REF **Optokinetic**

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

OPTOKINETIC is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. **Optokinetic** is a software used for the rehabilitation of balance and vestibular system disorders by stimulating the optokinetic reflex (horizontal, vertical or rotatory visual scroll in various possible environments)

INDICATIONS

Rehabilitation of balance disorders by stimulation of the optokinetic reflex

CONTRAINDICATIONS

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

FOR USE BY

Healthcare professionals: Physiotherapists; Neuropsychologists; ENT doctors; Neurologists; PM&R physicians (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

Virtual Reality Immersion is a powerful tool, especially for optokinetic stimulation, optical flow, motorway simulations, dynamic SVV etc.

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)

This type of rehabilitation must be undertaken progressively, especially in Virtual Reality where the stimulation is much more "powerful" than with traditional optokinetic stimulators.

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
- XBOX 360 Joysticks
- Posturography platforms (StaticVR or MotionVR)
- 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:

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

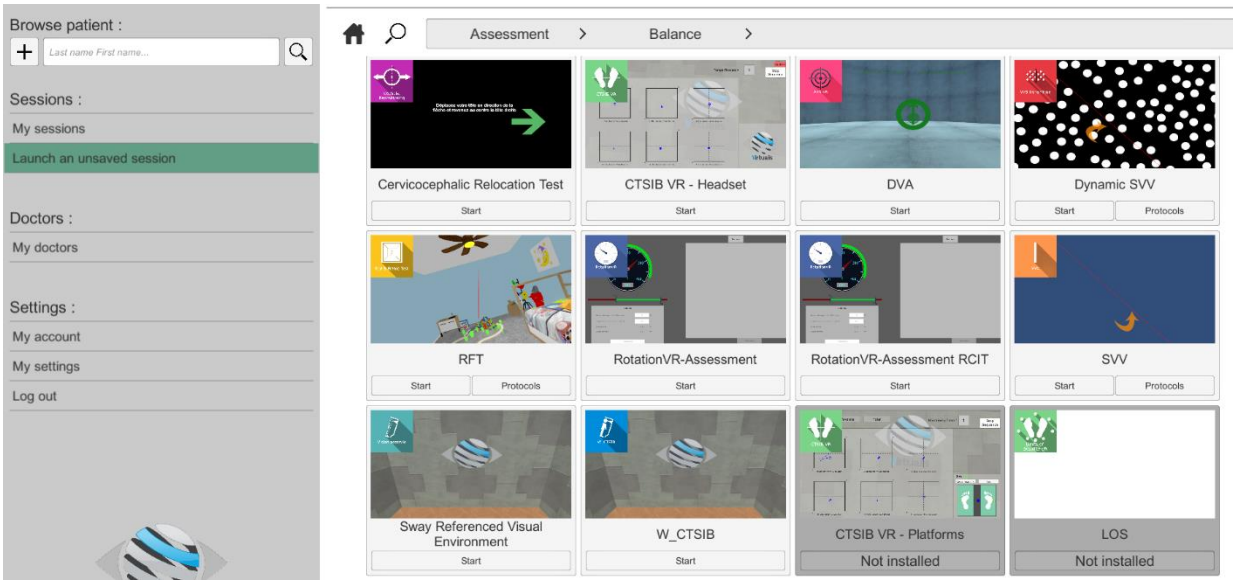
RAM
8 Go

2. USE of PATIENT MANAGEMENT

Once connected to the Patient Management software, you 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.

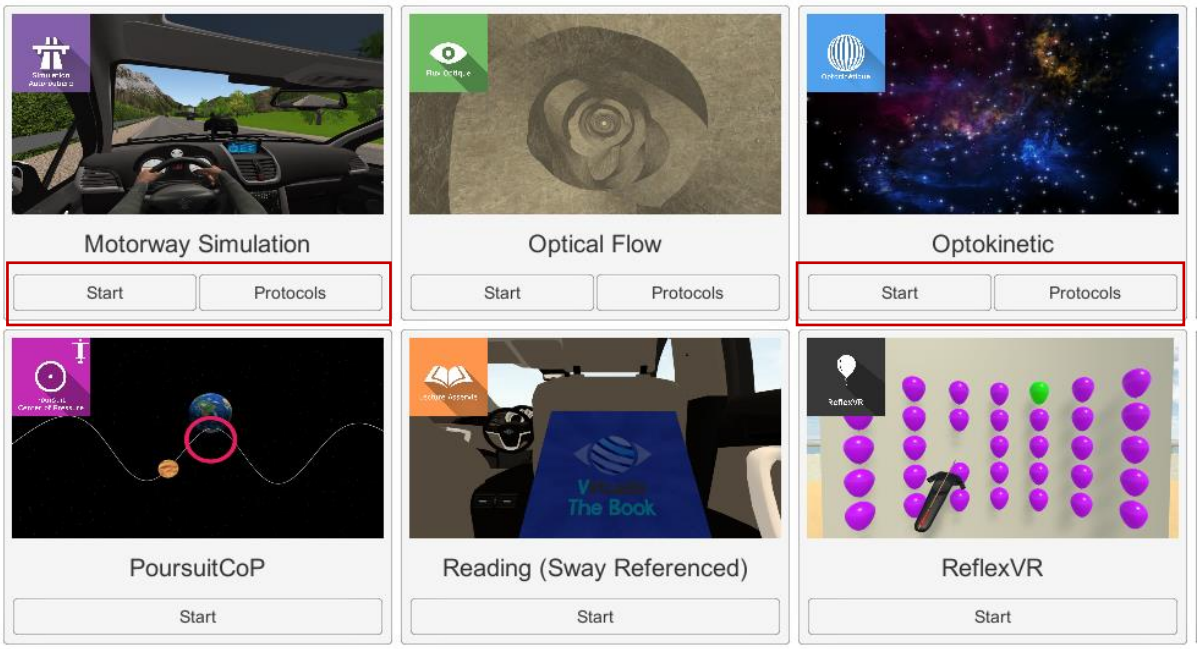
The softwares can be grouped according to criteria such as "Assessment" or "Rehabilitation" and then by pathology type: Neurology, Balance, Functional or Motion sickness.

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

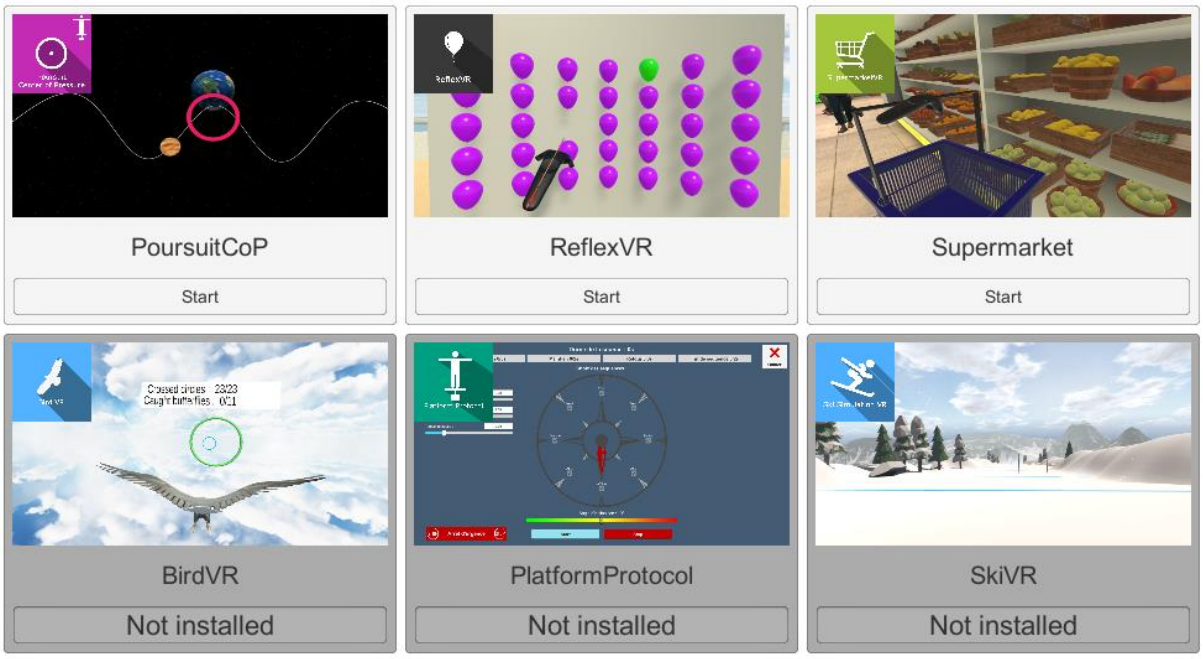


A number of softwares can be started either in ***manual mode***, by directly clicking the "Start" button, or in ***protocol mode*** by clicking the "Protocols" button.

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.

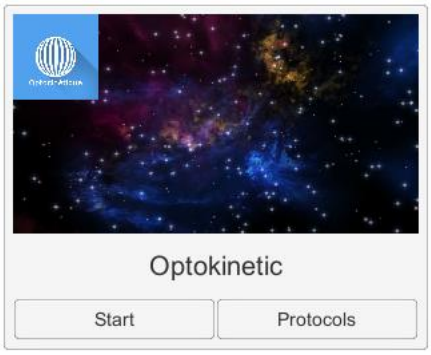


Softwares which are not included in your subscription package are grayed out. If you want to use them, please contact our sales department.



3. OPTOKINETIC

3.1. Start interface



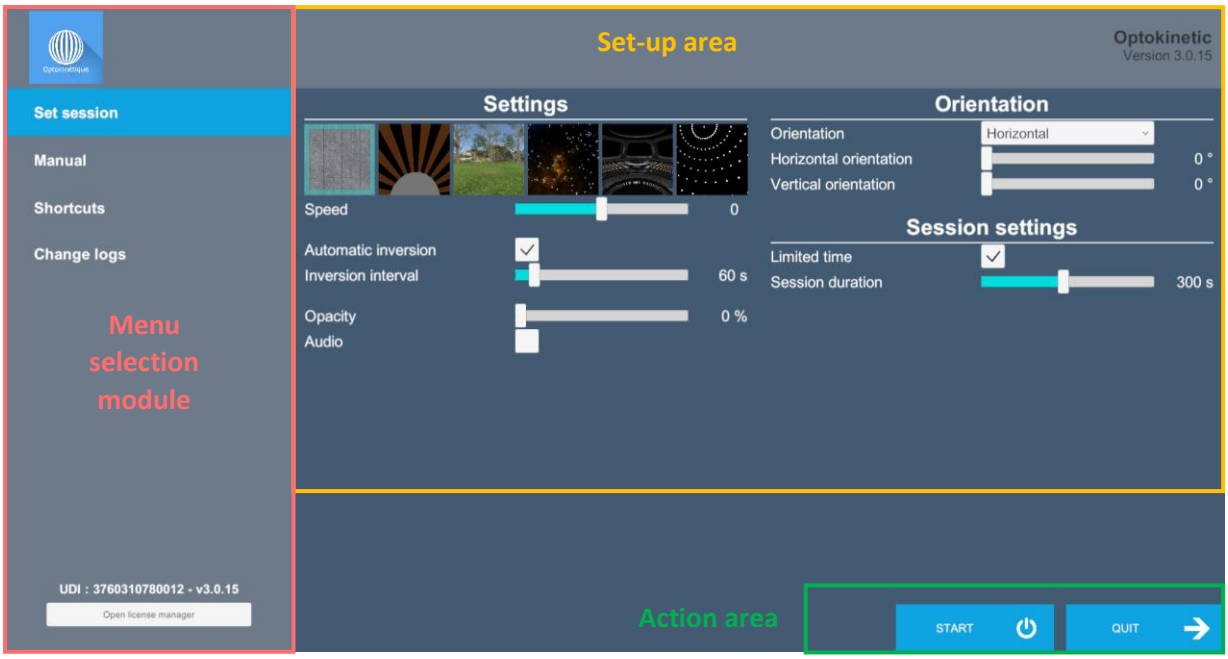
To start the Optokinetic software from Patient Management you have two possibilities: ***manual mode*** ("Start" button) or ***protocols***.

When launching the software in ***manual mode***, 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 "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.



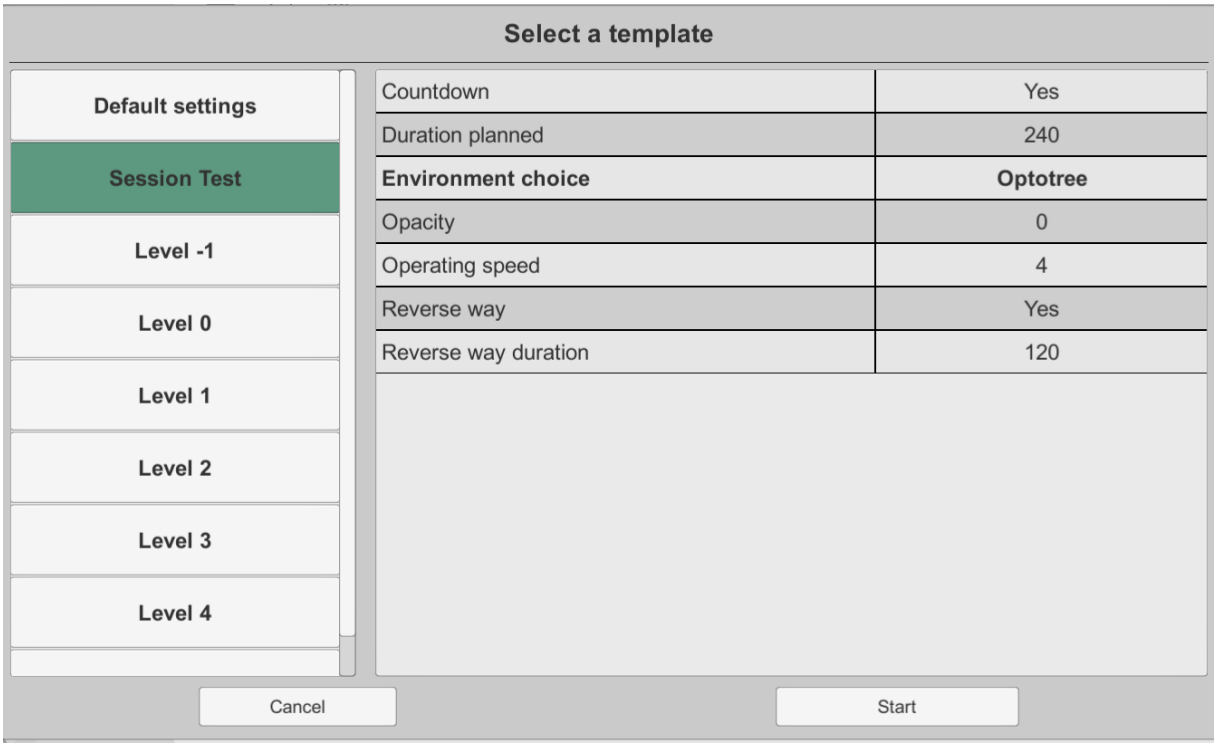
Once this button has been pressed, the software is launched, taking into account the specified settings. You can also modify a number of settings after the software has been launched, using the mouse, keyboard shortcuts or the joystick used as a remote control.

The Start / Pause and Quit buttons are used to Play / Pause the environment, or to stop it completely to adapt the experience to the patient's perception.

When you start the Optokinetic software from Patient Management in ***protocol mode***, you will arrive on a home page from which you can find a test session and seven protocols of difficulty levels ranging from level -1 to level 5.

It is recommended to start by a "session test" to measure patients' tolerance to the stimulation and the proposed VR environment.

For each proposed protocol the different settings are already in place. Just validate the selected protocol to start the application.



Once an environment has been selected, it launches in the headset, and you can see and track what is happening in your patient’s headset using the software window.

3.2. Software field of application

The Optokinetic software puts the patient in various environments which can be set in motion using the "speed" section.

These are simply a limited number of tips from the literature and our personal experience.

Indications:

- Lowering the Visual input weight in the patient's balancing strategy
- Treatment of visual dependence, PPPD, retinal slip intolerance

Complaints:

Patients disturbed by movement around them: movement of cars when crossing, crowds moving around them in shops for example, discomfort on escalators, when a vehicle passes in front of them (train, underground, tram) etc.

Visual Dependence often sets in naturally with age, progressively, and sometimes also appears suddenly after a vestibular disorder (neuritis, repeated Meniere's disease crises, sometimes BPPV) and almost systematically in balance disorders of central origin (after a stroke+++, Parkinson's, MS, etc...).

TIP: Optokinetic stimulation has no effect on spontaneous nystagmus (a totally different neural circuit).

Environment

It is strongly recommended to systematically start with a short 3 to 4-minute session using the **Optotree** environment **at 7° or 8°/s,** reversing the direction halfway (2 min). At the next session, ask the patient how their evening went. Sometimes minor disturbances (nausea, instability) may appear a few hours after the stimulation. Then gradually increase the duration to **10 to 15 minutes**.

3.3. Installing the patient

These are simply a limited number of tips from the literature and our personal experience.

Except in specific cases, prefer the standing position on stable ground. At a later stage, some use a foam block or pitched plane.

Stay in contact with the patient who is at risk of falling +++ during vertical stimulations, or install him in a closed and safe environment, such as a dynamic posturography platform fitted with a guardrail or safety harness.

3.4. Session settings

These are the initial settings, when the stimulation starts for a launch of the software in manual mode. Most of these settings can be changed at all times using the joystick (remote control) or keyboard shortcuts (see tab: Shortcuts).

Environment choice:

Defines the stimulation "scenery".

The stimulation "power" is progressive depending on the environment and orientation:

Environments:

- 3D Sphere: moderate disturbance
- Barany drum: more intended for research (configurable spatial frequency)
- Optotree: the least disturbing; horizontal ++ vection at low speed: 4 to 8 °/s
- OptoSpace: the most disturbing. The sky-line is gone. Vection can be horizontal, vertical or rotating.
- Optostation: Scrolling of a "space station" environment in a horizontal, vertical or rotational direction.
- Planetarium: Corresponds to the classic optokinetic ball environment, which can be largely configured.

TIP: Nebulae can be removed from the Optospace environment using the "W" key for a stimulation closer to the traditional "mirror ball" type of Optokinetics.

A bright spot (dynamic element in optokinetics) can be obtained using the controllers (see the "Shortcuts" tab). The patient will have to look for it and fix it while the VR environment is running.

Speed

Environment rotating speed; by convention, anticlockwise rotations are negative and clockwise rotations are positive.

TIP: For an optimum vection sensation, prefer low speeds (4 to 8 °/s) during horizontal stimulations. To cause anteroposterior instability, prefer moderate speeds (15 to 30 °/s) for vertical rotations.

Orientation

A rotation can be selected on a predefined axis: Vertical (X-axis), Horizontal (Y-axis), or Rotational (Z-axis), or on a custom axis. For "sphere" type environments, the tilt can be adjusted using the Xbox joystick Pad.

Horizontal Angle: The axis that will "move" the environment forwards or backwards, in the sagittal plane

Vertical Angle: The axis that will "move" the environment in the frontal plane

The Optotree orientation cannot be modified (stimulation realism)

TIP: The choice of orientation has a strong impact on the patient's tolerance to stimulation and induced instability.

Orientation: Horizontal: "Low" disturbance

Vertical: Moderately to highly disturbing (Instability++, risk of falling)

Rotatory: Strong to extreme disturbance (to be reserved for certain cases only)

Opacity

Allows the stimulation to appear progressively for the most sensitive patients

Varies the transparency of the environment (adds a more or less opaque filter in front of the patient's eyes).

Automatic inversion

This is used to automatically reverse the rotation direction every X seconds.

Click the corresponding box to activate it and select a value in seconds using the cursor.

Audio

This is used to add a sound following the environment rotation

Limited time

This is used to define the session duration

Coupling

The image is coupled to the head movements. The image appears "stabilized" in front of the patient and tilts following his own head tilts.

Stripe frequencies (for the Barany drum environment)

This is used to adjust the stripe width using the cursor

Light settings (for the Optospace and Planetarium environment)

Number of stars

The number of stars can be adjusted using the cursor

Star size

This is used to adjust the stars' diameter using the cursor

Spacing of points

The distance between points can be adjusted using the cursor

Brightness

Brightness can be adjusted using the cursor

Size of points

The size of points can be adjusted using the cursor

Room brightness

Activating this setting is used in order to see the room

Room settings

Environment

There are two types of environments: room and sphere

In the "sphere" environment, the size of the sphere can be adjusted using the cursor

In the "room" environment, the distance between the patient and the front wall, the left wall and the right wall can be customized using the cursor

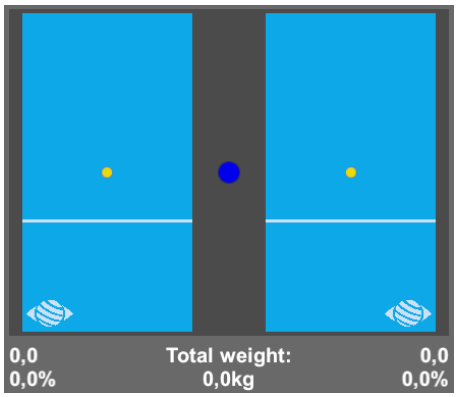
StaticVR settings

Raw data sent by the platforms

Yellow dots: Center of Pressure (CoP) of each foot

Blue dot: Overall Center of Pressure (CoP)

The weight distribution for each foot is displayed



Smoothed data & settings:

Tare

Platform reset (must be carried out when empty)

Smoothing

Smoothing force applied to the data

Sensitivity

Multiplier applied to the data received

Decrease to reduce motion sensitivity

MotionVR settings

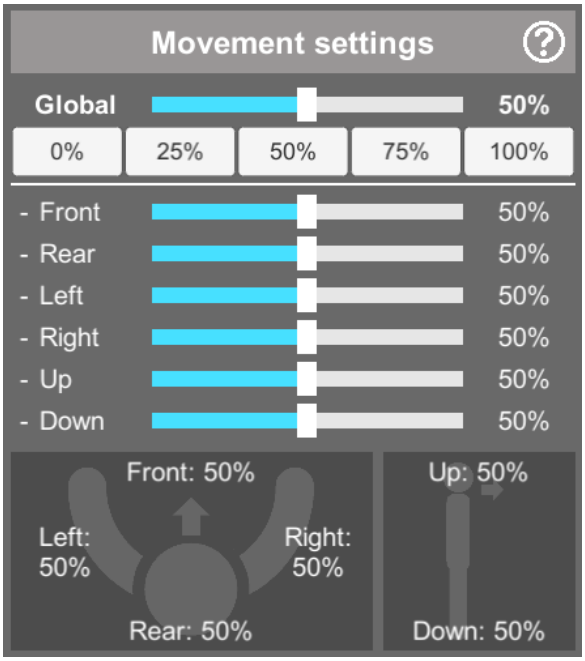
Movement settings

Platform amplitude values can be defined either by using the cursor or by selecting one of the proposed values by simply clicking on the corresponding button.

You can select an overall or per-axis movement amplitude, the presets provide a smooth transition.

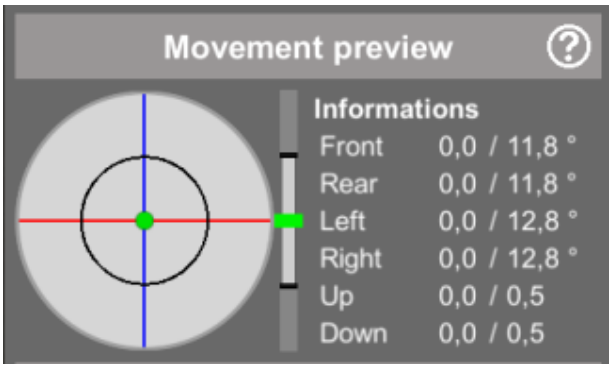
For example:

- To work in anteroposterior mode, reduce the left and right amplitude
- To work in mid-lateral mode, reduce the front and rear amplitude

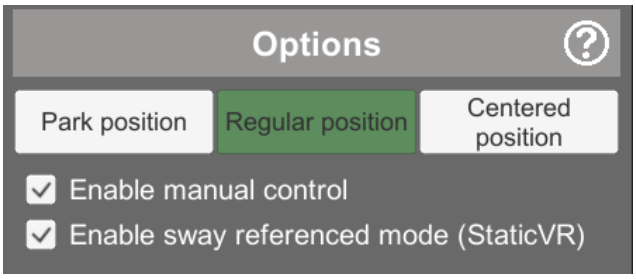


Movement preview

This is used to view the platform tilt, height and amplitude settings (the action area is delimited by a black circle).



Options



Platform positions

Park position: forces the platform to ground level. The height of the platform is set to the minimum.

Regular position: allows the platform to move normally, as provided for in the software

Centered position: forces the platform into a horizontal position at its operating height

Enable manual control

This is used to move around using the arrow keys on the keyboard and the "+ " and "-" keys on the numeric keypad (up and down).

Enable sway referenced mode (for StaticVR platforms)

The platform movement is coupled to the patient's center of gravity

If you press the emergency stop button, the platform will freeze in its current position.

A window opens and the following message appears

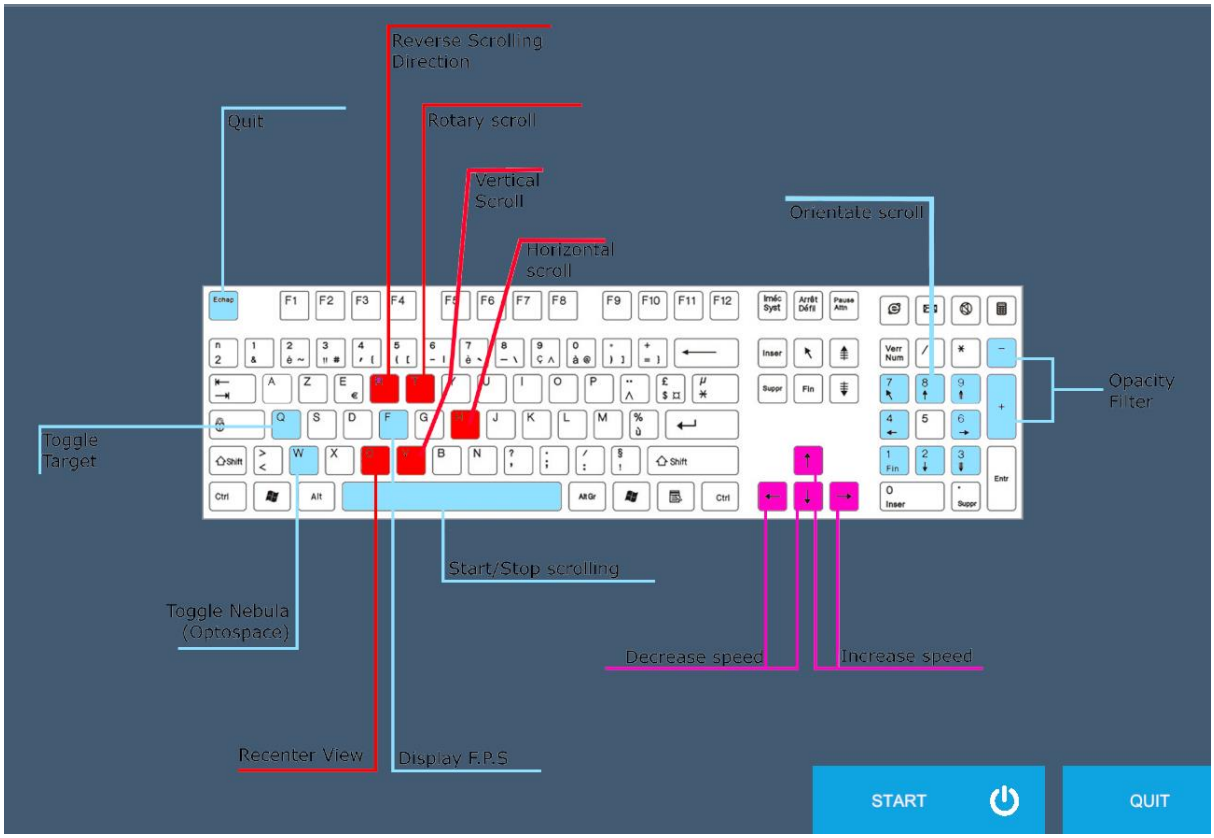
Warning:

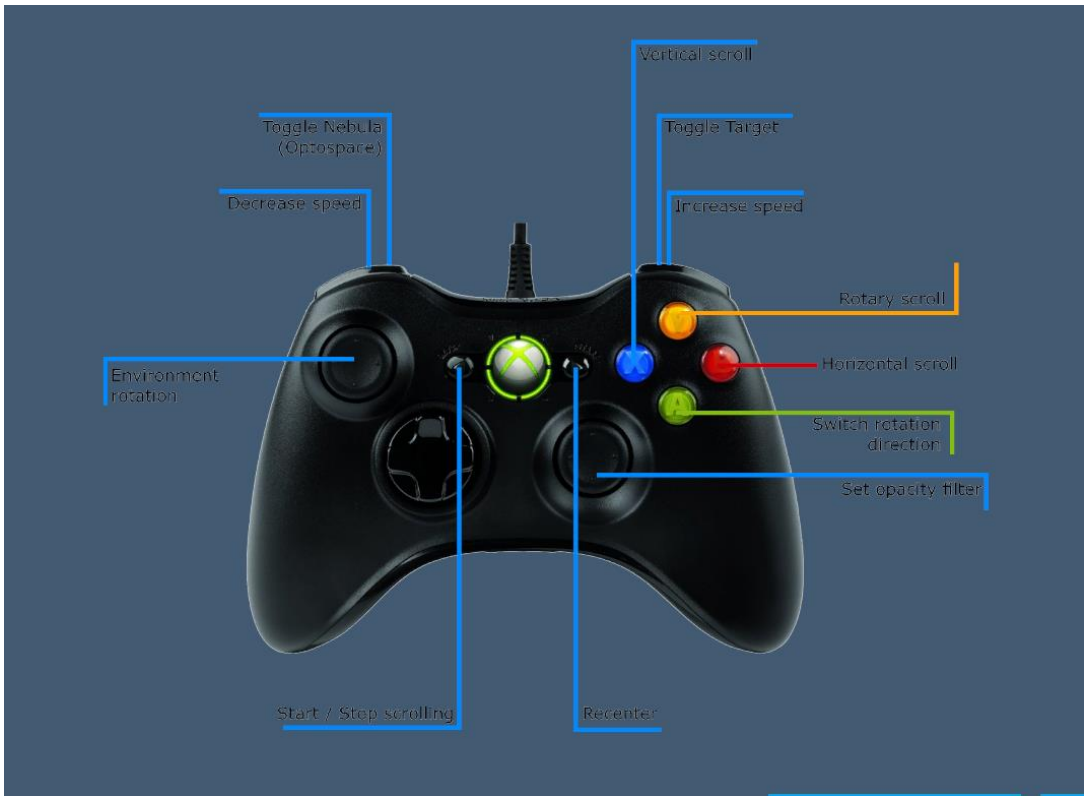
Stopping the software or changing the window may cause the platform to reset to the default position and cause movement that could be dangerous for the patient. It is therefore advisable not to touch the computer again until you have secured the patient when the emergency stop is triggered.

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




Vertical scroll
Toggle Nebula (Optospace)
Toggle Target
Decrease speed
Increase speed
Rotary scroll
Horizontal scroll
Environment rotation
Switch rotation direction
Set opacity filter
Start / Stop scrolling
Recenter


Laser
VIVE

3.6. Data processing

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