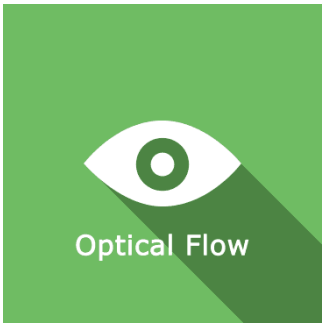


REF **OPTICAL FLOW**

CE Class I Medical Device

User manual

Distribution mode

Available for direct download at

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

Use under licence

VIRTUALIS

Avenue de l'Europe - 34830 CLAPIERS - Tel. 09 80 80 92 91

DESCRIPTION

OPTICAL FLOW 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. **Optical Flow** is a software used for balance disorder rehabilitation using linear or curved visual scrolling.

INDICATIONS

Rehabilitation of visual flow scrolling disorders

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

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 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)

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.

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.

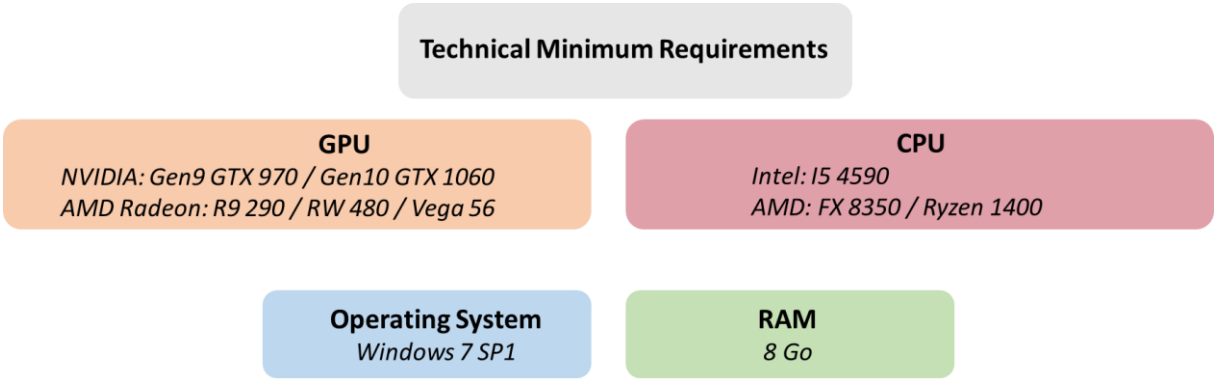
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

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
- Dynamic posturography platform (MotionVR)
- USB HUB

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



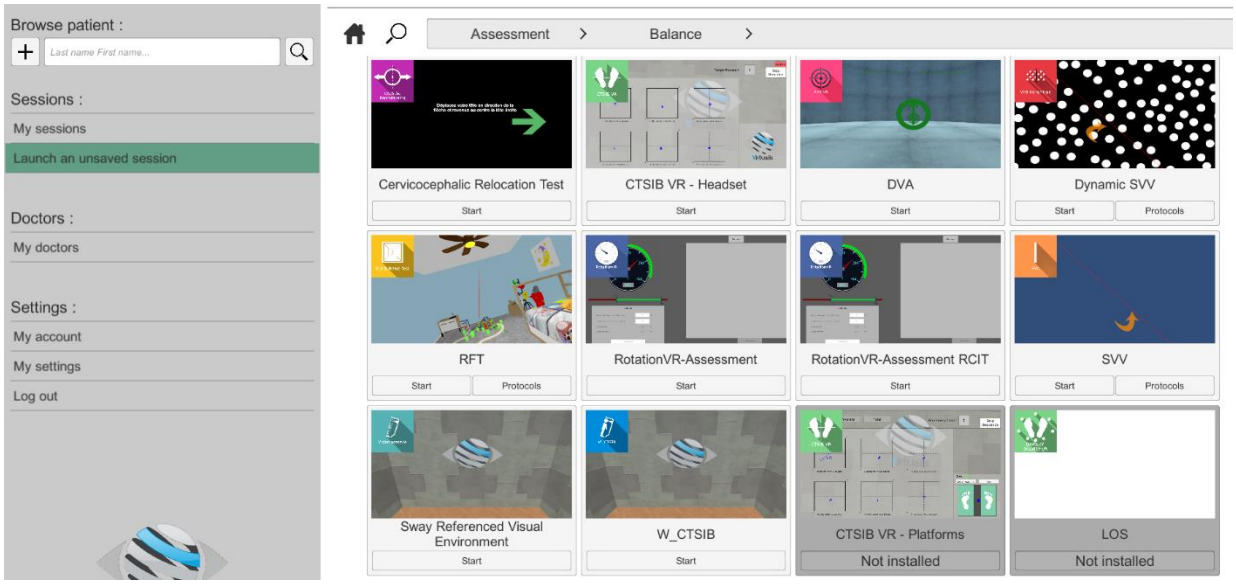
2. USE OF PATIENT MANAGEMENT

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, split into different modules, 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 Kinetosis.

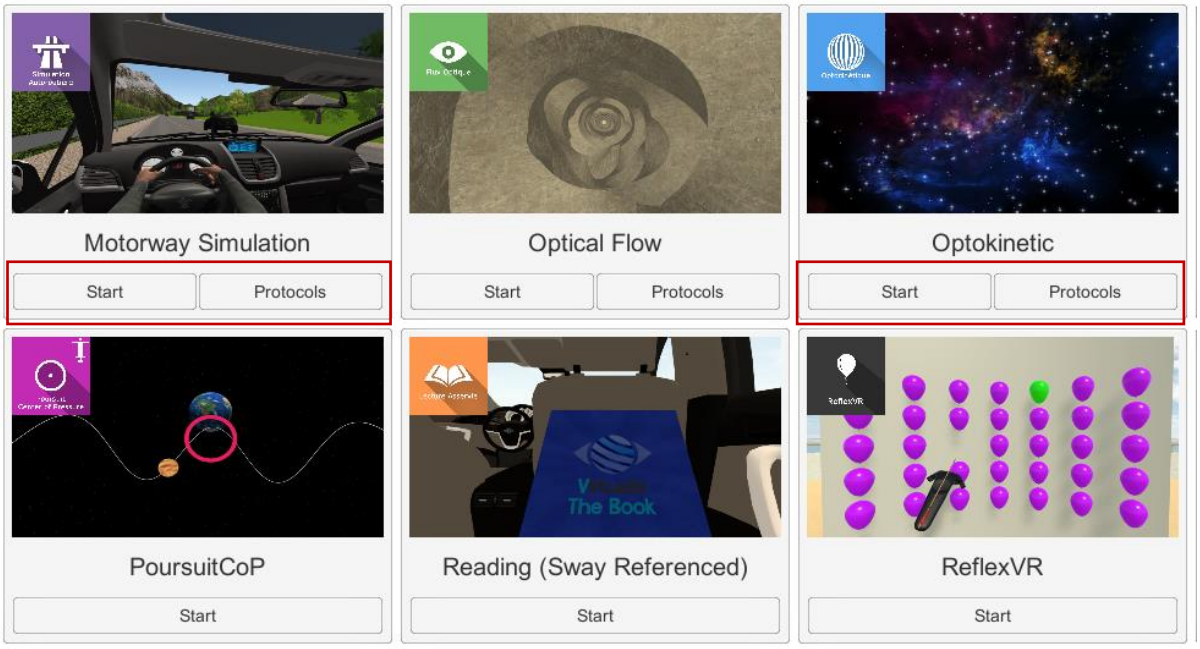
RVR software contains the following modules: Optokinetics, Optical Flow, Motorway Simulation, SVV, Dynamic SVV, Rod & Frame Test and Coupled vision.

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

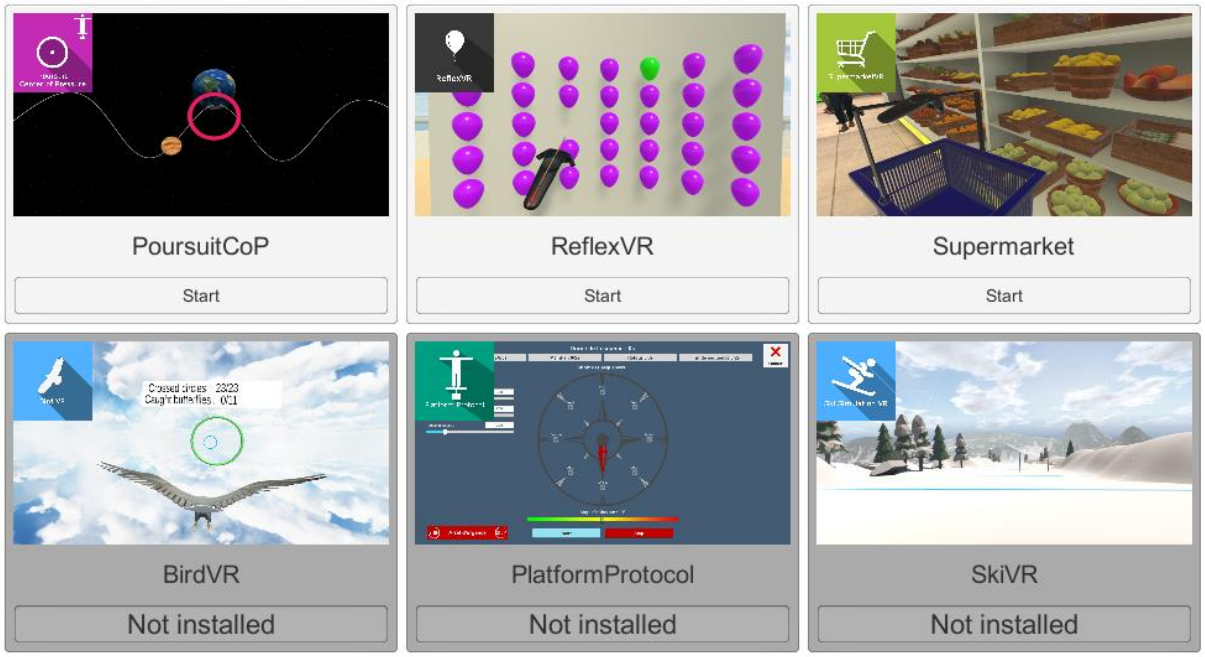


Some software can be started either in ***manual mode***, by directly clicking the "Start" button, or in ***protocol mode*** by clicking the "Protocols" button.

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.

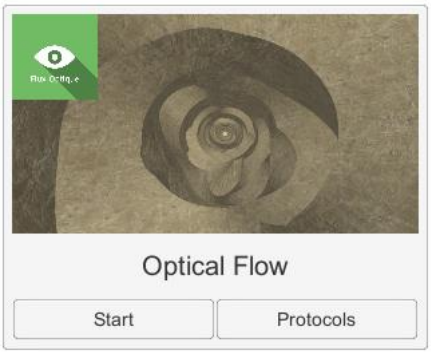


Software that is not part of your subscription package is greyed out. If you want to use it, please contact our sales department.



3. OPTICAL FLOW

3.1. Start interface



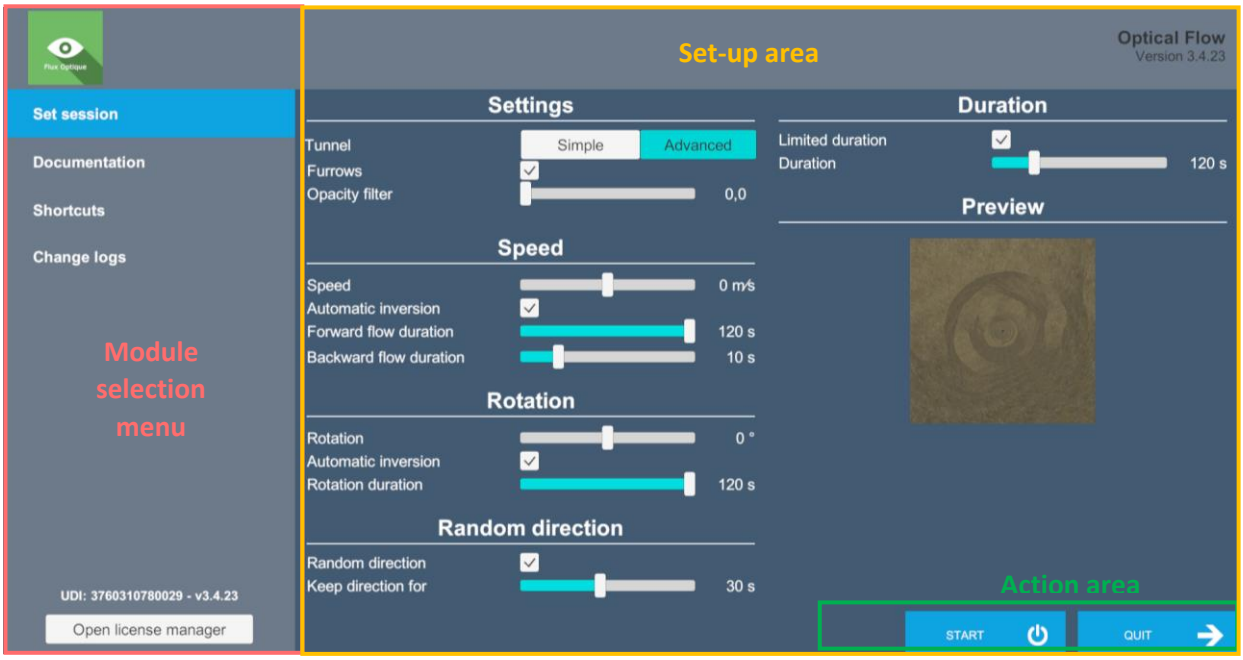
To start the Optical Flow software from Patient Management you have two possibilities: start in ***manual mode*** ("Start" button) or ***protocols***.

When the software is started in ***manual mode***, 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.

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.



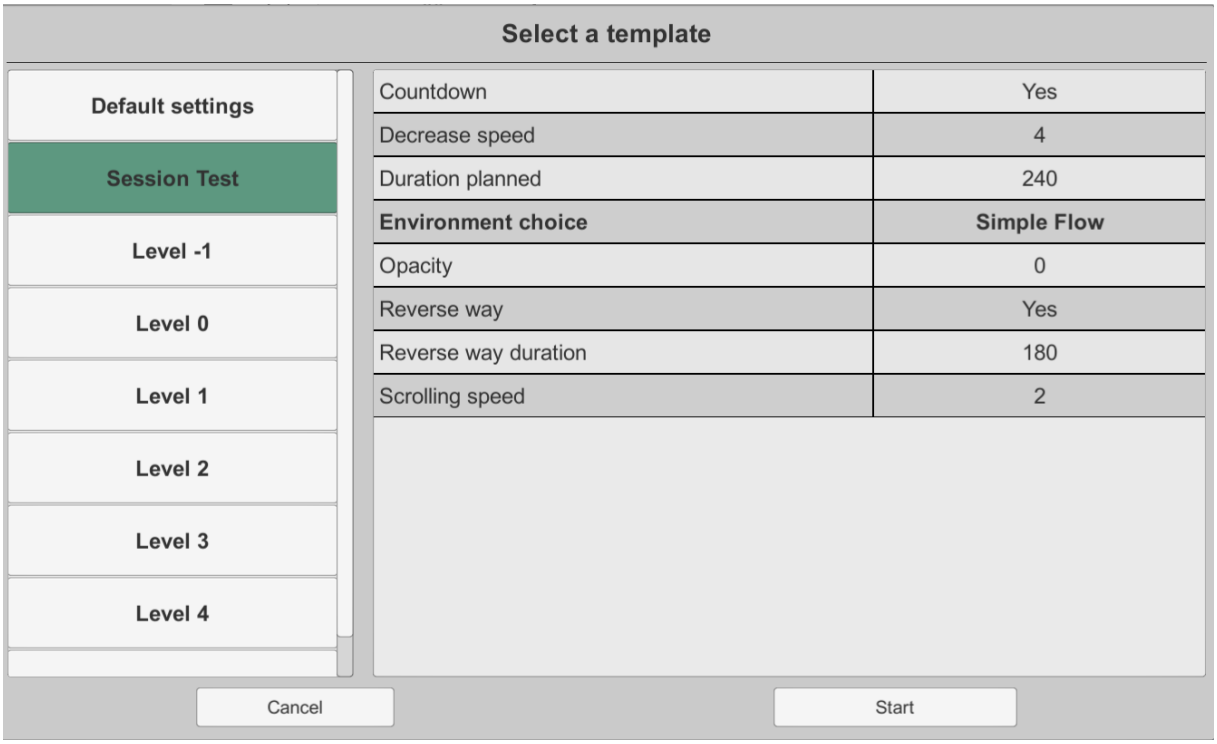
Once this button is pressed, the module starts by taking into account the specified settings. You also have the possibility to modify some settings when the module has been launched, using the mouse.

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

When you launch the Optical Flow 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 "test session" to measure patients' tolerance to the stimulation and the proposed VR environment.

For each proposed protocol, the different options are already set. Just validate the selected protocol to launch the application.



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. Module field of application

Indications:

- Decrease the importance of Visual input in the patient's balancing strategy
- Treatment of Visual Dependence - Scrolling Syndrome
- Otolith disorders
- Work on proprioception
- Neurological balance disorders (e.g. Parkinson's disease)
- Support transfers, Posture correction

Complaints:

Patient disturbed by visual scrolling: supermarket shelves, lights in tunnels, sensation of reversing when stopping in a car, etc.

Can be used as one of the tools in the treatment of certain forms of otolith syndrome.

3.3. Installing the patient

These are simple, limited numbers of tips drawn from the literature and from our personal experience

Except in special cases, prefer the standing position. The use of a foam block can direct the re-education towards more "posture/Proprioception" type work, mainly with the "Advanced" environment by varying the turn tilts.

Stay in contact with the patient who is at risk of falling +++ during vertical stimulations, or install them 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).

Choice of environment

- Linear Flow: Radial Optical Flow, linear, without turn possibilities, 3D elements (asteroids) can be activated/deactivated using the "Q" key (See Shortcuts).
- Advanced Flow: Used to orientate the tunnel with bends to strengthen balance, Proprioception, Posture work

Furrows

Enabling this setting is possible for the "advanced" tunnel.

Used to have a less smooth texture of the scenery

Opacity

Allows the stimulation to appear progressively for the most sensitive patients

Varies the transparency of the environment.

Speed

Scenery scrolling speed either backwards or forwards

Automatic inversion

Used to program changes in the scrolling direction by indicating a *forward* and *backward* time

CAUTION: The inversion causes significant anteroposterior postural reactions, risk of falling +++ .

One of the possible tools in the treatment of patients suffering from false linear otolithic sensations

Rotation

Scenery rotation backwards or forwards; by convention, anticlockwise rotations are negative and clockwise rotations are positive.

Automatic reversal allows the direction of rotation to be programmed by indicating a time.

Random orientation

Sets the tunnel orientation randomly for a given time. Be sure to select at least two directions by clicking on the corresponding arrows (to deactivate a direction click on the arrow again) to see the effects of this setting. These settings can be varied during the session (see shortcuts).

Session duration

The session duration can be defined for an imposed duration by checking the "Limited time" box and indicating the required value using the cursor.

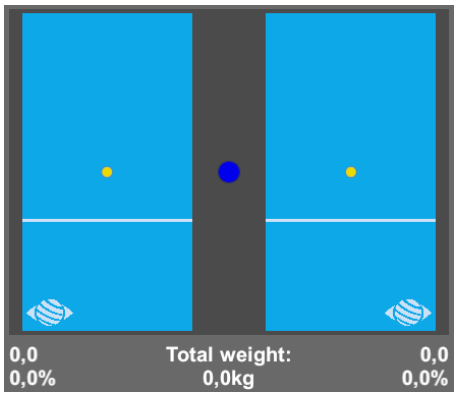
StaticVR settings

Raw data sent by the platforms

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

Blue dot: Global 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 received data

Decrease to reduce motion sensitivity

MotionVR settings

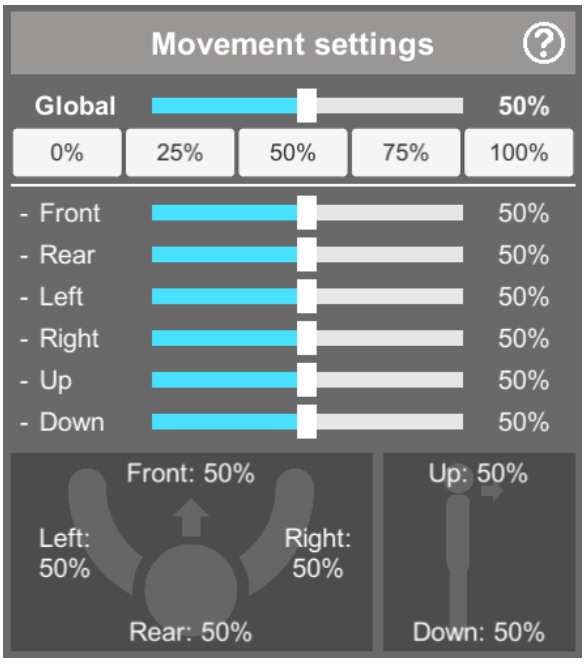
Movement settings

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

There is the possibility to choose an overall or per-axis movement amplitude, the presets provide a smooth transition.

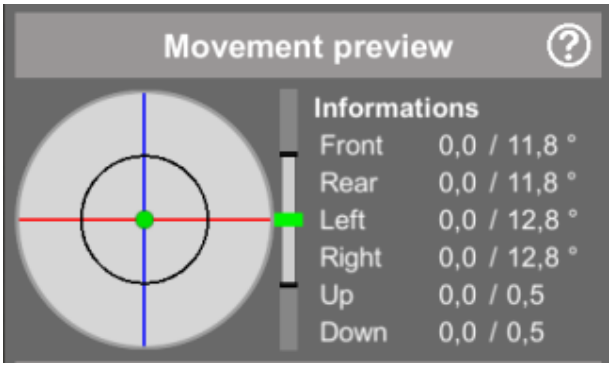
For example:

- To work in anteroposterior mode, reduce the left and right amplitude
- To work in the mid-lateral position, reduce the forward and backward amplitude

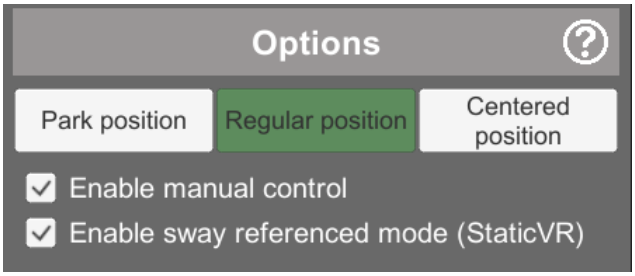


Movement preview

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 level with the ground. 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 to move into a horizontal position at its operating height

Enable manual control

Use the arrow keys on the keyboard and the "+" and "-" keys on the numeric keypad (up and down) to move around.

Enable sway referenced mode (for StaticVR platforms)

The platform movement is controlled by the patient's center of gravity

The button on the launch interface at the bottom right provides access to other advanced options:

Check the corresponding box to **"Enable development options"**

Two types of display are possible:

- [StaticVR] Display graphics
- [StaticVR] Display port status

These boxes are development options used to control devices connected to the computer. It is not advisable to use them (slows down the software).

Recording Options:

You have the possibility of choosing the type of data to be recorded by ticking the corresponding box:

StaticVR:

- Raw data
- Smoothed data

MotionVR

- Gross position (pitch & height)

Select the location on the computer to save the data and press the "Start Recording" button

If you press the “emergency stop” button, the platform freezes in its current position.

A window opens and the following message appears

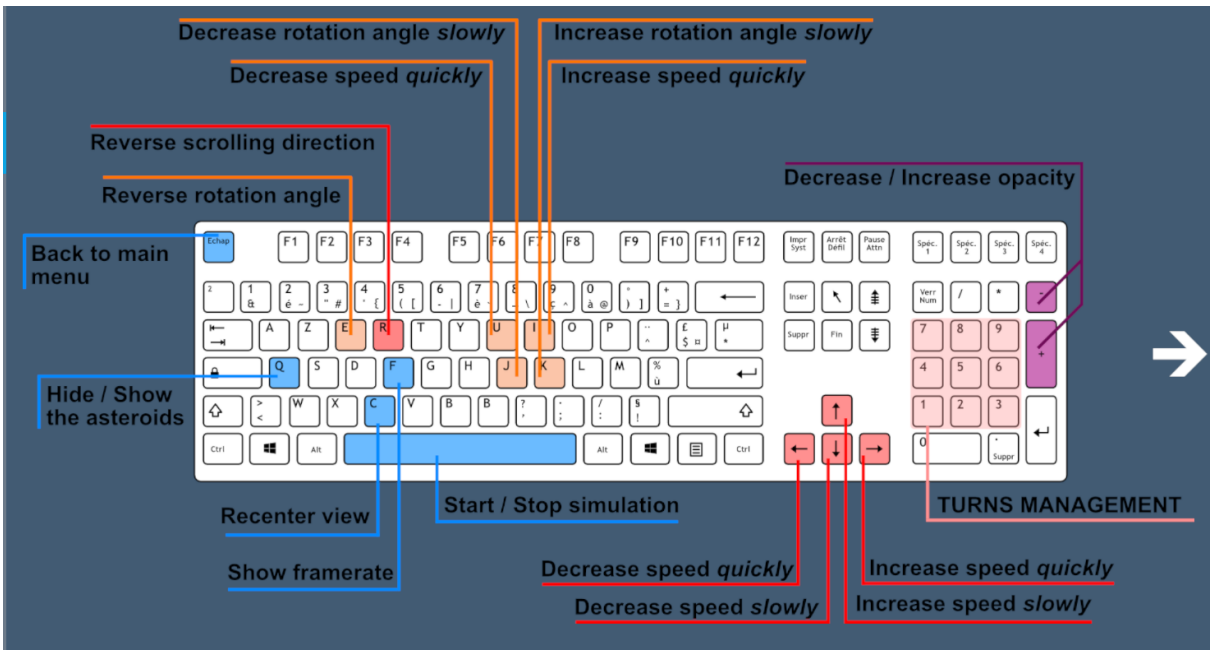
Warning:

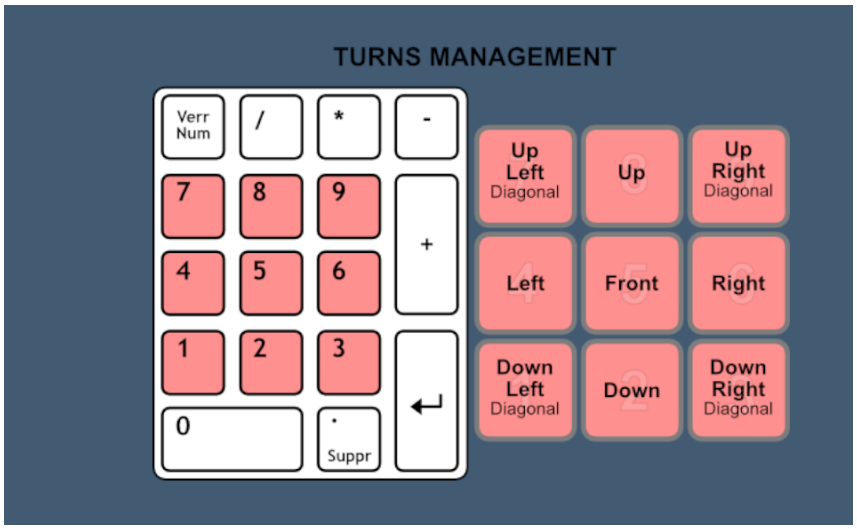
Stopping the software or changing the window may cause the platform to reset to the default position and cause movement that could be dangerous for the patient. It is therefore advisable not to touch the computer again until you have secured the patient when the emergency stop is triggered.

3.5. Shortcuts

Keyboard or joystick shortcuts can be accessed in two ways:

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


Decrease rotation angle slowly
Increase rotation angle slowly
Decrease speed quickly
Increase speed quickly
Reverse scrolling direction
Reverse rotation angle
Decrease / Increase opacity
Back to main menu
Hide / Show the asteroids
Recenter view
Start / Stop simulation
TURNS MANAGEMENT
Show framerate
Decrease speed quickly
Increase speed quickly
Decrease speed slowly
Increase speed slowly


TURNS MANAGEMENT
Verr Num
Up Left Diagonal
Up
Up Right Diagonal
Left
Front
Right
Down Left Diagonal
Down
Down Right Diagonal
Suppr


Decrease rotation angle quickly
Increase rotation angle quickly
Decrease speed quickly
Increase speed quickly
(Press) Recenter flow
(Move) Turns management
Reverse rotation angle
Hide / Show the asteroids
Reverse scrolling direction
Decrease / Increase rotation angle slowly
(Press) Reset simulation
(Move) Decrease / Increase opacity
Decrease / increase speed slowly
Recenter view
Start / Stop simulation

3.6. Data processing

Data retrieval and analysis uses the Patient Management software.