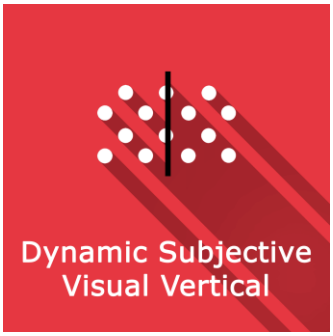

REF

Dynamic Subjective Visual Vertical

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

Dynamic Subjective Visual Vertical (DSVV) 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. **DSVV** is a software used to assess the perception of verticality with optokinetic disturbance.

INDICATIONS

Assessment of the perception of verticality in the context of balance disorders or neurological diseases (e.g. strokes).

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.

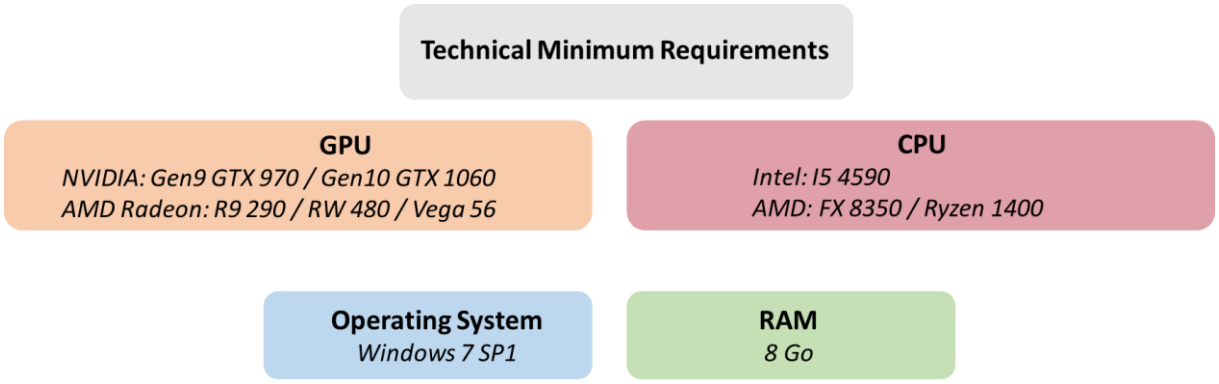
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

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
- Thrustmaster T150 Wheel and pedals
- 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:

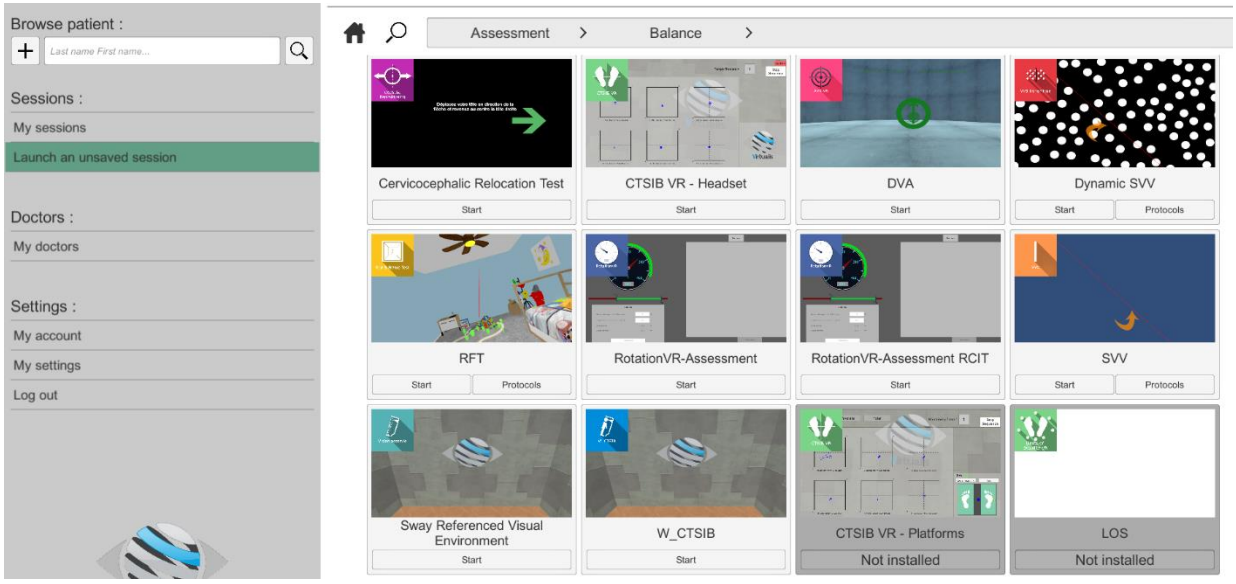


2. USE OF PATIENT MANAGEMENT

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, split into different modules, as well as the other Patient Management functions.

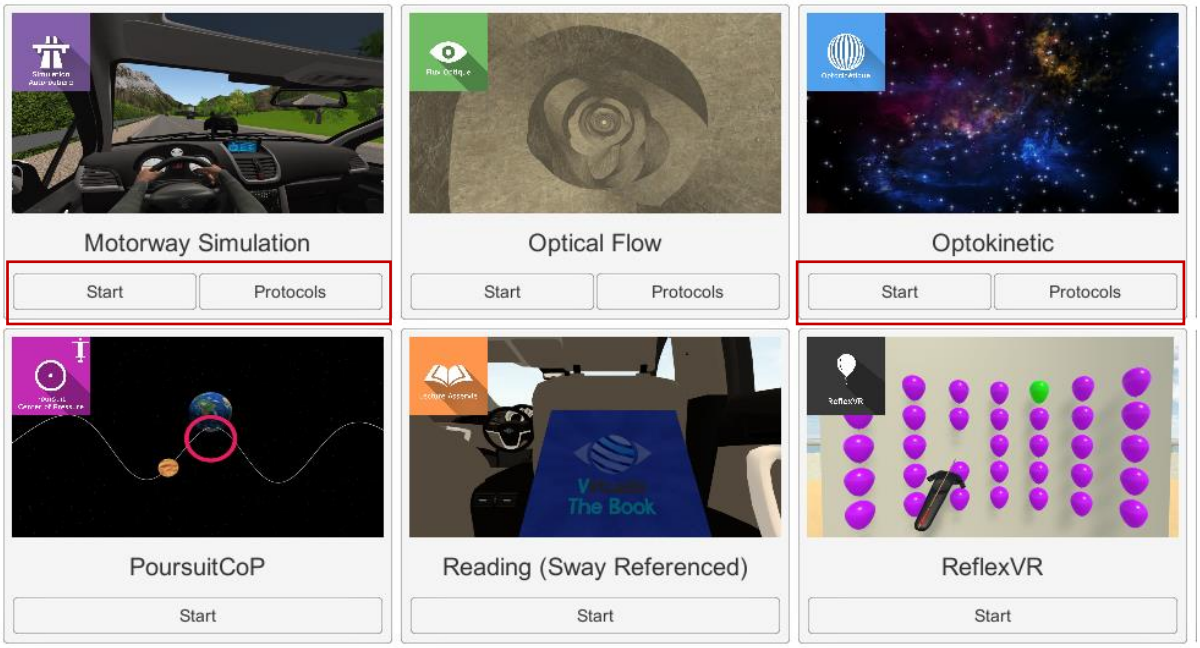
The software can be grouped according to criteria such as "Assessment" or "Re-education" and then by pathology type: Neurology, Balance, Functional or Kinetosis.

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

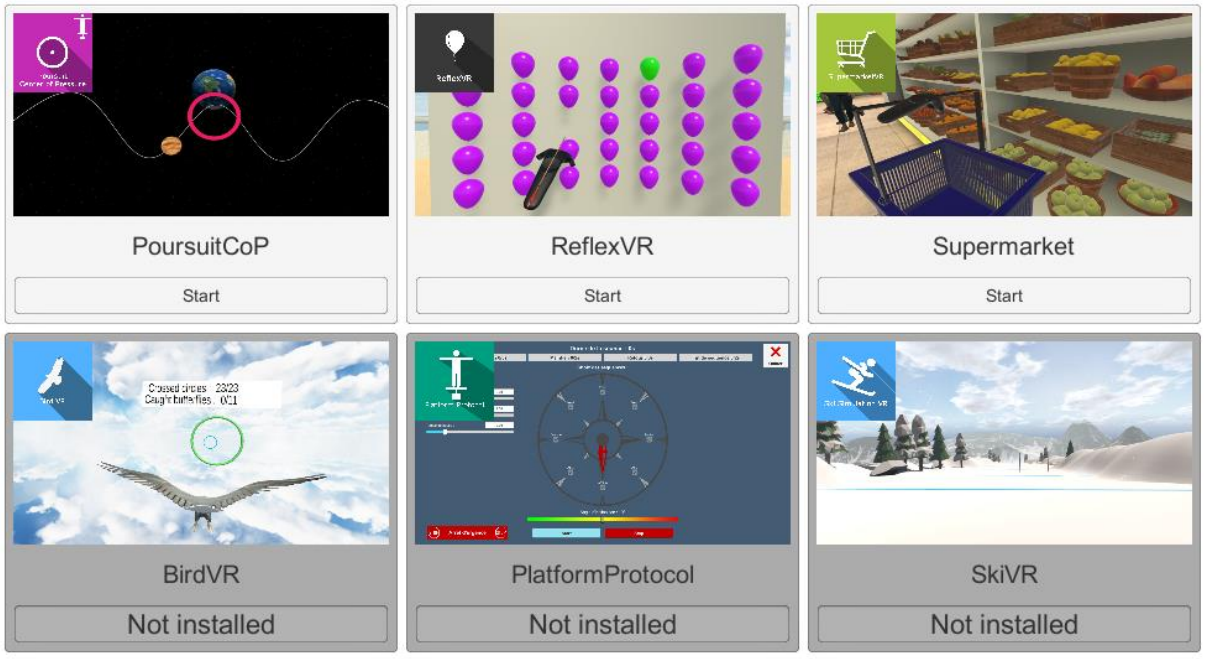


Some software can be started either in ***manual mode***, by directly clicking the "Start" button, or in ***protocol mode*** by clicking the "Protocols" button.

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.

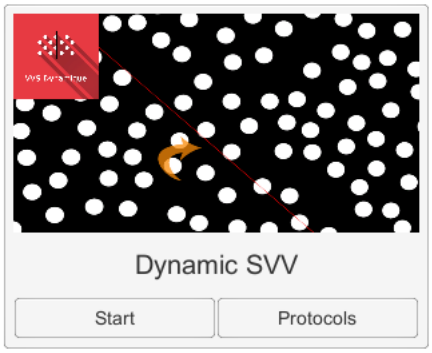


Software that is not part of your subscription package is greyed out. If you want to use it, please contact our sales department.



3. DSVV (Dynamic Subjective Visual Vertical)

3.1. Start interface



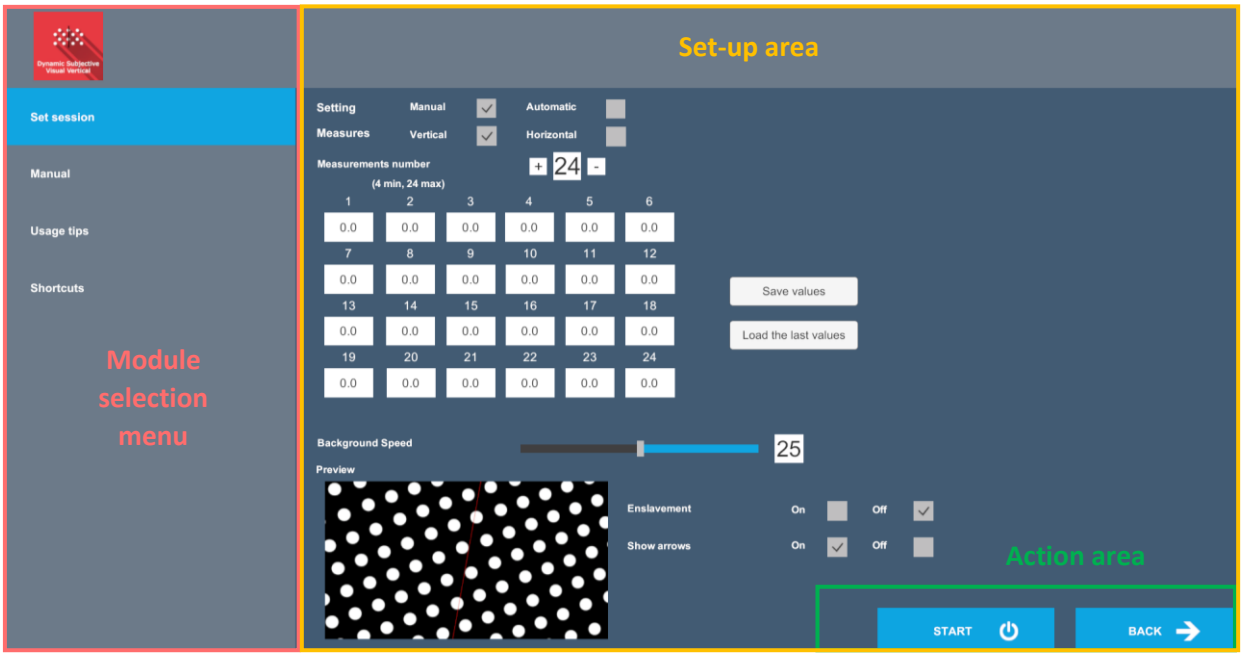
To start the DSVV software from Patient Management you have two possibilities: ***manual mode*** ("Start" button) or ***protocols***.

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.

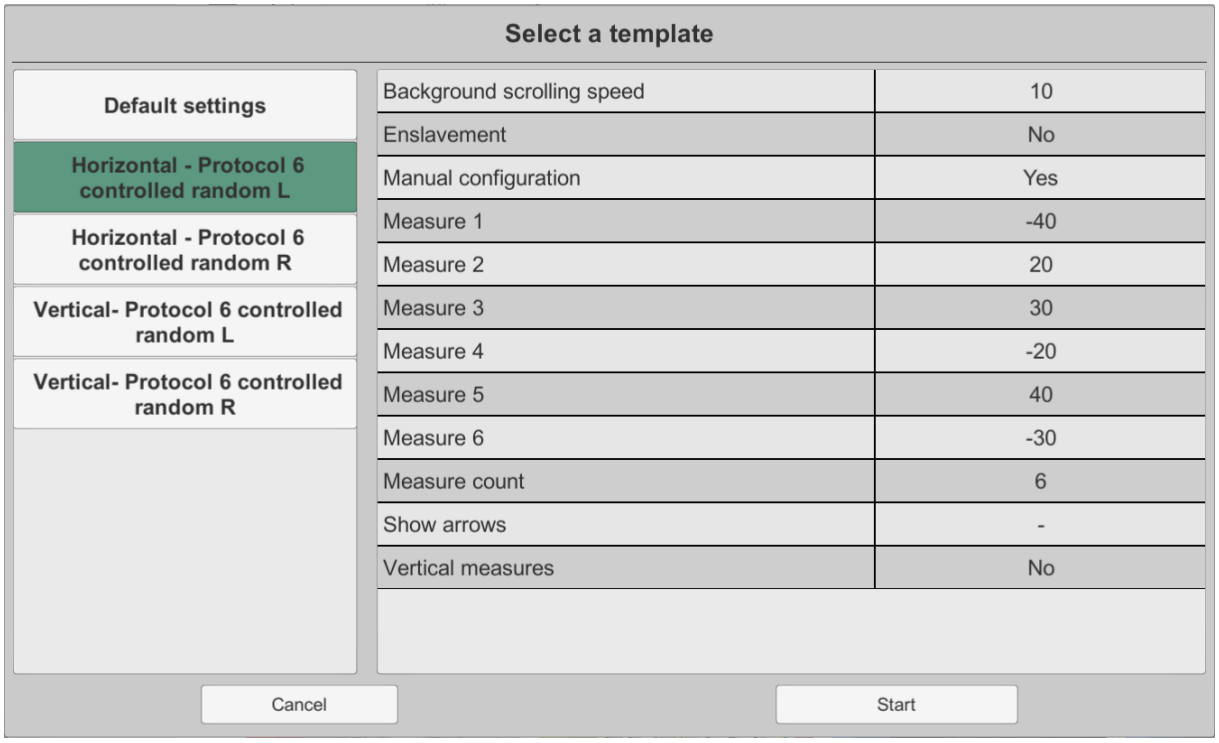


Once this button is pressed, the module starts by taking into account the specified settings. You also have the possibility to modify some settings when the module has been launched, using the mouse.

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

When you start the DSVV software from Patient Management in ***protocols mode*** you arrive on a home page from which you can find four protocols for horizontal or vertical (left and right), each protocol making it possible to take six measurements.

For each proposed protocol, the different options are already set. 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 patients' headset from the software window.

3.2. Module field of application

There are many different protocols in the literature

It is often recommended to take:

- More than 6 measurements (8 to 10)
- 40° start angle (or -40)
- Alternating Sequence
- Variable speed

It has been recommended (C. Lopez, M. Lacour et Al, "Perception de la verticale en présence d'informations visuelles dynamiques, Efficiences et Déficiences du contrôle Postural", Solal 2006) that the patient should be allowed 10 seconds before each measurement to "adapt" to the visual stimulus.

3.3. Installing the patient

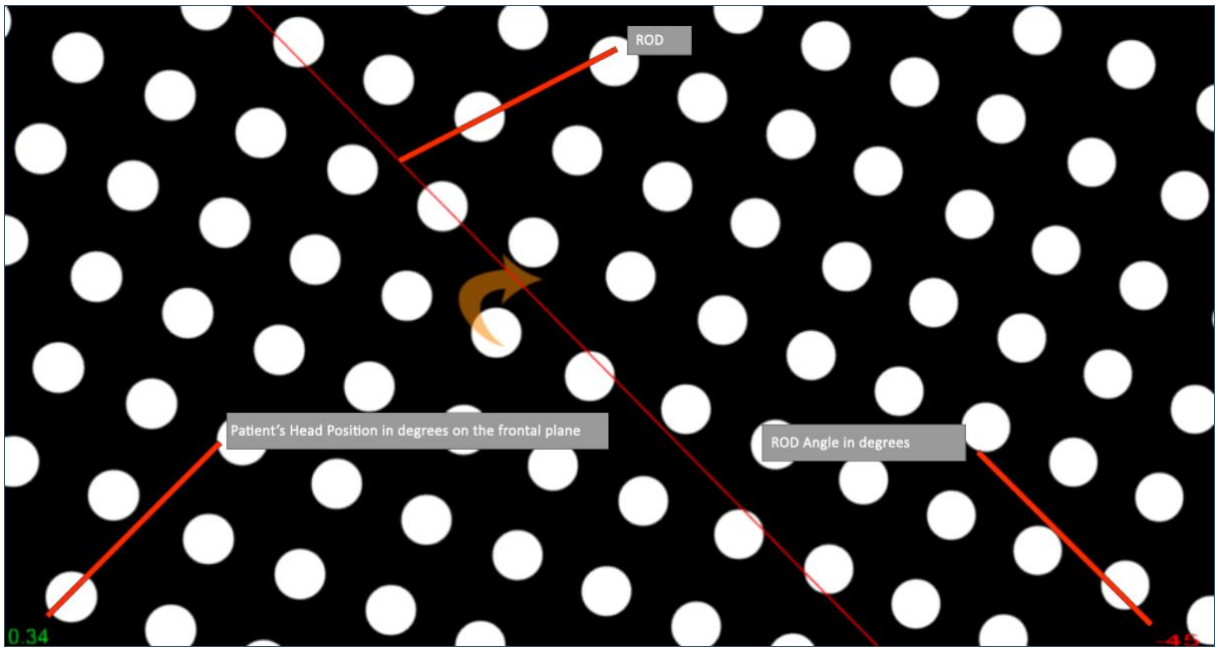
These are simple, limited numbers of tips drawn from the literature and from our personal experience

The principle of measuring patients' Subjective Visual Vertical is that they have no vertical or horizontal, visual or proprioceptive reference.

It is therefore recommended to take the measurements using the following installation:

- Patient seated (preferably on an "upholstered" seat, a swivel chair is ideal)
- Feet on a footrest, not on the ground
- Controller in hand so that they can take the measurements themselves

3.4. Session settings



The variable settings for this module are as follows:

Settings

In manual mode, the marker starting angles must be entered manually

In automatic mode the starting angles are fixed or random

Measurements

Used, for the entire protocol that follows, to choose between vertical or horizontal measurements

Number of measurements

Number of measurements recorded during the session

Initial angle

Fixed: will "mirror" the indicated value, sometimes to the right, sometimes to the left (noted -)

Random: Genuine randomness. The values are not "mirrored", it is possible (randomly) to have more values tilted to the right than to the left for example, and with different values. A "symmetrical random" version is under development.

Initial direction

Indicates left if the initial angle is negative and vice versa

Sequence

Menu Inactive if the initial angle is "Random"

Alternating: Alternately shows the bar with the initial angle selected and then its opposite (-45, so 45° to the left, then +45, so 45° to the right)

Linear: Will show the bar successively x times with the initial angle, then x times with the opposite angle

Sway reference

ON: The image is coupled to the head movements. The bar is as if "fixed" in front of the patient and tilts following their own head tilts. The measured values are relative to the earth's vertical, without taking into account the tilt of the head. (More like experimental conditions)

OFF: The bar is in "real conditions", as if it were floating in the room. It is therefore unaffected by the subject's head movements.

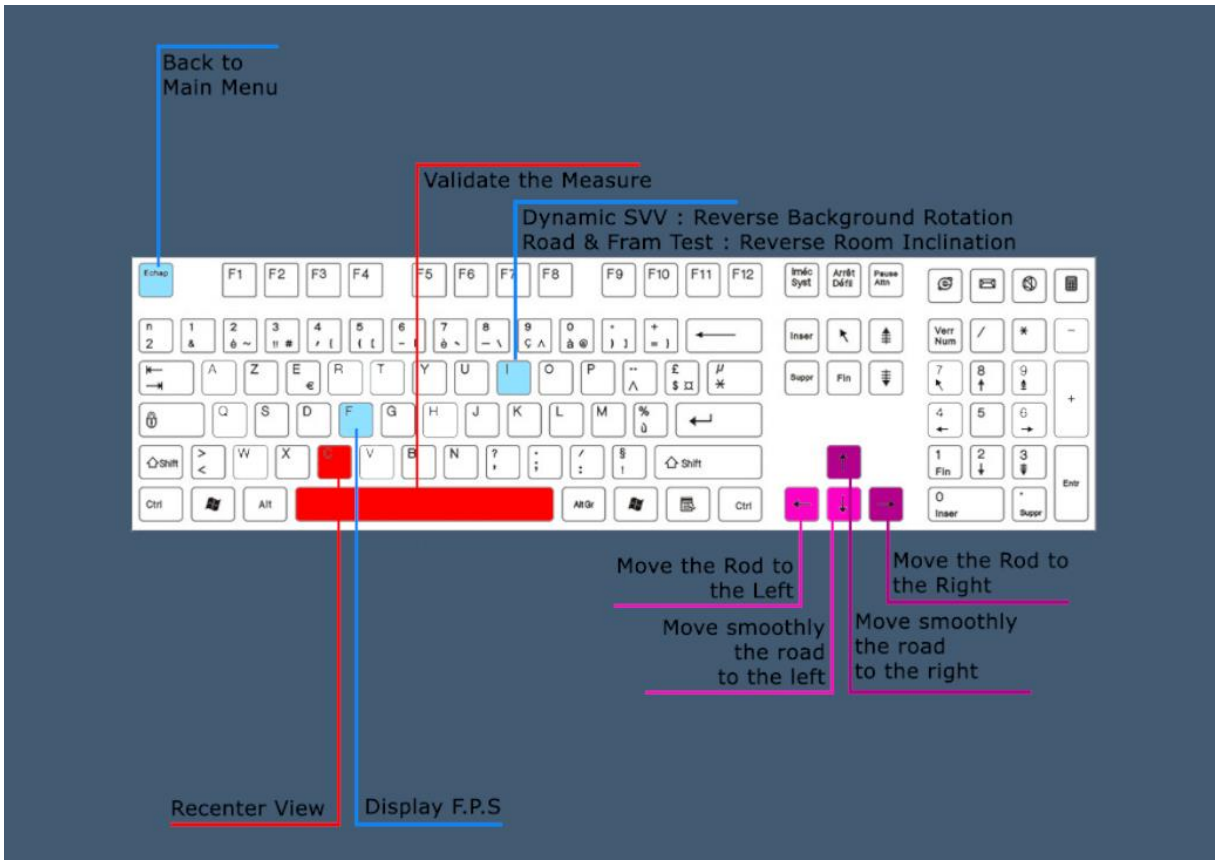
Background speed

Determines the optokinetic disk rotation speed, the rotation direction follows the direction in which the bar is tilted.

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


Back to
Main Menu
Validate the Measure
Dynamic SVV : Reverse Background Rotation
Road & Fram Test : Reverse Room Inclination
Move the Rod to
the Left
Move the Rod to
the Right
Move smoothly
the road
to the left
Move smoothly
the road
to the right
Recenter View
Display F.P.S


Move the Rod to
the Left
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the Rod to the
Left
Move smoothly
the Rod to the
Right
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Measure
Recenter View
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Background Rotation
Road & Fram Test : Reverse
Room Inclination

3.6. Data processing

Data retrieval and analysis uses the Patient Management software.