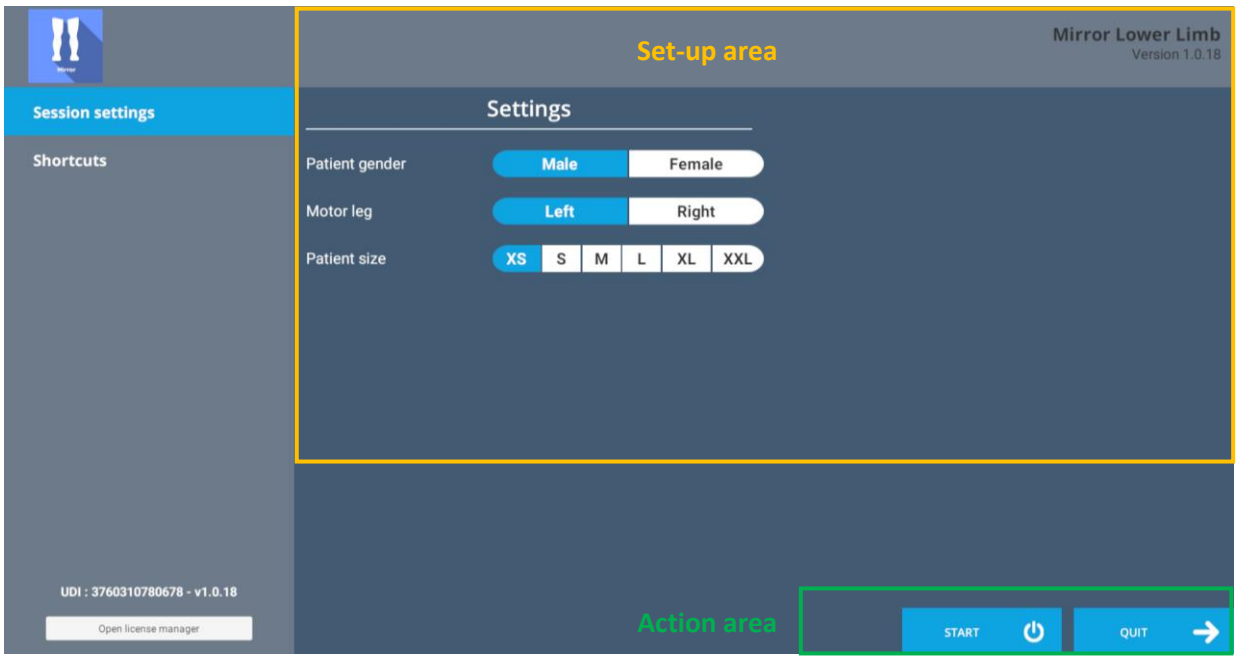


When launching the software in ***manual mode*** from Patient Management ("Start" button), it opens a launch interface consisting of a module selection menu on the left, a set up area on the right, and an action area at the bottom right.

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 "Back" 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

Software used as part of a new approach to Mirror Therapy. The motor leg may be hidden or immobilized during the mirror exercise. Visualization by 3D modeling of the limb in VR in real time.

3.3. Installing the patient

Use with the patient sitting down.

Recenter at the beginning of the session.

3.4. Session settings

The software's variable settings are as follows:

Patient gender

Possibility to select: male or female

Motor leg

The motor leg can either be the right leg or the left leg depending on the patient.

Patient size

There are several sizes available: XS, S, M, L, XL and XXL

Settings are predefined for each size.

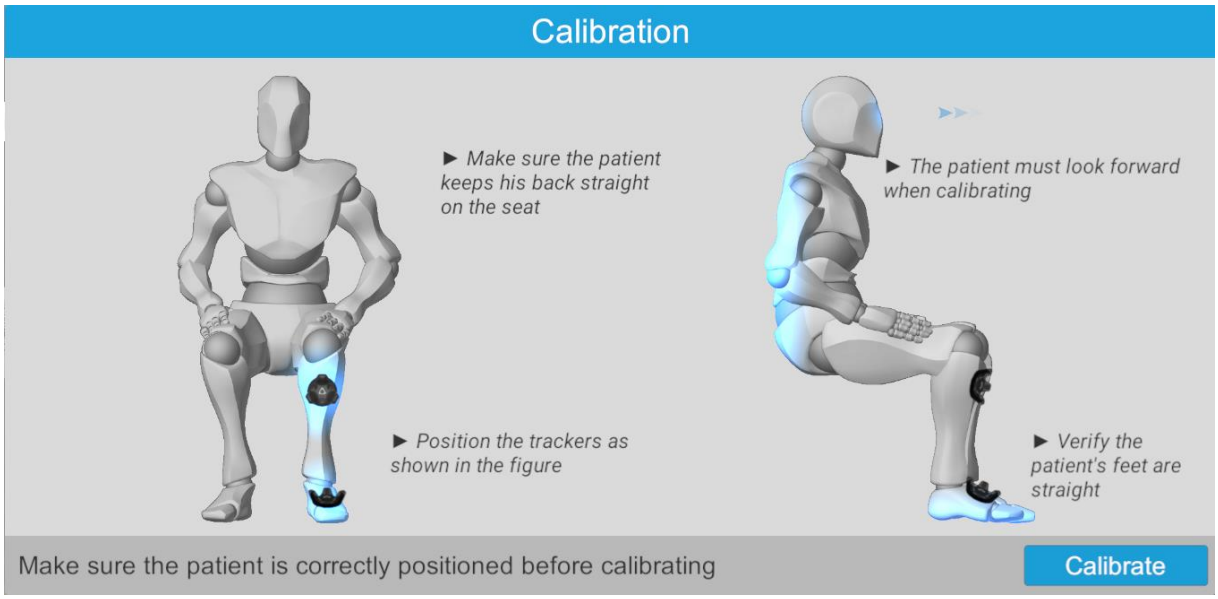
Session duration

The practitioner can view the duration of the session in the window that opens at the bottom right of the screen, once the software has been launched

Calibration

Before each calibration, the patient must be seated, with his back straight and looking straight ahead

The 3D immersive modeling is done by positioning 2 trackers on the leading limb. Both trackers should be attached to the leg and aligned in the body axis as shown in the following figure:



NB: an offset in the positioning of the trackers with respect to the body's sagittal axis results in the limb segment in the VR modeling being oriented in relation to the offset axis.

Advanced settings

Each sequence can be configured if the advanced settings option is activated.

The following settings will appear: Hip width, thigh thickness and length, calf thickness and length, foot thickness and length.

Mirror settings

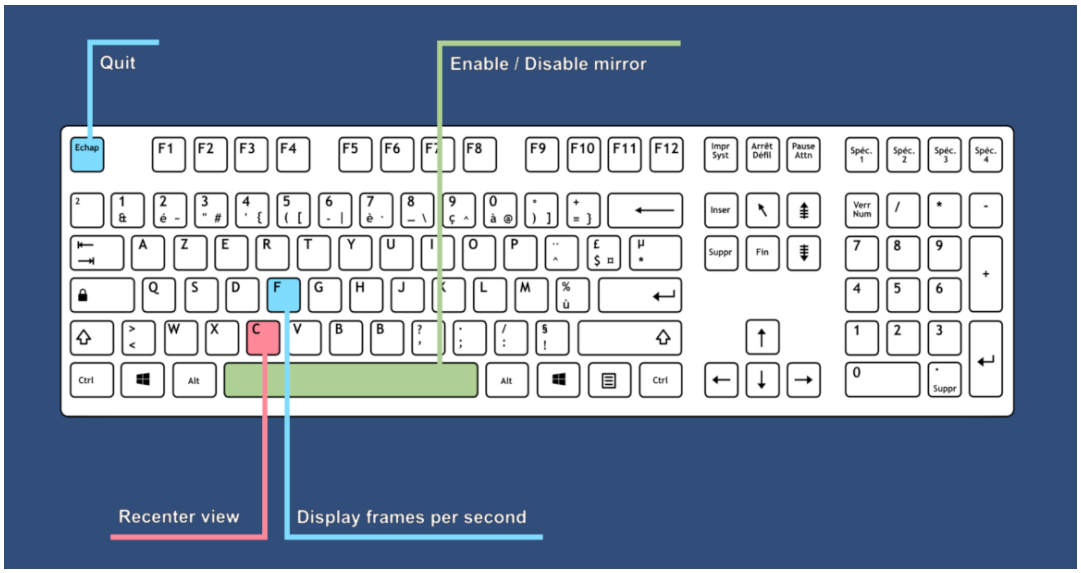
The mirror mode can be activated using the "activate mirror" button. The following settings are available.

- Freeze motor leg: this is used to freeze the motor leg in its last position
- Hide motor leg: is used to restrict the view to the "mirror" leg only

3.5. Shortcuts

Keyboard or joystick 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



3.6. Data processing

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