REF **UPPER LIMB ROM**

CE Class I Medical Device

User manual

Distribution mode

Available for direct download at

http://virtualisvr.com/espace-client/

Use under licence

VIRTUALIS

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DESCRIPTION

UPPER LIMB ROM software is an immersive 3D simulation based on virtual reality technology, i.e. it allows a person to be immersed in an artificial digitally created world. **UPPER LIMB ROM** is complete software for shoulder amplitude assessments.

INDICATIONS

Assessment of articular amplitudes of one or both shoulders.

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

Table of Contents

1. GENERAL

1.1. Advice for use

This type of re-education must be undertaken progressively, especially when using Virtual Reality.

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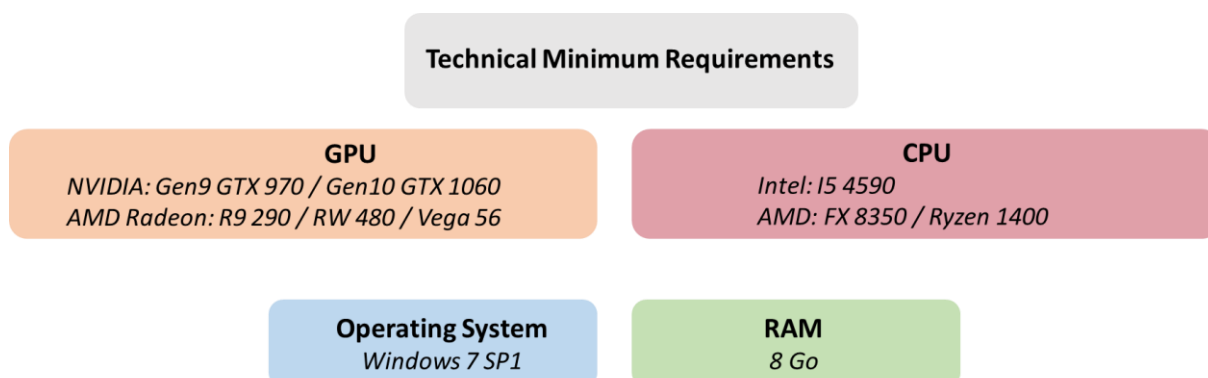
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

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)
- XBOX 360 Controllers
- HTC VIVE Controller

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	CPU
NVIDIA: Gen9 GTX 970 / Gen10 GTX 1060 AMD Radeon: R9 290 / RW 480 / Vega 56	Intel: I5 4590 AMD: FX 8350 / Ryzen 1400

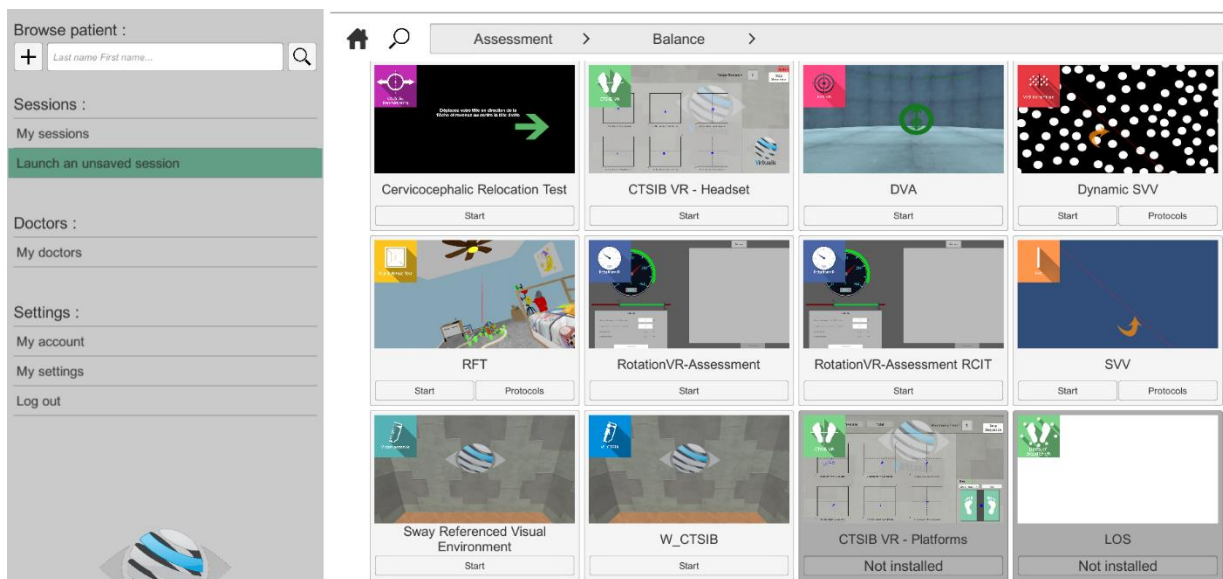| Operating System	RAM
Windows 7 SP1	8 Go

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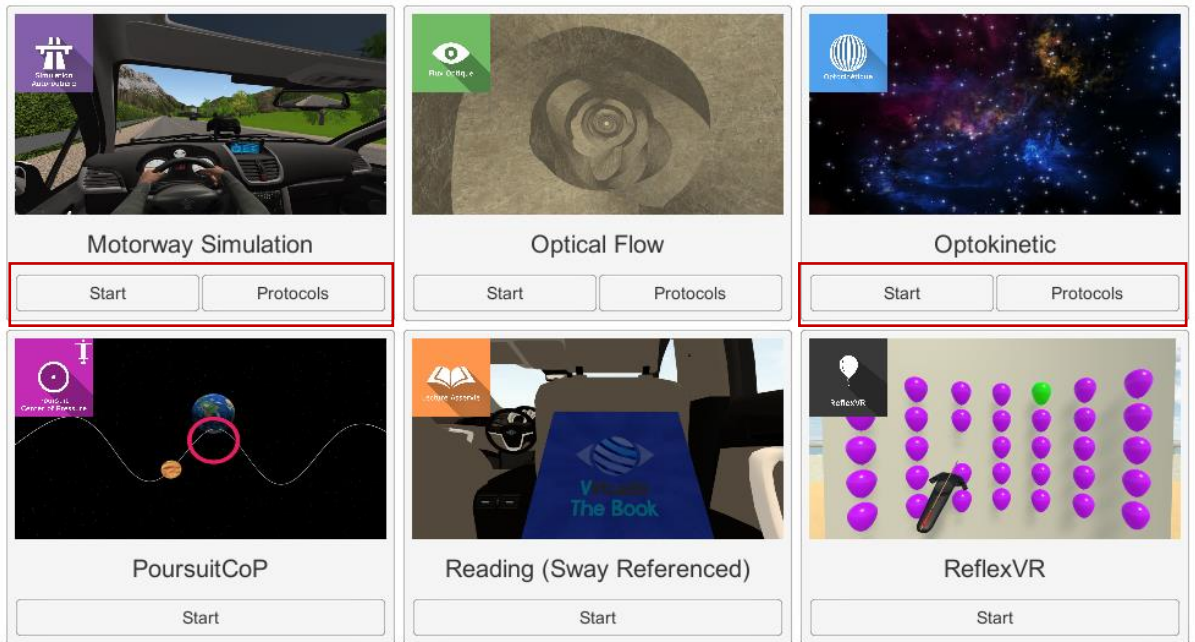
The software can be grouped according to criteria such as "Assessment" or "Re-education" and then by pathology type: Neurology, Balance, Functional or Travel sickness.

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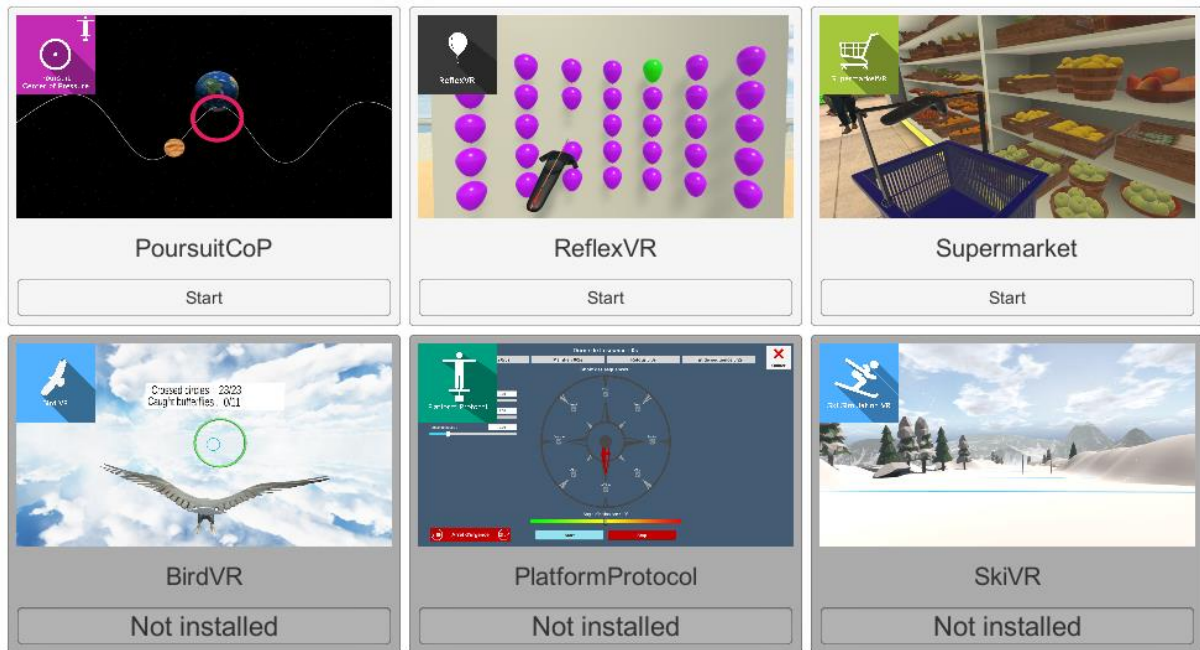

Some software can be started either in *manual mode*, by directly clicking the "Start" button, or in *protocol mode* by clicking the "Protocols" button.

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.
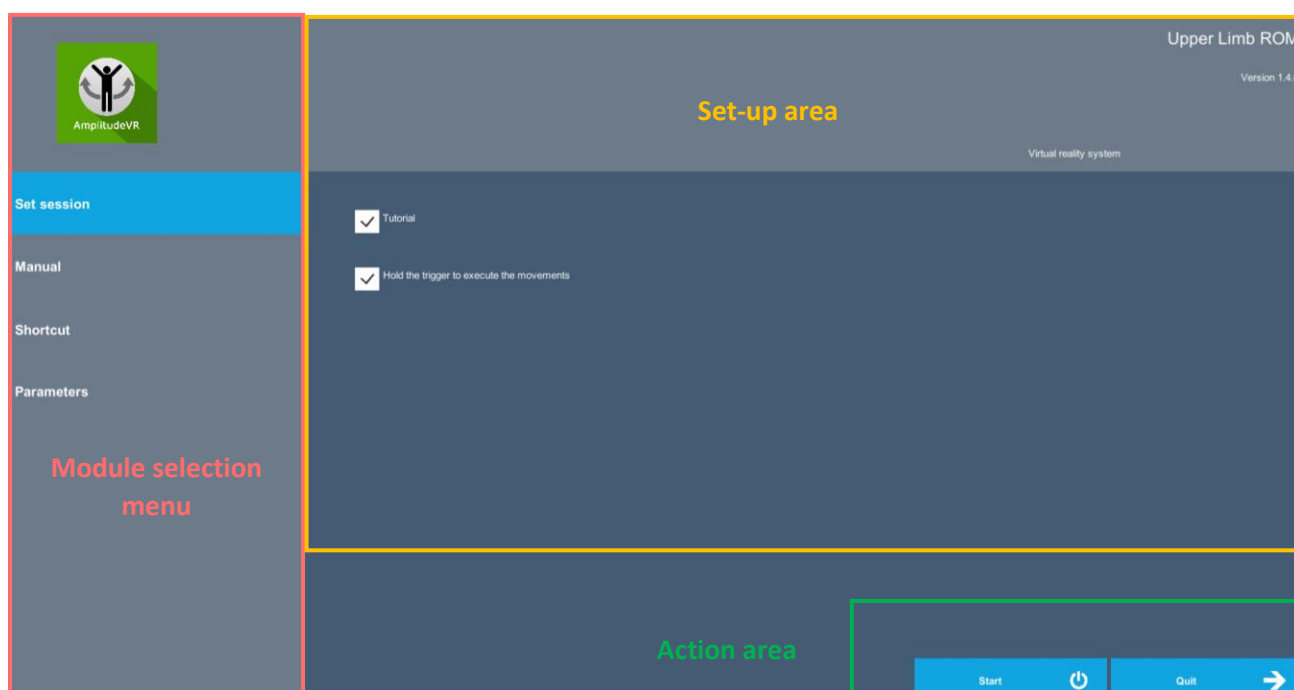
3. UPPER LIMB ROM

3.1. Start interface

When starting the software in manual mode ("Start" button) from Patient Management, the software is opened 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.

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 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.

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

3.2. Module field of application

This module measures the shoulder amplitude patients can reach. The exercises available in this module allow patients to carry out six types of movement:

- Lateral elevation (= abduction)
- Anterior elevation (= flexion)
- Extension
- Horizontal abduction
- External rotation (= lateral)
- Internal rotation (= medial)

3.3. Installing the patient

Use in a standing position centered at the beginning of the session.

3.4. Session settings

The variable settings for this module are as follows:

Tutorial

Possibility of activating or deactivating the tutorial.

If the tutorial is activated, a dialogue box appears to help you carry out the exercises.
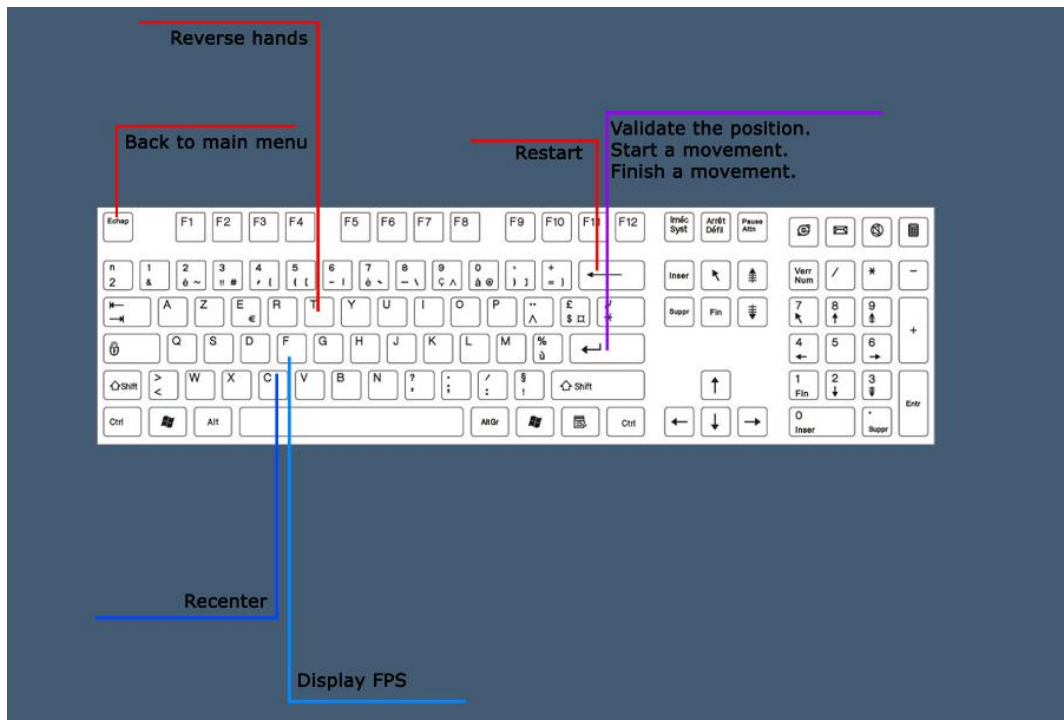
How to execute the movements

Possibility of holding the trigger to carry out the movements or pressing the trigger at the beginning of the exercise and at the end of the exercise.

The controller button measures the threshold of pain felt by the patient.

3.5. Shortcuts

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

- on the "Shortcuts" tab available at the start interface level
- within the module, by clicking on the joystick icon in the upper right corner of the screen

4.6. Data processing

Data retrieval and analysis uses the Patient Management software.