

REF Rod & Frame Test (RFT)

CE Class I Medical Device

User manual

Distribution mode

Available for direct download at
<http://virtualisvr.com/espace-client/>

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1. GENERAL

1.1. Description

Rod & Frame Test (RFT) 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.

RFT is a software used to assess the perception of verticality with the influence of the visual field (tilting).

1.2. Indications

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

1.3. Contraindications

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

1.4. Software field of application

Evaluation of the perception of verticality and the influence of the visual field in the context of balance disorders or neurological conditions (e.g. stroke).

Software for measuring Subjective Visual Vertical.

The patient must orientate a line vertically in a space devoid of vertical reference points.

1.5. Intended user

Healthcare professionals: physiotherapists; occupational therapists; neuropsychologists; ENT doctors; neurologists; PMR doctors (physical medicine and rehabilitation), etc.

Research Centers: CNRS, CHU, INSERM, etc.



1.6. Warnings and caution

Immersion in Virtual Reality is a powerful tool, especially for stimuli that can induce sensory conflicts.

WARNING



These stimulations can potentially cause certain disorders: vagal discomfort, epileptic seizures, migraines, vomiting, malaise, dizziness, syncope etc.

This type of re-education must be approached progressively, particularly in Virtual Reality where the stimulation is "powerful".

The contraindications are identical: mainly epilepsy and migraines.

RECOMMENDATION



As postural reactions can be spectacular, we **STRONGLY** recommend that you place the patient in a secure environment and stay close to him/her throughout the session to anticipate any loss of balance or discomfort caused by the use of virtual reality.

RECOMMENDATION



It is also recommended to increase the duration and intensity of stimulation very gradually after an initial short session to ensure the patient's tolerance to this type of stimulation.

Motion sickness is treated by "habituation", so you need to recreate the symptoms experienced during transport.

WARNING



It is essential to stop the session when the first symptoms appear, generally "sweating".

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.

It would be counterproductive to take into account the fact that some motivated patients may wish to go further. It's up to the professional to "dose" immersion so as not to provoke neurovegetative symptoms. This type of symptom can intensify in the hour following the session.

Nor can Virtualis be held responsible for any disturbances suffered by patients during or use of their software.



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.



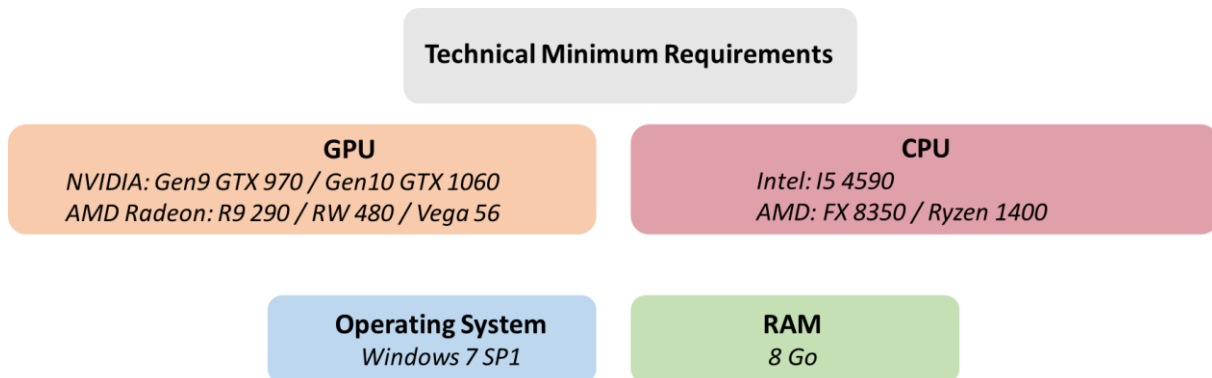
Any serious incident should be notified in writing to qualite@virtualisvr.com

1.7. 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)

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



1.8. Required accessories

Headset. Xbox controller, Hive controller(s) or keyboard are all optional.

2. SOFTWARE USE

2.1. Patient setup



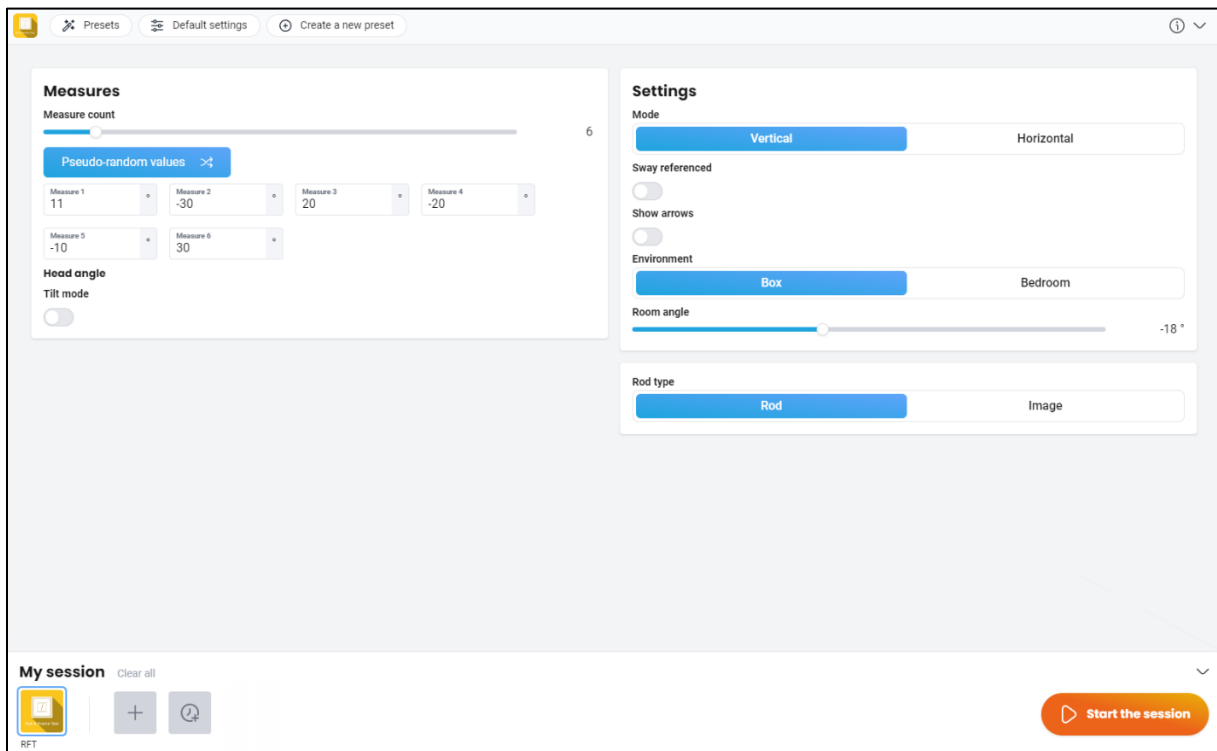
These are simple, limited numbers of tips drawn from the literature.

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

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.
- Keyboard, controller(s) or Xbox controller in hand so they can take the measurements themselves (if possible).

2.2. Session settings



The variable settings for this module are as follows:

2.2.1. Measures

The screenshot shows the 'Measures' configuration screen. At the top, there is a 'Measure count' slider set to 6. Below it is a blue button labeled 'Pseudo-random values' with a refresh icon. Underneath are six input fields for individual measurements: Measure 1 (10), Measure 2 (-30), Measure 3 (20), Measure 4 (-20), Measure 5 (-10), and Measure 6 (30). Each field has a small circular icon to its right.

Measure	Value
Measure 1	10
Measure 2	-30
Measure 3	20
Measure 4	-20
Measure 5	-10
Measure 6	30

Used to define the value of the various measurements for the entire protocol.

There are many different protocols in the literature.

It is often recommended to take:

- At least 6 measurements (6 to 12).
- Variable initial angle, same tilts to the right and left in random order.
- Alternating Sequence.
- Scenery angle: several studies recommend 18° (right or left).

Measure count:

Number of measures taken during the session.

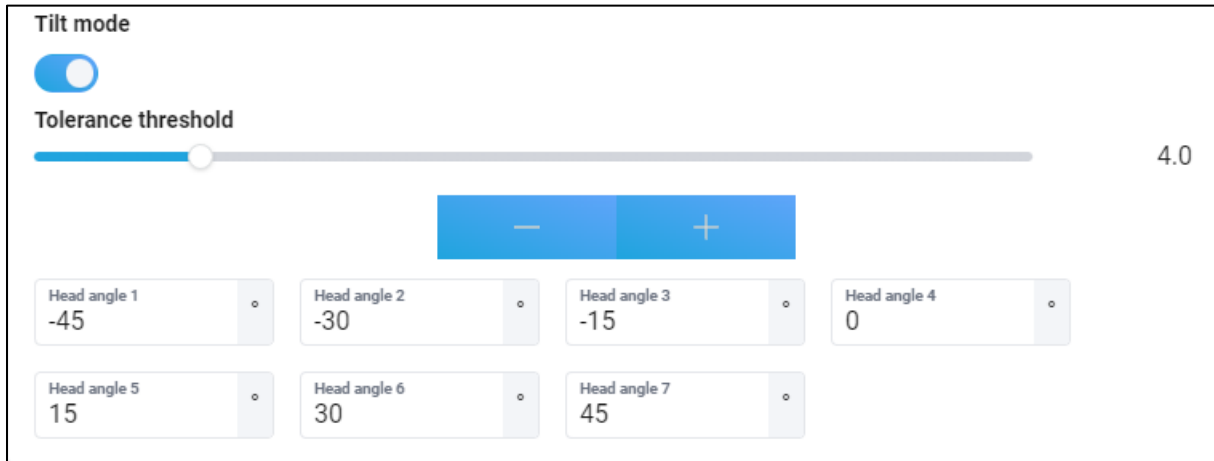
Value: 4 to 24.

Pseudo-random values:

Defines pseudo-random values for measurements. Values are mirrored: they are tilted both to the right (positive values) and to the left (negative values).

2.2.2. Tilt





The screenshot shows the 'Tilt mode' settings. At the top, there is a toggle switch for 'Tilt mode' which is turned on. Below it is a 'Tolerance threshold' slider set to 4.0. Underneath the slider are two blue buttons with minus and plus signs. At the bottom, there are seven input fields for 'Head angle' with values: -45, -30, -15, 0, 15, 30, and 45.

Tilt mode:

Checking this option unlocks the following parameters:

- **Tolerance threshold:**

Modifies the tolerance threshold for the head tilt angle.

Value: 1.0 to 20.0.

- **Head angle:**

Used to define head inclination values to be measured.

Delete or add measures by clicking on the “-” or “+” button.

2.2.3. Settings

A screenshot of the 'Settings' menu. It contains several options: 'Mode' with a radio button selected for 'Vertical' and 'Horizontal' unselected; 'Sway referenced' with a toggle switch turned off; 'Show arrows' with a toggle switch turned off; 'Environment' with a radio button selected for 'Box' and 'Bedroom' unselected; and 'Room angle' with a slider set to -18 degrees.

Settings

Mode

Vertical Horizontal

Sway referenced

Show arrows

Environment

Box Bedroom

Room angle

-18 °

Mode:

Allows you to choose between vertical or horizontal measurements for the entire protocol.

Sway referenced:

Check this option to have the image displayed in the VR headset matched to the patient's head movements.

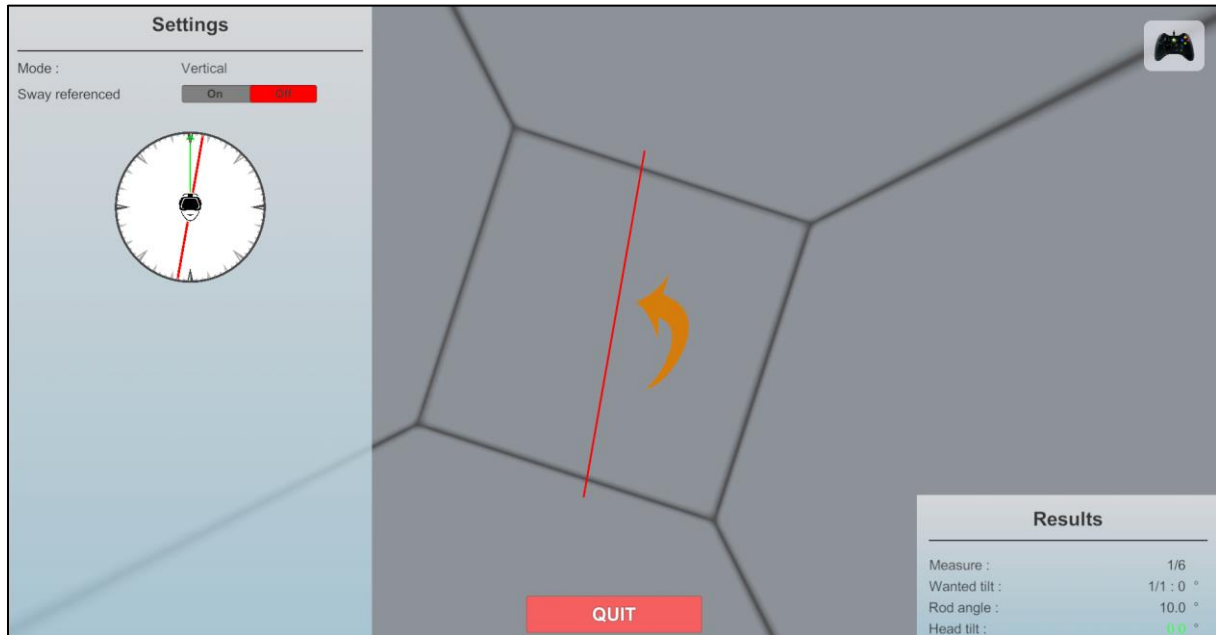
If enabled, the bar is “fixed” in front of the patient, and tilts with the patient's own head tilts. Measured values are relative to the earth's vertical, without taking head tilt into account.

Otherwise, the bar is in “real conditions”, as if it were floating in the room. It is therefore unaffected by the patient's head movements.

Show arrows:

Check this option to make the arrows visible and help the patient visualize the direction of movement of the bar (right or left).





Environment:

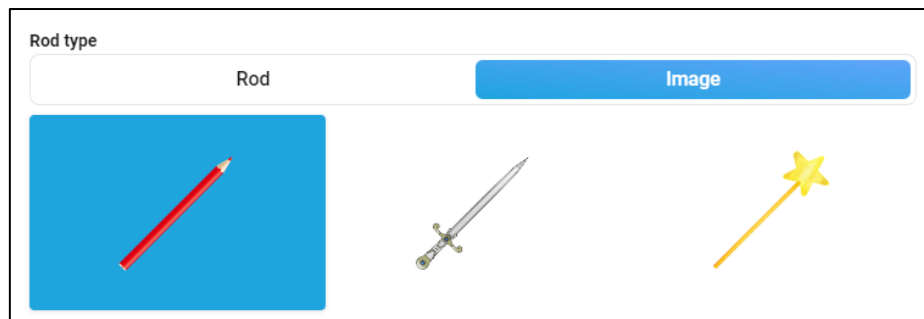
- **Box:** repeats the original Rod and Frame Test principle.
- **Bedroom:** tilting room with many references, for an examination in more "natural" conditions.

Room angle:

Determines the scenery tilt angle (box or bedroom) (-18 or +18 recommended).

Value: -90 to 90°.

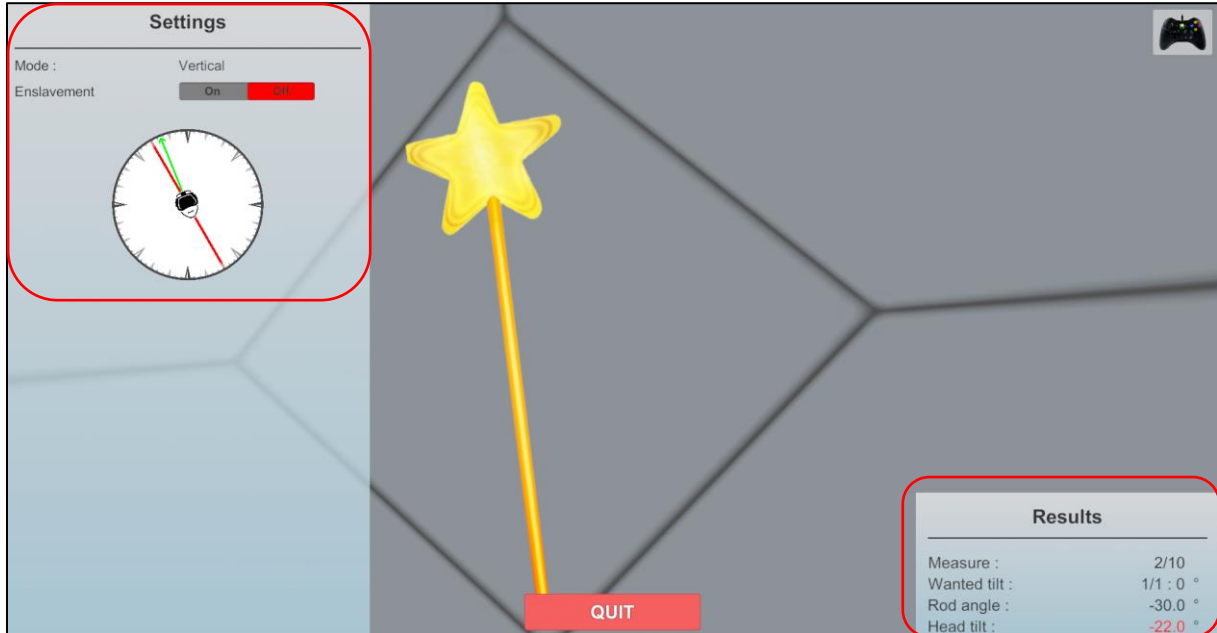
2.2.4. Rod type



Changes the type of rod displayed on the screen.

2.3. Session

Once the presets have been selected, the user can launch the virtual interface by selecting the "**Start the session**" button in the bottom right of the screen.

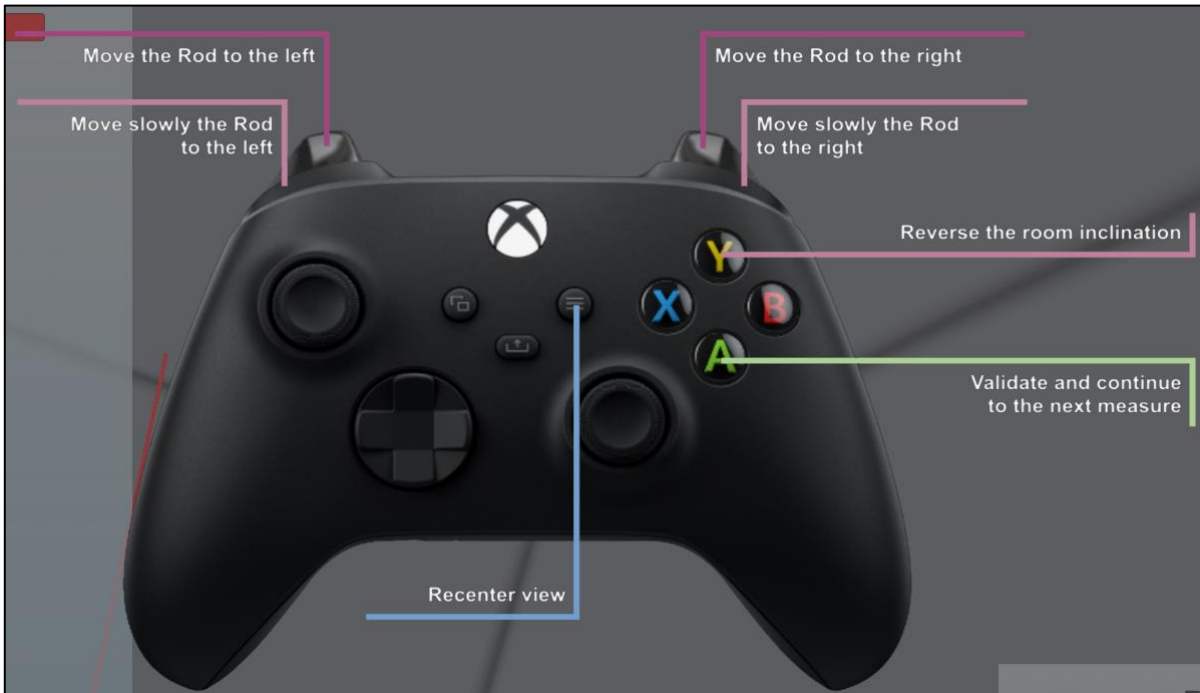
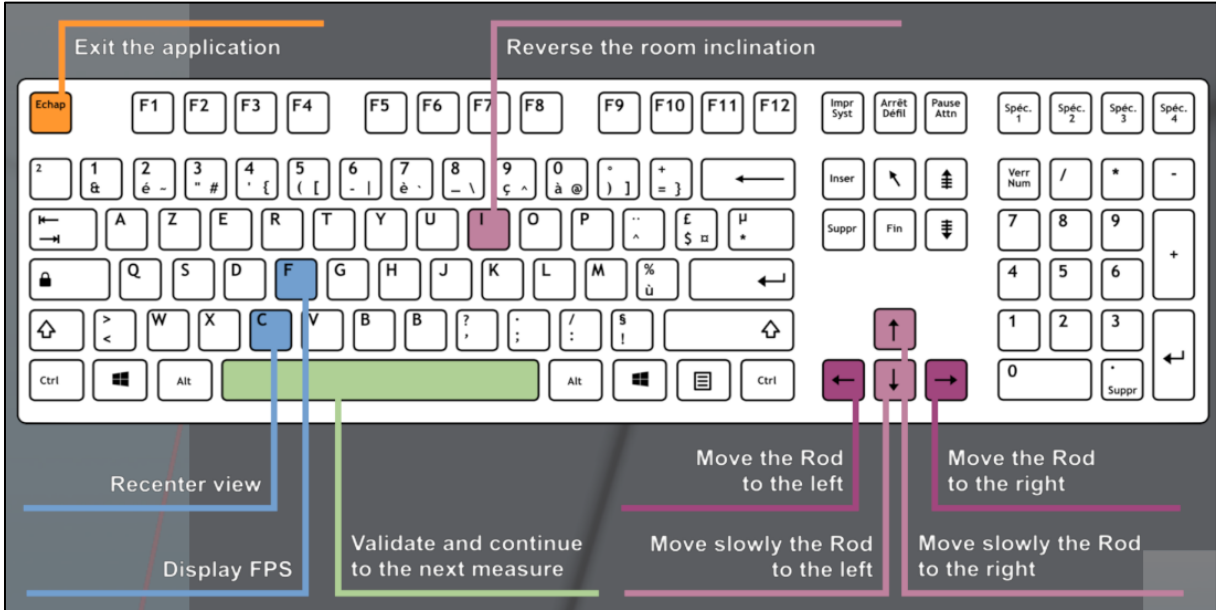


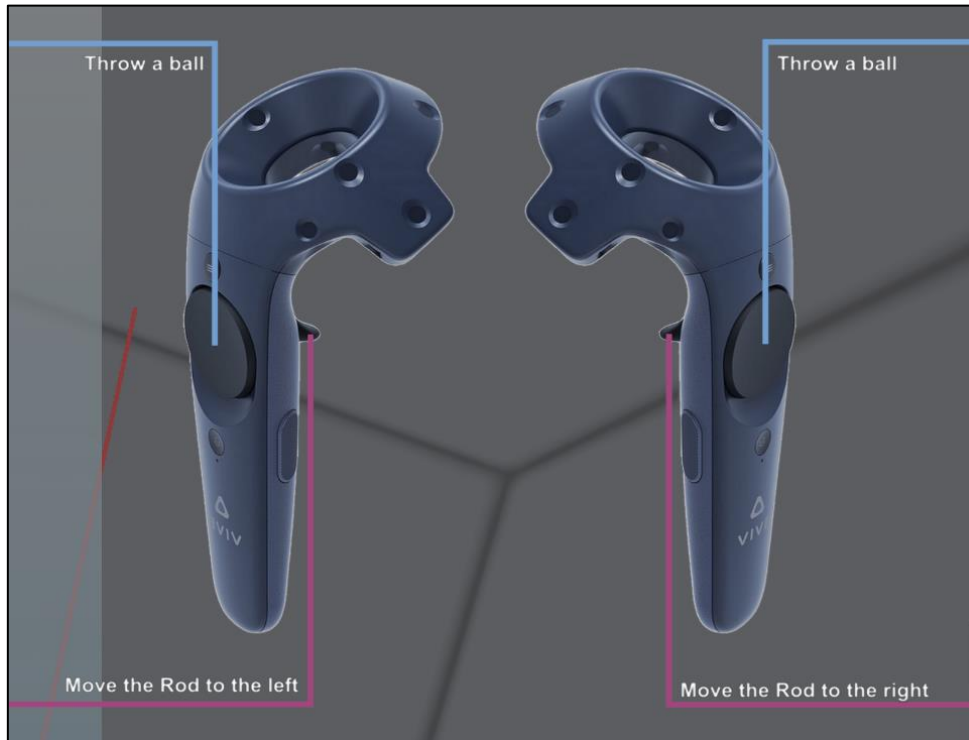
During the session, the user can modify the parameters from the **left side of the screen**. They are not visible to the patient.

In the bottom right corner of the screen, the user can view the results of the session in real time.

2.4. Shortcuts

Keyboard or joystick shortcuts can be accessed within the module, by clicking on the joystick icon in the upper right corner of the screen.





2.5. Results

At the end of the session, the different head inclination values of the patient are displayed.

2.6. Data processing

Data retrieval and analysis uses the Patient Management software (see dedicated user manual).