REF **Optical Flow**

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

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.

1.2. Indications

Rehabilitation of visual flow scrolling disorders.

1.3. Contraindications

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

1.4. Software field of application

- 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.

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 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.

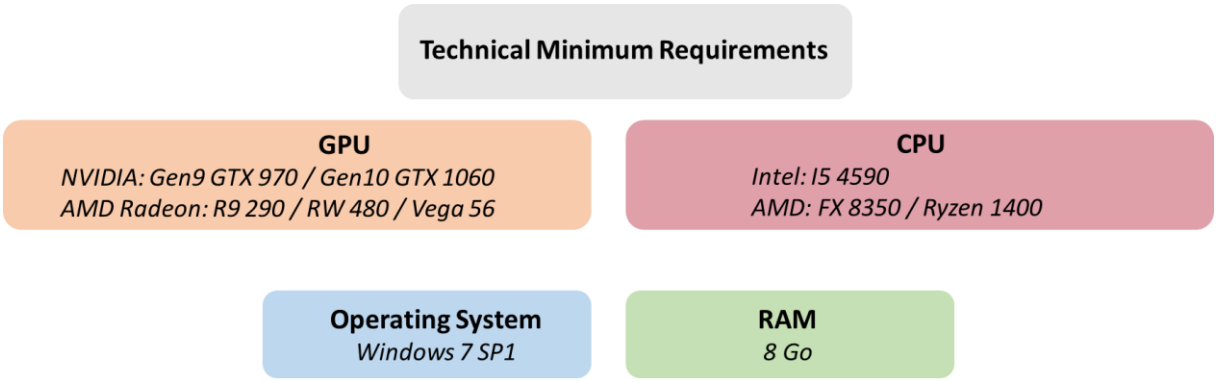
Any serious incident should be notified in writing to qualite@virtualisvr.com

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)
- StaticVR or MotionVR platforms (optional)

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 only **OR** Headset and StaticVR force platforms or MotionVR dynamic posturography platform.

2. SOFTWARE USE

2.1. Patient setup

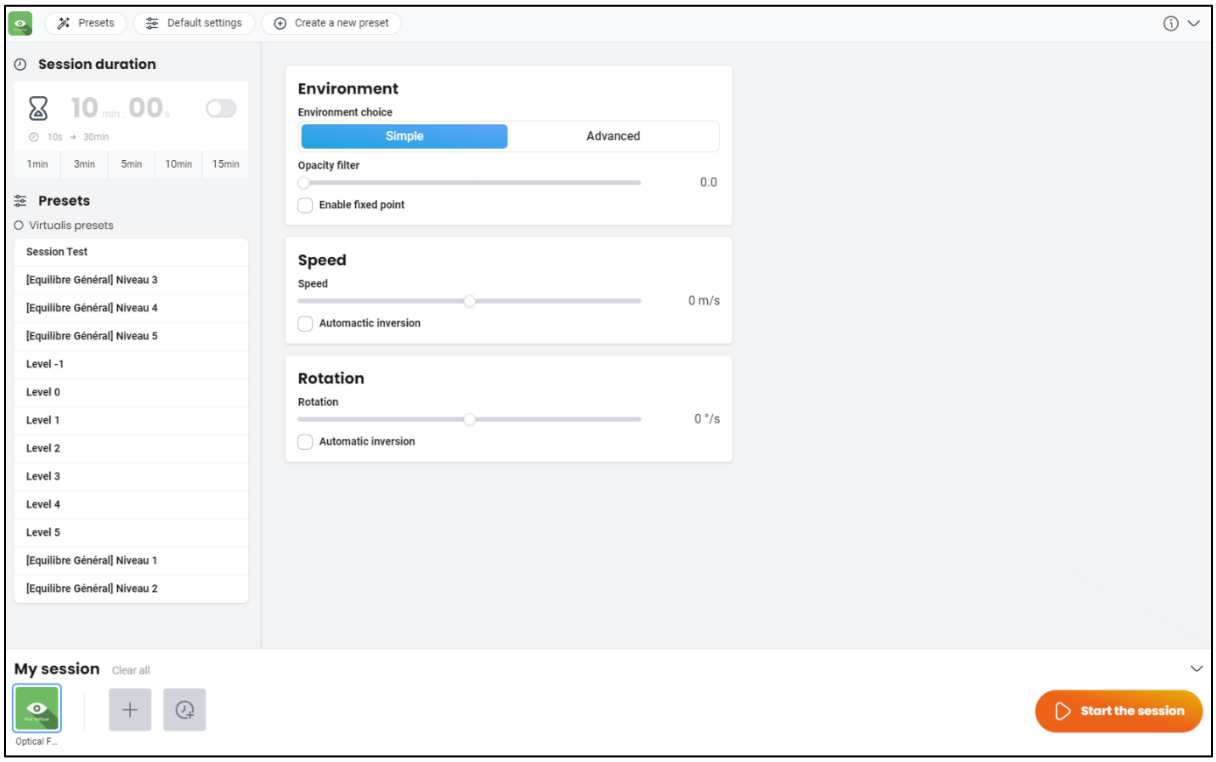
These are simple, limited numbers of tips drawn from the literature.

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.

RECOMMENDATION

Stay in contact with the patient who is at risk of falling during vertical stimulations, even if they are standing on a dynamic posturography platform.

2.2. Session settings



2.2.1. Presets

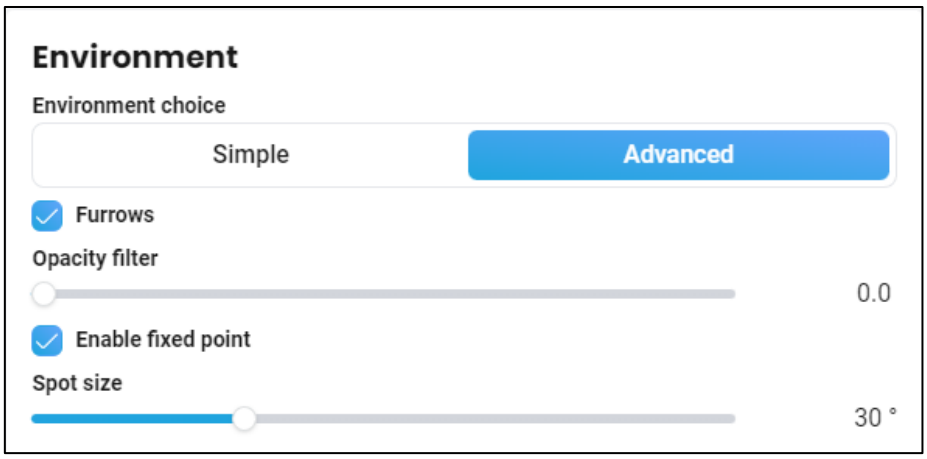
Several different protocols are available. Each protocol corresponds to specific parameters.

RECOMMENDATION

Start with 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.

2.2.2. Environment



Environment choice:

- **Simple**: radial optical flow, linear, without turn possibilities. 3D elements (asteroids) can be activated/deactivated using the "**Q**" key (See Shortcuts).
- **Advanced**: used to orientate the tunnel with bends to strengthen balance, proprioception, and work on the patient's posture.

Furrows:

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

Used to have a less smooth texture of the scenery.

Opacity filter:

Allows the stimulation to appear progressively for the most sensitive patients.

Varies the transparency of the environment.

Value: 0,0 to 1,0.

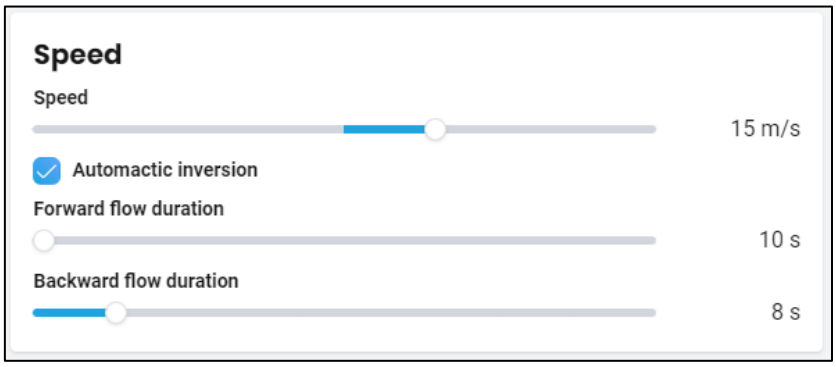
Enable fixed point and point size:

Allows a fixed point to appear in the patient's field of vision.

The point's size can be adjusted using the slider.

Value: from 5 to 90°.

2.2.3. Speed



Speed:

Scenery backward or forward scrolling speed.

Value: -50 to 50 m/s.

Automatic inversion:

Used to program changes in the scrolling direction by indicating a **forward** and **backward flow** duration.

Forward flow duration:

Value: 10 to 120 s.

Backward flow duration:

Value: 5 to 30 s.

ATTENTION

The inversion causes significant anteroposterior postural reactions, and a high risk of falling.

2.2.4. Rotation

Rotation:

Backward or forward scenery rotation. By convention, anticlockwise rotations are negative and clockwise rotations are positive.

Automatic inversion allows the direction of rotation to be programmed by indicating a duration.

Value: -30 to 30°/s.

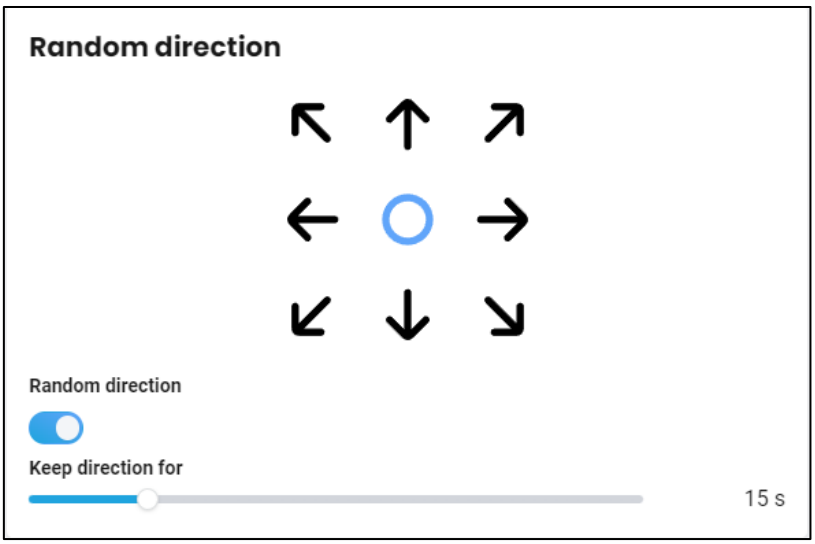
Automatic inversion:

The automatic reversing function allows you to program changes in the direction of rotation by selecting a time with the slider.

Rotation duration:

Value: 10 to 120 s.

2.2.5. Random direction



Random direction:

Sets the tunnel orientation randomly for a given time.

Make 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.

This setting can be modified during the session (see Shortcuts).

Keep direction for:

Value: 5 to 60 s.

2.3. Session

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

2.3.1. StaticVR and MotionVR plateforms tare and statokinesigram

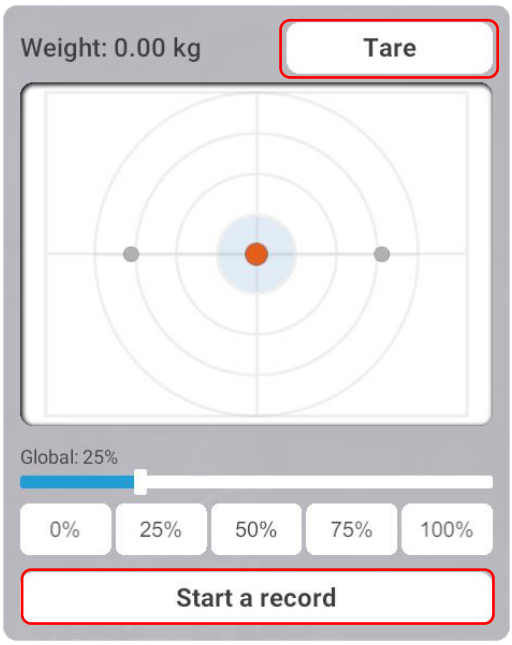
The Optical Flow software is compatible with the StaticVR and MotionVR platforms. To use it with one of these platforms, follow these steps:

1. Click on the "**Tare**" button **before letting the patient step up onto the platform** (StaticVR or MotionVR).

2. Help the patient onto the platform.

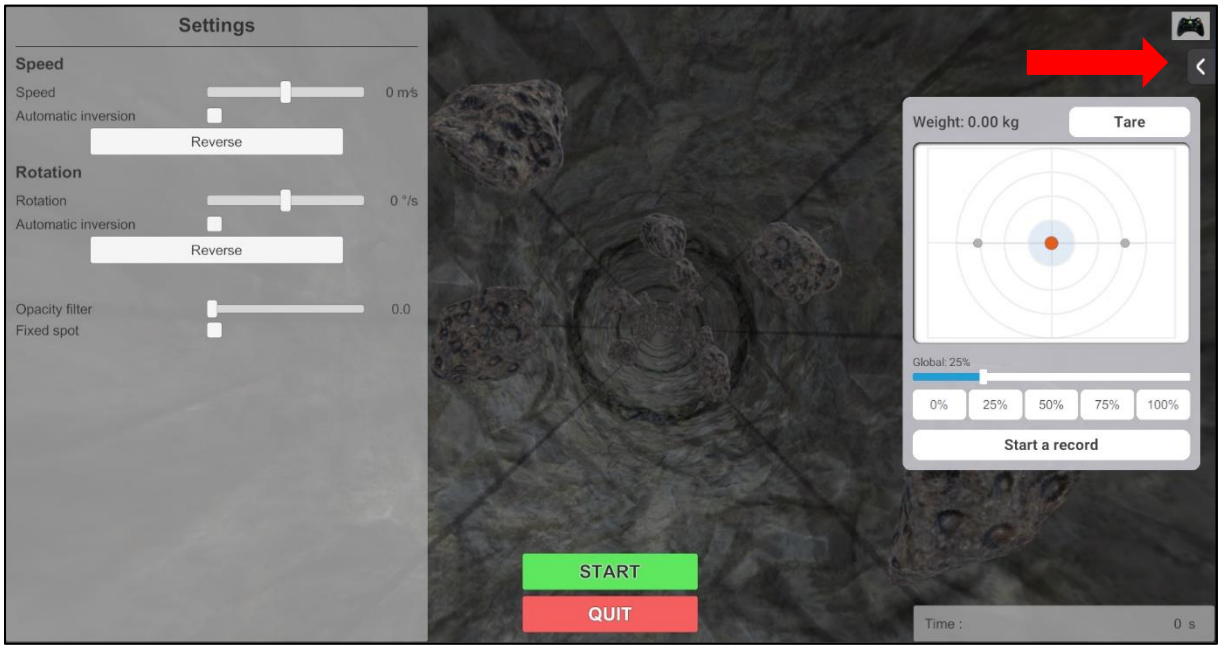
3. Click on "**Start a record**" to record the patient's statokinesigram.

MotionVR display

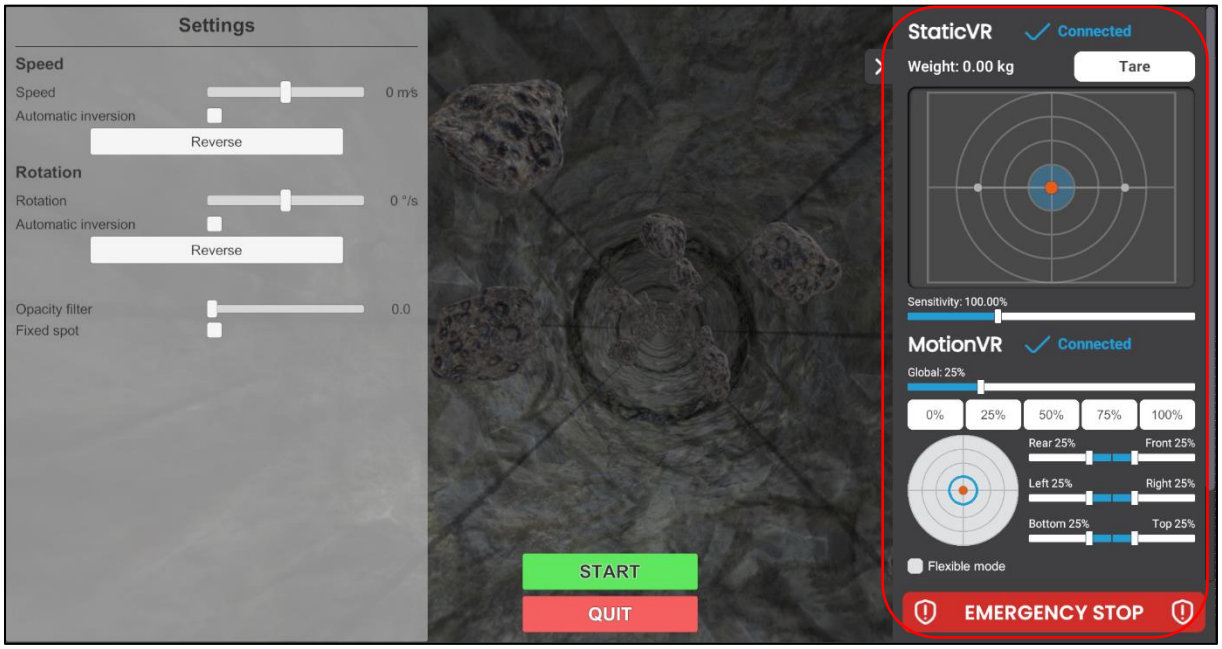


StaticVR display

4. Click on the arrow in the upper right corner of the screen to display the MotionVR or StaticVR platforms' settings.

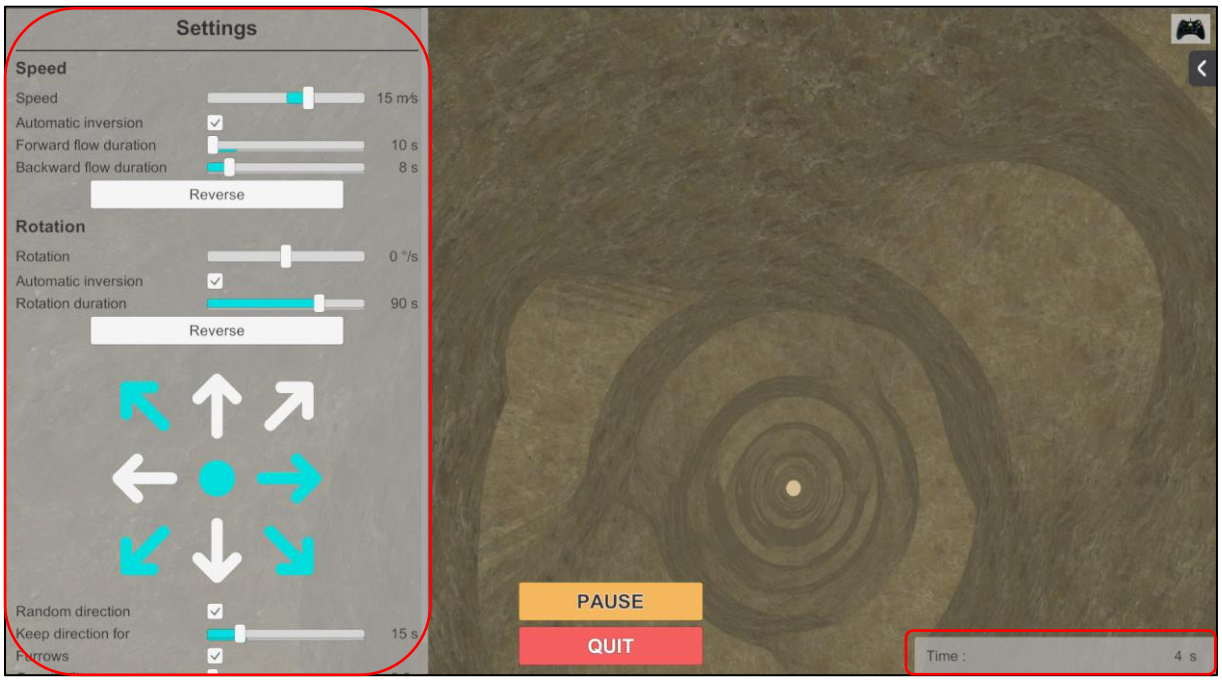


5. Modify the platforms' settings at any point during the session.



6. If the patient standing on the MotionVR platform encounters any issue, click on the "**Emergency stop**" button. The platform's movements will immediately stop.

2.3.2. During the session

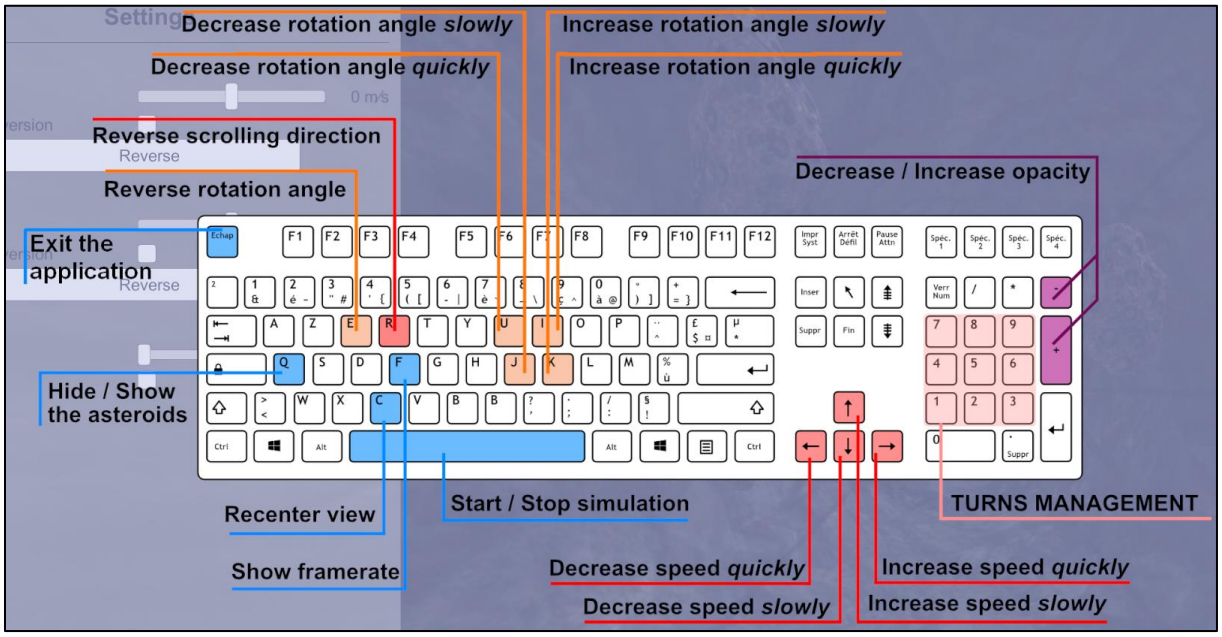


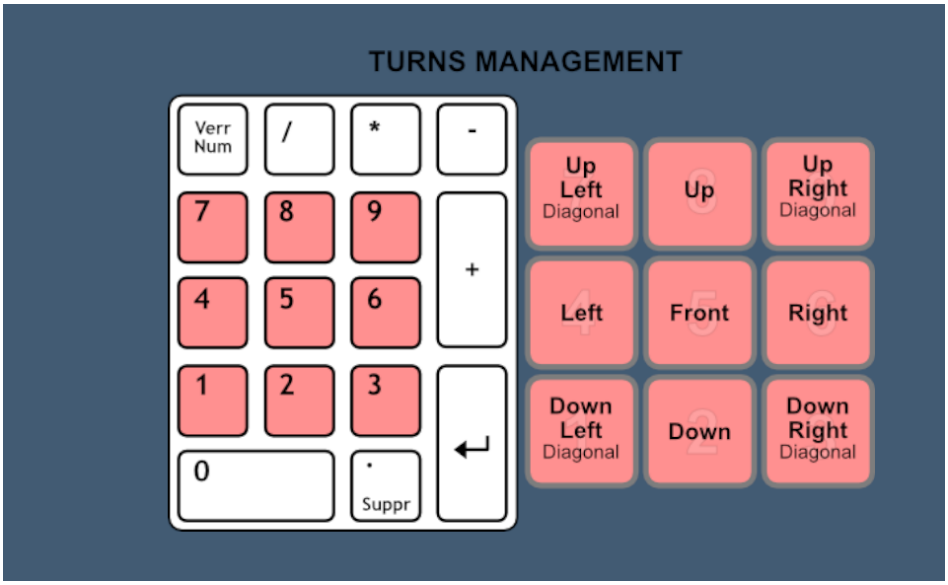
During the session, the user can modify the parameters from the **left side of the screen**. They are not visible to the patient.

In the bottom right of the screen, the user can observe the results of the session live.

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

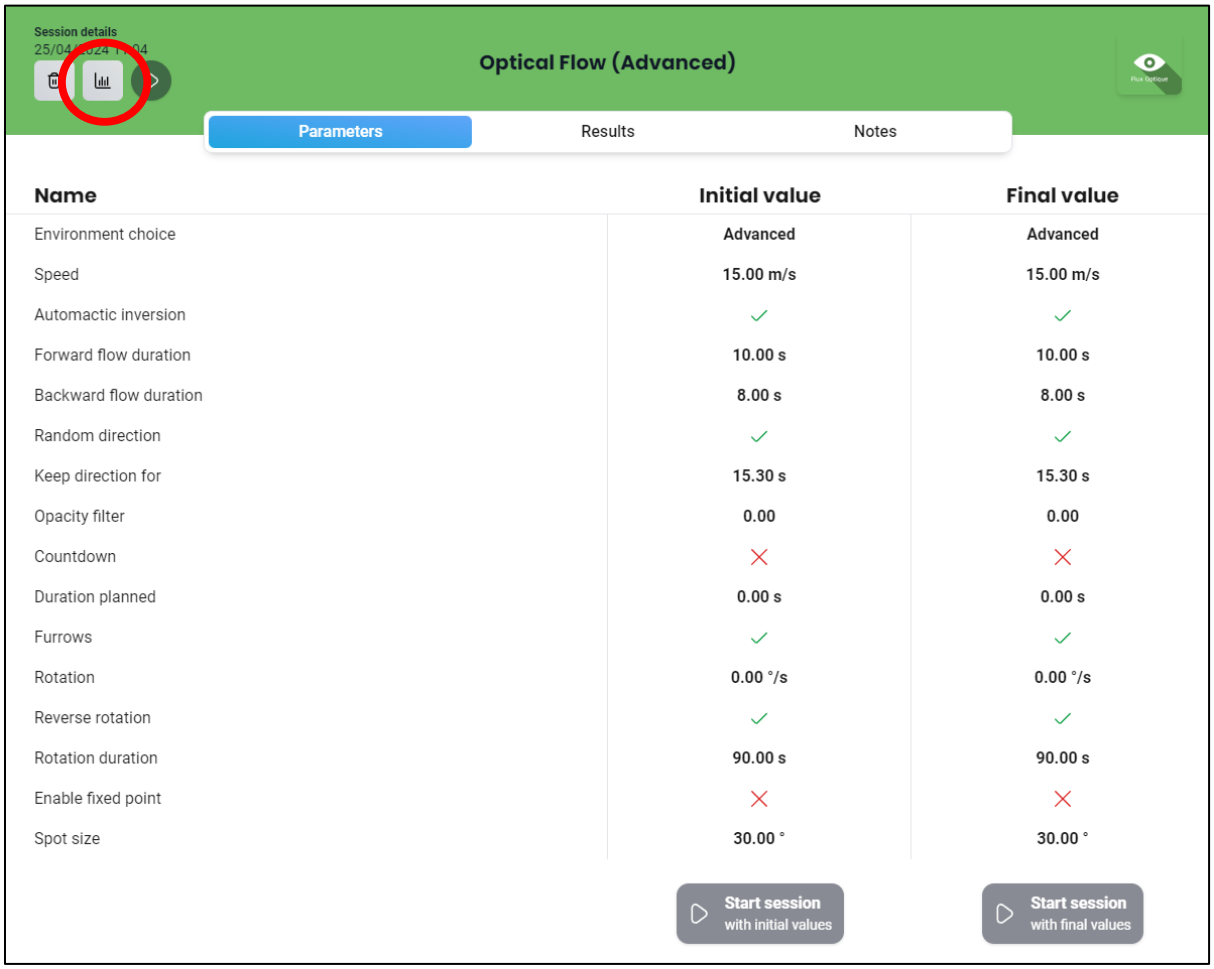
Once the session is over, you can view the results.

2.5.1. Summarized results

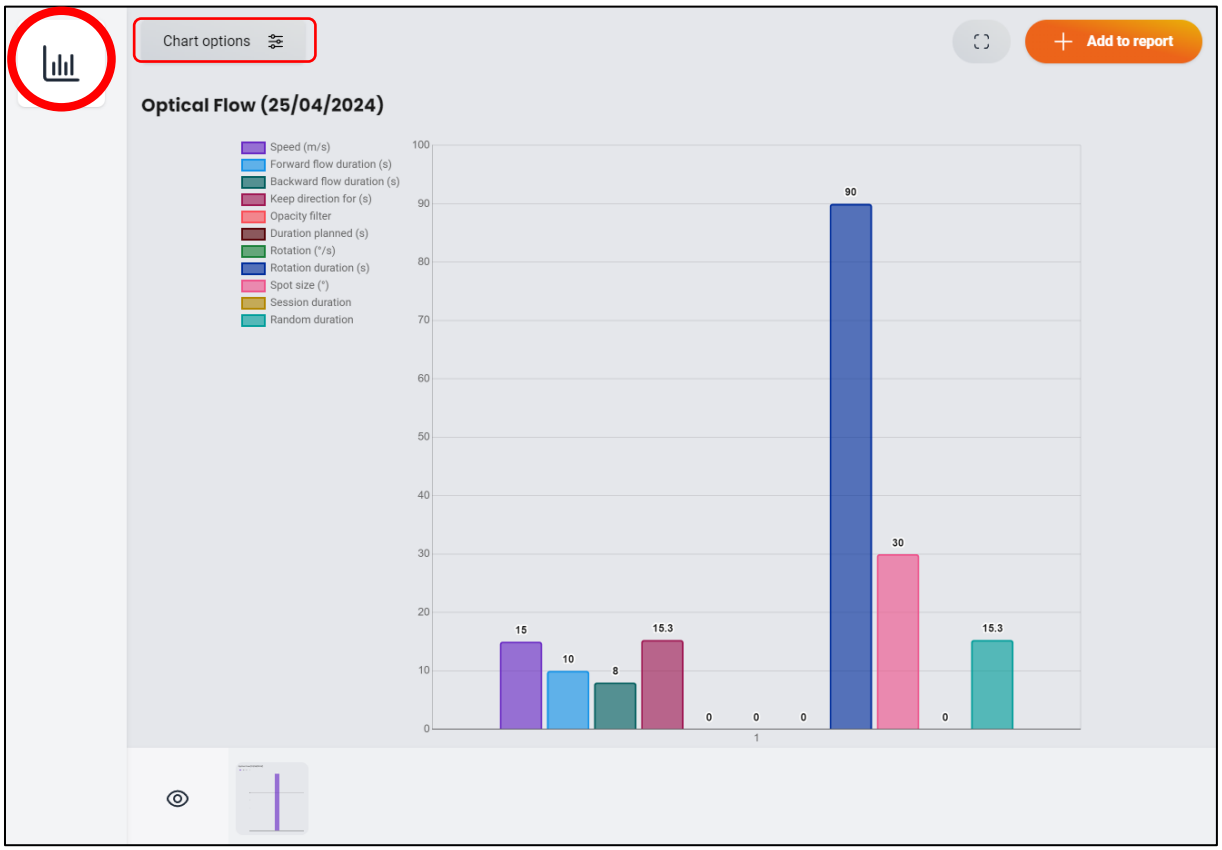
Summarized results are not available for this module.

2.5.2. Graphs and report

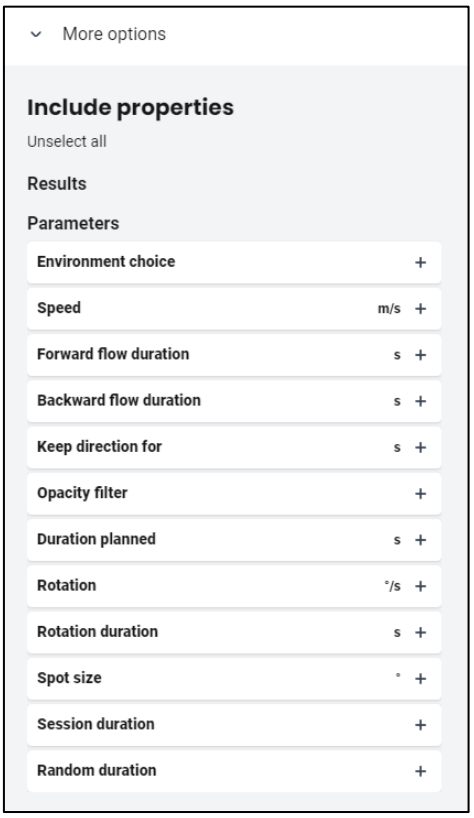
To find the detailed results and to generate a report, click on the histogram icon.


Session details
Optical Flow (Advanced)
Parameters
Results
Notes
Name
Initial value
Final value
Environment choice
Advanced
Advanced
Speed
15.00 m/s
15.00 m/s
Automactic inversion
Forward flow duration
10.00 s
10.00 s
Backward flow duration
8.00 s
8.00 s
Random direction
Keep direction for
15.30 s
15.30 s
Opacity filter
0.00
0.00
Countdown
Duration planned
0.00 s
0.00 s
Furrows
Rotation
0.00 °/s
0.00 °/s
Reverse rotation
Rotation duration
90.00 s
90.00 s
Enable fixed point
Spot size
30.00 °
30.00 °
Start session with initial values
Start session with final values

Several display modes are available for viewing results:



You can access other results by clicking on "**Chart options**".



2.6. Data processing

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