REF   **Cervical Range of Motion**

$C\epsilon$ Class I Medical Device
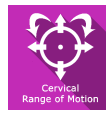
User manual

Distribution mode

Available for direct download at

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

Use under licence

VIRTUALIS

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DESCRIPTION

Cervical Range of Motion software is an immersive 3D simulation based on virtual reality technology which allows a person to be immersed in an artificial digitally created world. **Cervical Range of Motion** is an assessment software of the cervical spine's amplitudes and pain thresholds.

INDICATIONS

Assessment of cervical spine amplitudes. Assessment of pain thresholds.

CONTRAINDICATIONS

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

FOR USE BY

Healthcare professionals: Physiotherapists; Occupational therapists; 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.

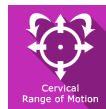Define a working area of about 3m² to allow for risk-free movements.

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**

Table of Contents

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 Controller
- XBOX 360 Controllers
- USB HUB

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.
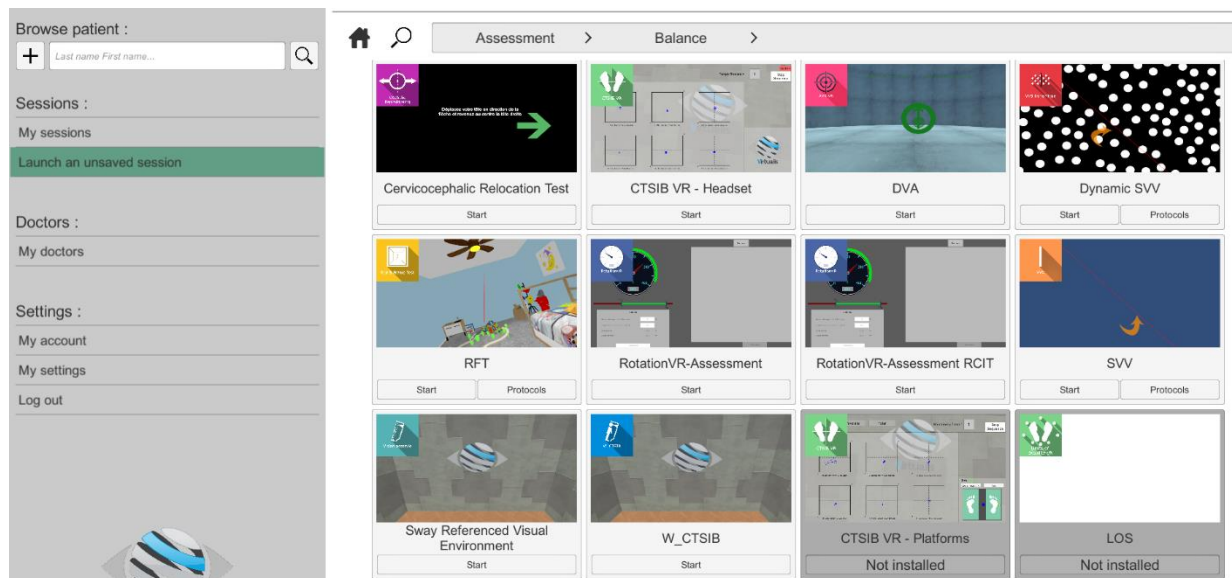

Some software can be started either in *manual mode*, by directly clicking the "Start" button, or in *protocol mode* by clicking the "Protocols" button.

The *manual mode* allows users to choose the settings for each environment. The *protocol mode* offers several sessions with different difficulty levels to test and gradually accustom patients to the VR environment.
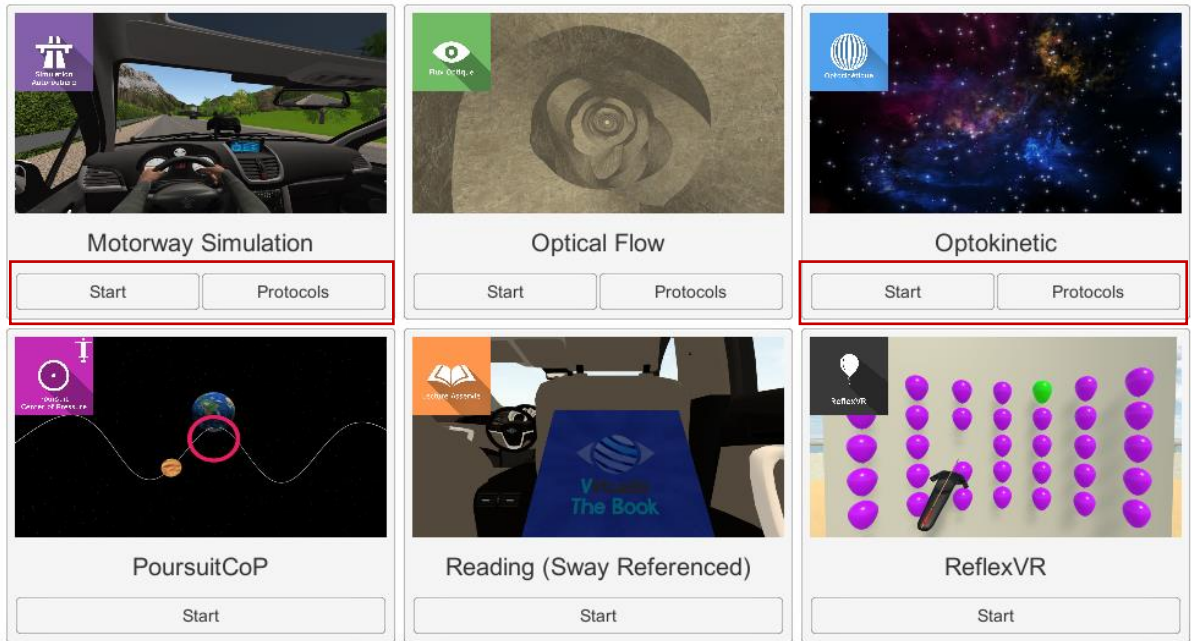
Software that is not part of your subscription package is greyed out. If you want to use it, please contact our sales department.
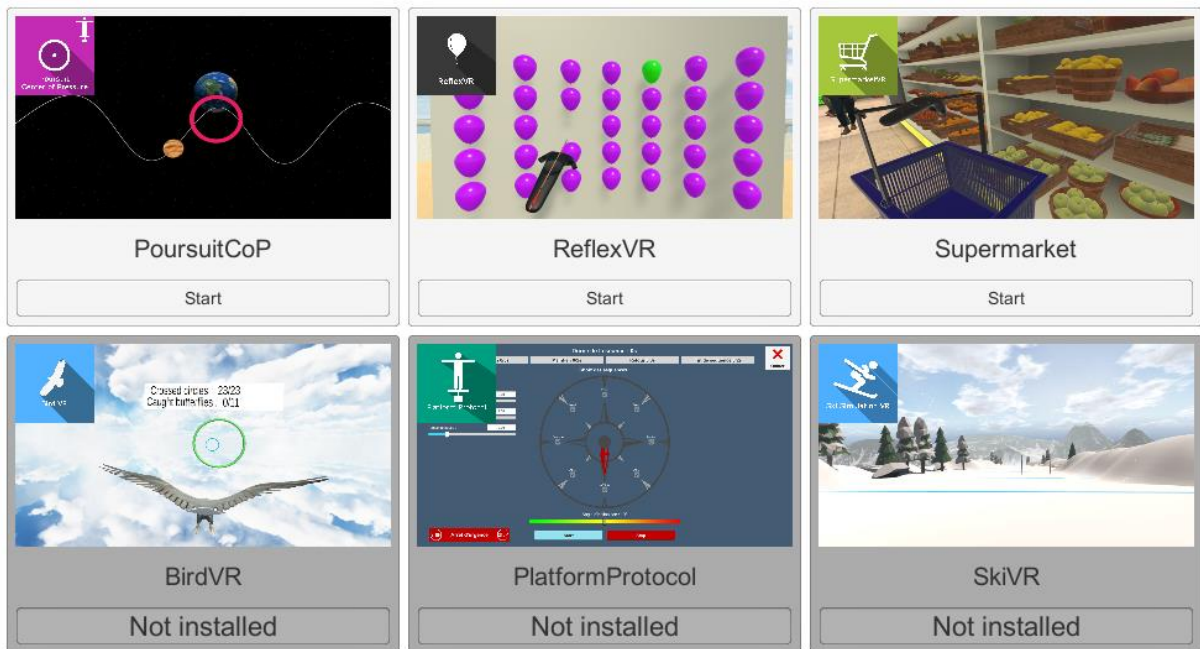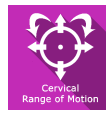
3. CERVICAL RANGE OF MOTION

3.1. Module field of application

This module is used to measure cervical spine articular amplitudes that patients can reach. The exercises available in this module allow patients to carry out three types of movement:

- Flexion and extension
- Right and left rotation
- Right and left tilt

This module also uses a button referenced in the shortcuts (key enter on the keyboard or the controller button) to measure patients' pain threshold.

3.2. Installing the patient

At the start of the exercise, patients should stay still (without moving the trunk, pelvis or legs) while aiming at the target in front of them.

Ideally, patients should be seated in a chair with their hands clasped behind their back to avoid thoracic/lower back compensation. A counter grip should be applied at shoulder level, especially when measuring tilts.

They must then follow the direction of the arrow, which depends on the exercise configuration (three movement types are possible), with their head and then return to the initial position.

Patients must indicate when pain appears by pressing the specific button, and then continue the movement to define the maximum articular amplitude.

3.3. Session settings

Amplitude measurements can be sequenced together by selecting automatic mode. In manual mode, you can switch from one exercise to another using the "enter" key on your keyboard.
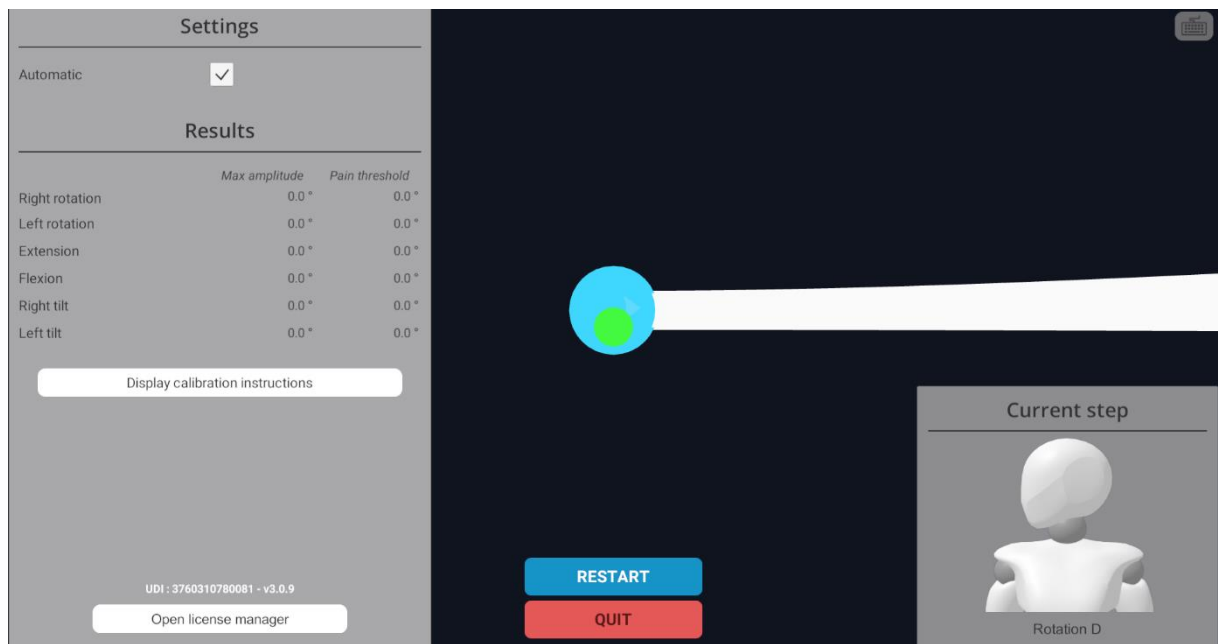
The Start/Quit buttons allow the environment to be played back or stopped entirely to adapt the experience to the patient's sensations.

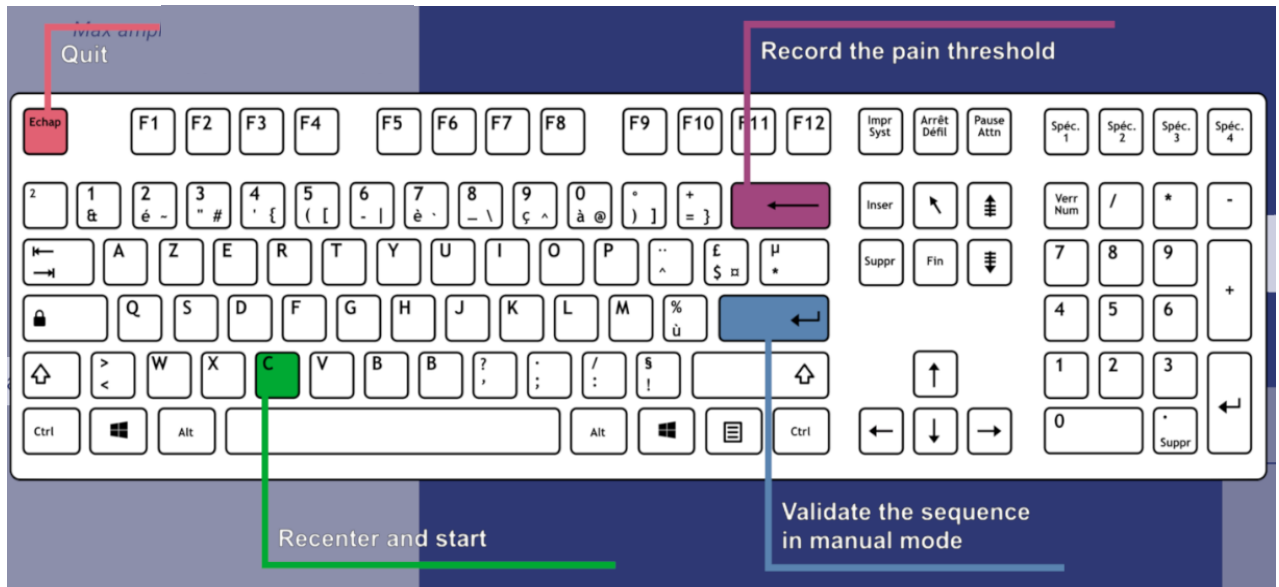To start or restart the amplitude measurement, press the "C" key on the keypad.

To measure the pain threshold felt by patients, press the "enter" key on the keypad or the controller button.

3.4.   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

Max ampl
Quit

Record the pain threshold

Recenter and start

Validate the sequence
in manual mode

Validate the sequence
in manual mode

Quit application

Recenter and start

3.5. Data processing

Data retrieval and analysis uses the Patient Management software.