REF **SEA SIMULATION**

CE Class I Medical Device

User manual

Distribution mode

Available for direct download at
http://virtualisvr.com/espace-client/
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VIRTUALIS 78 Allée John Napier Immeuble ATRIUM
34000 MOTPELLIER France
Tel : +33 (9) 80 80 92 91 contact@virtualisvr.com

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1. General

1.1. DESCRIPTION

SEA SIMULATION is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world.

The software is used for desensitization in cases of naupathia (sea sickness).

1.2. INDICATIONS

Treatment of naupathia (kinetosis), landing sickness.

1.3. CONTRAINDICATIONS

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

1.4. MODULE FIELD OF APPLICATION

This simulation is designed specifically for the desensitization of naupathia (seasickness).

Most often, through immersion, it makes it possible to physically feel abdominal sensations felt in live conditions on a boat in the waves.

Wave frequency and amplitude (height) are configurable.

The boat is fully steerable using the joystick. Possibility of facing the oncoming waves (less triggering) or from the side, to move forward, turn, reverse etc.

The aim here is to reproduce the “optokinetic” type visual-vestibular conflict, i.e. when the vision perceives a movement, and the vestibular apparatus does not. Added to that are "physical" sensations very close to those actually felt on a boat.

The realistic environment adds a psychological immersion aspect in the triggering environment.

Visual-vestibular conflict:

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- Visual Information: present.
- Vestibular Information: absent (in seated position).

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.

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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.

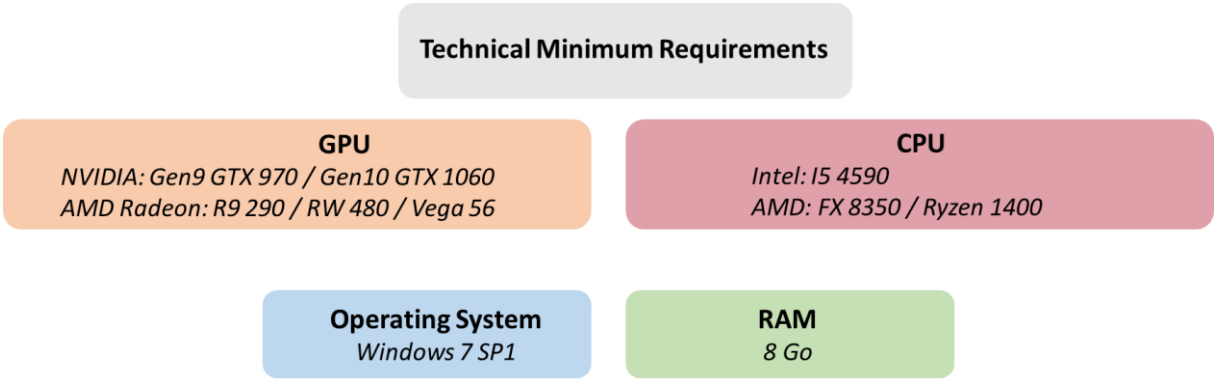
Any serious incident should be notified in writing to qualite@virtualisvr.com

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 only or headset paired with a dynamic posturography platform (MotionVR).

2. Software use

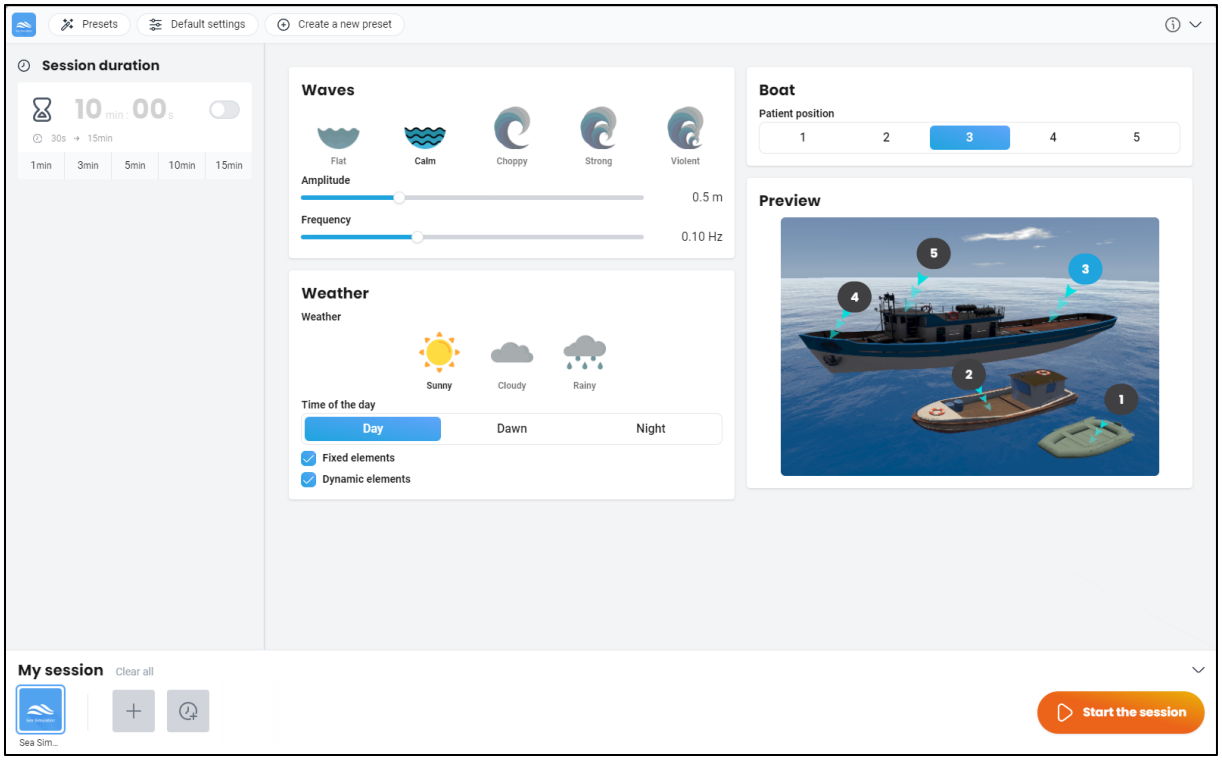
2.1. PATIENT SETUP

The patient's setup is up to the therapist. The patient can be seated or standing. We remind you that Sea Simulation can provoke strong postural reactions due to the sensory conflicts this module allows.

WARNING

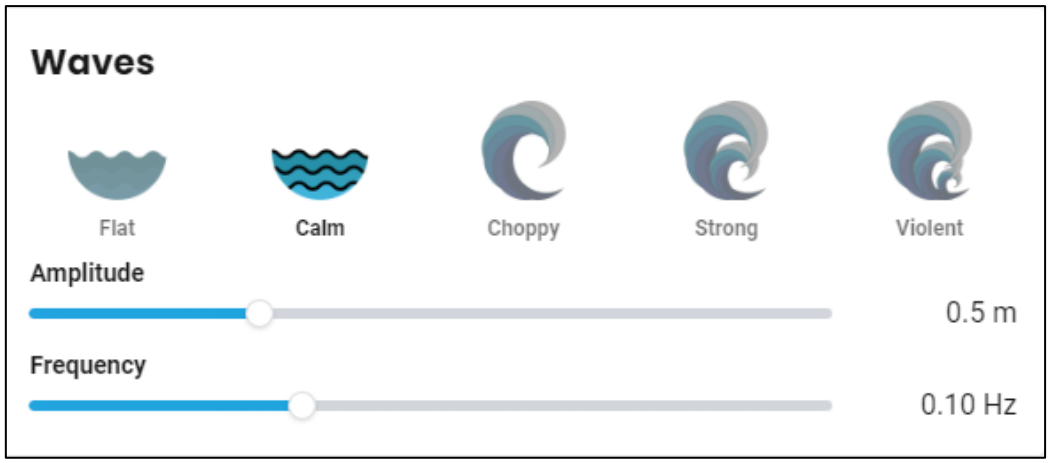
Stay in contact with the patient who is at risk of falling during vertical stimulations, regardless of whether they are standing on a dynamic posturography platform.

2.2. SESSION SETTINGS



The variable settings for this module are as follows:

2.2.1. Waves



5 different wave intensities are suggested:

Each option (flat, calm, choppy, strong and violent) comes with a set wave amplitude and frequency.

Wave amplitude:

The higher this value, the higher the waves will be.

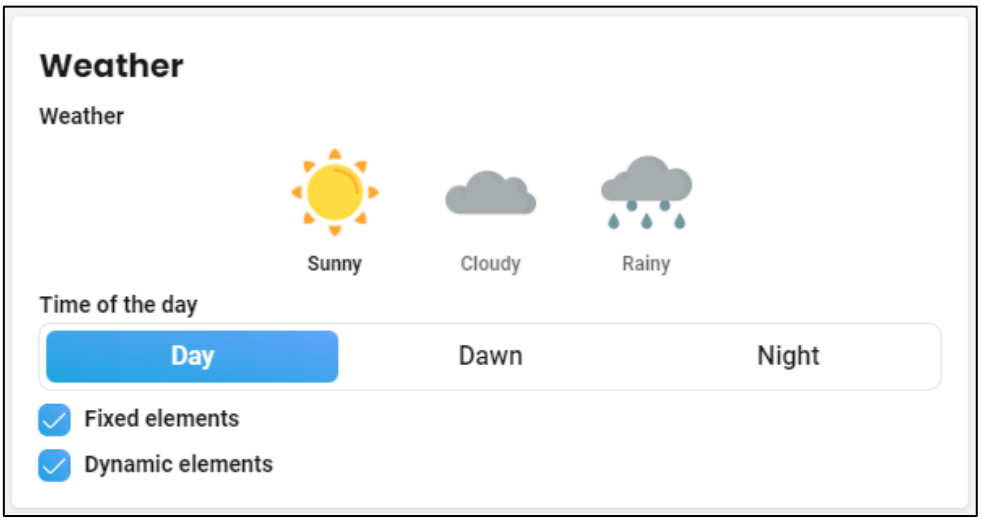
Value: 0,0 to 1,8 m.

Wave frequency

Corresponds to the number of waves per second; the higher this value, the more waves will be generated.

Value: 0,00 to 0,30 Hz.

2.2.2. Weather



Weather:

Choose between three different weather conditions: sunny, cloudy or rainy.

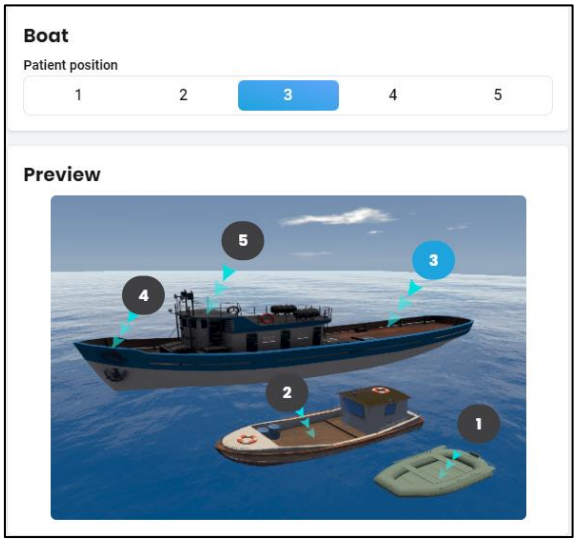
Time of day

Choose between three different times of day: day, dawn or night.

Fixed and dynamic elements:

Checking these options adds fixed or dynamic scenery elements to the environment.

2.2.3. Boat



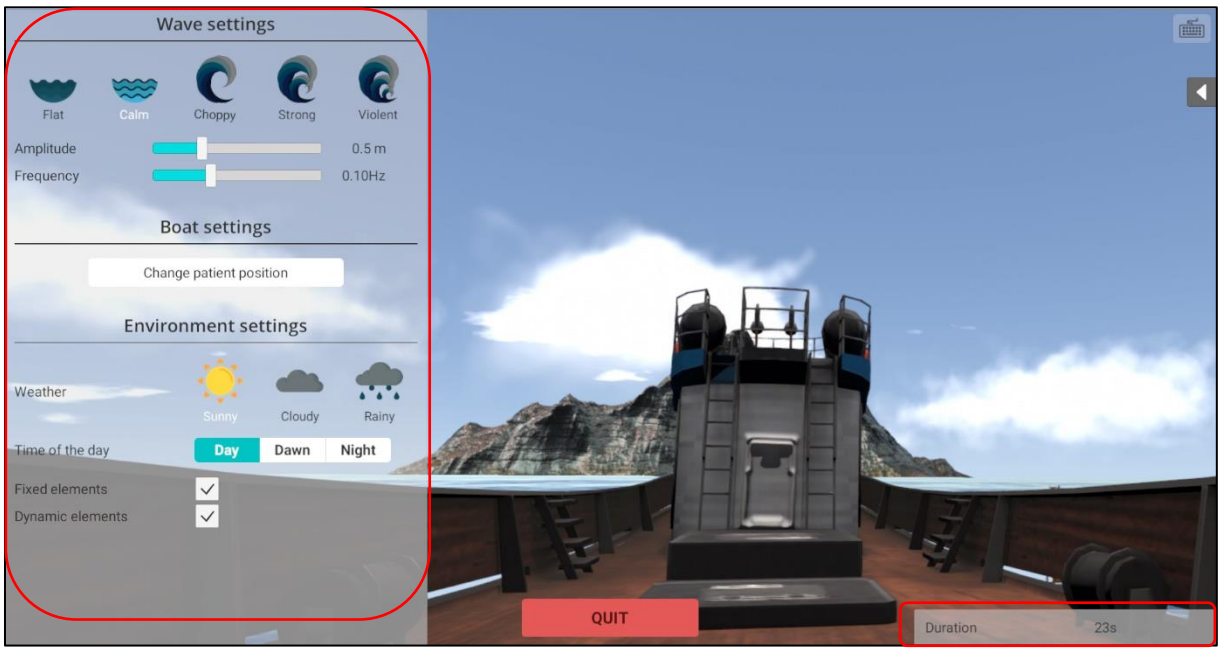
Patient position:

Select the patient's position.

The preview shows the environment corresponding to the chosen position.

2.3. SESSION

Once the presets have been selected, launch the virtual interface by clicking on "**Start the session**" in the bottom right corner 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.

Change the patient's location by clicking on the 

button.

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

2.3.1. Using the MotionVR platform

Sea Simulation is compatible with the Motion VR platform.

If a Motion VR platform is connected, the following window appears:

Refer to the **MotionVR manual** if you have any questions about operating the platform.

In the event of a problem with the patient, click on the "**Emergency stop**" button to interrupt the Motion platform's movements.

You can then press the "**Escape**" key on the keyboard to leave the software.

2.4. SHORTCUTS

During the session, the shortcut list is found by clicking on the keyboard icon in the upper right corner of the screen.

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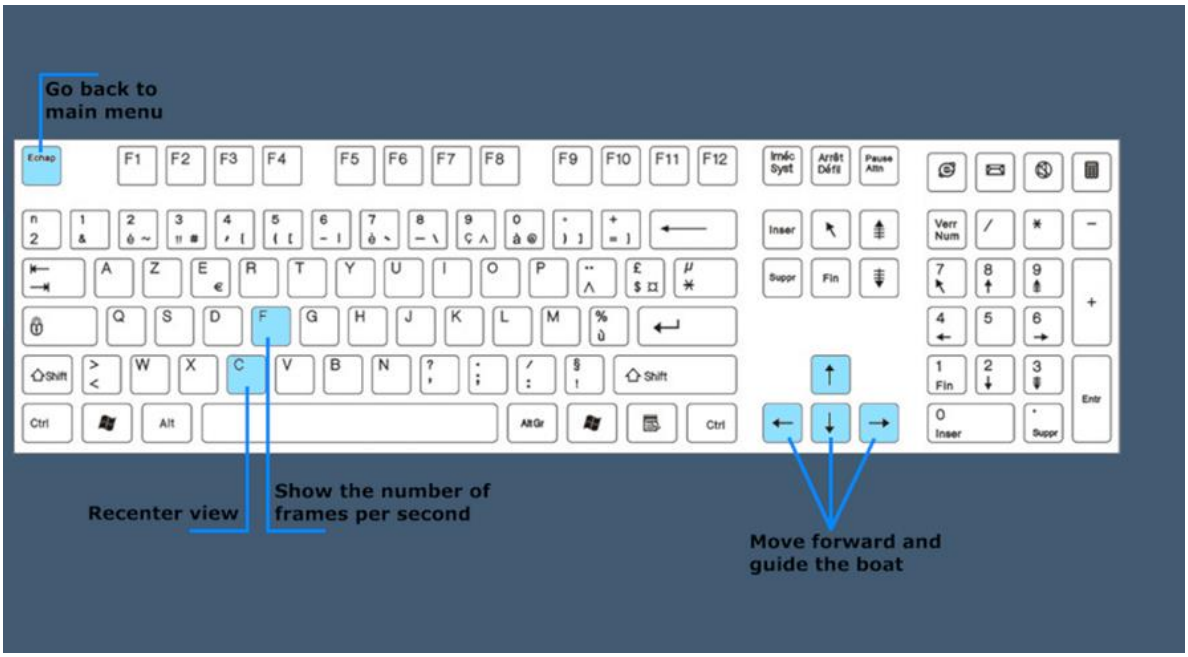

2.5. RESULTS

No results are displayed at the end of the session.

2.6. DATA PROCESSING

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

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