

REF Reading (Sway referenced)

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

READING (SWAY REFERENCED) is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. This software aims to help desensitize kinetosis related to reading in a moving car.

1.2. Indications

Treatment of Motion sickness (Kinetosis).

1.3. Contraindications

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

1.4. Module field of application

This simulation is designed to enable habituation to reading (or using a smartphone, etc.) in a car, by reproducing as closely as possible the visuo-vestibular conflict involved in this form of kinetosis. The image is fixed (no visual feedback of the movement felt, visual feedback of these movements is distorted: the patient sees a fixed image, which follows all his movements), the patient reads stories and turns the pages of the 3D book thanks to the Xbox controller or the keyboard during vestibular stimulations.

This is the visual-vestibular conflict most involved in motion sickness (reading in a car, cabin of a boat, etc..) where the vision does not perceive the vestibular movement. It is recommended to subject patients to vestibular stimulation during immersion to cause this specific visual-vestibular conflict.

Visual-Vestibular Conflict

- Visual Information: distorted (image dependent on the patient's head movements).
- Vestibular Information: present.

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.



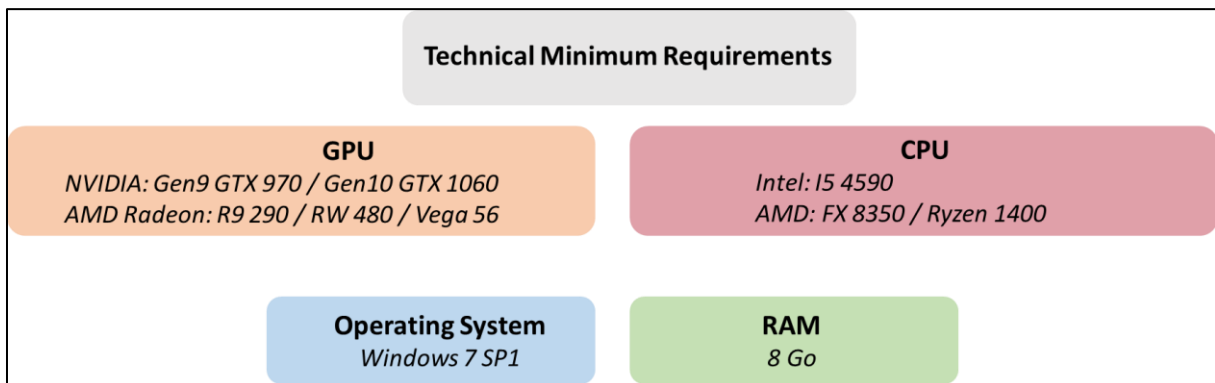
Any serious incident should be notified in writing to qualite@virtualisvr.com

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 and Xbox controller.



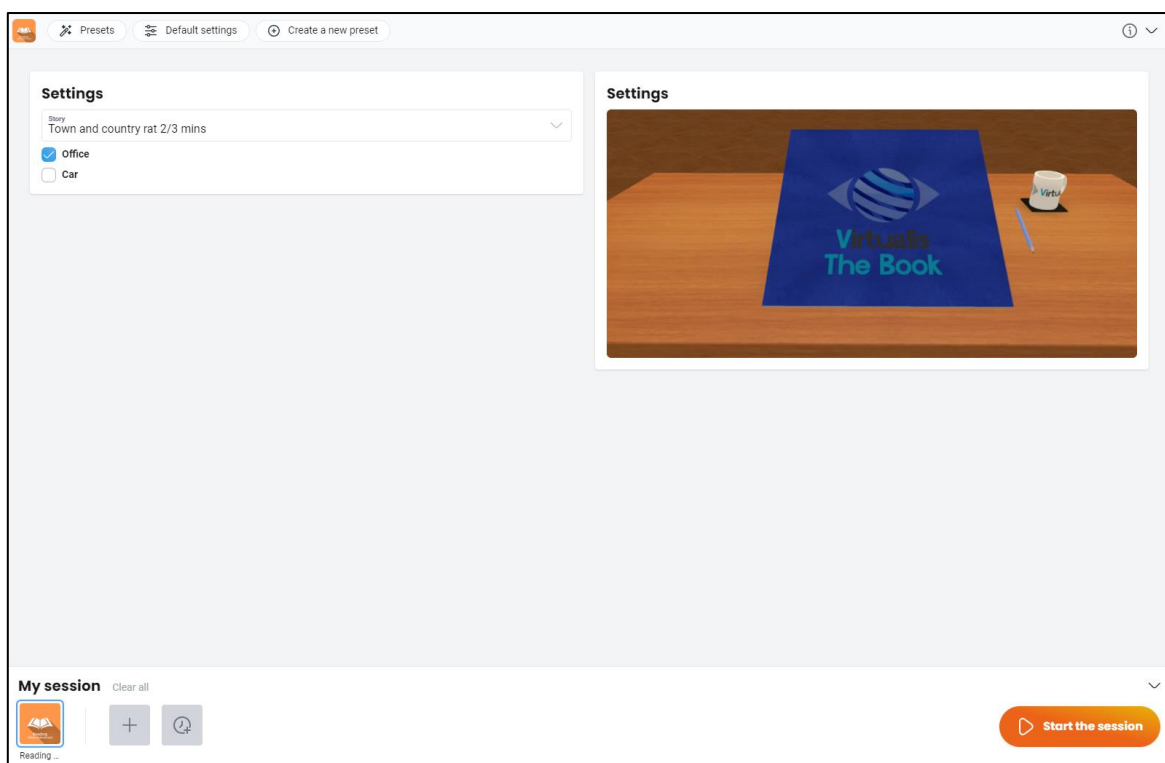


2. SOFTWARE USE

2.1. Patient setup

Patients must be seated on a chair or a rotating chair with the feet off the floor, so that the practitioner can carry out angular accelerations (rocking movements and random half-turns are sufficient).

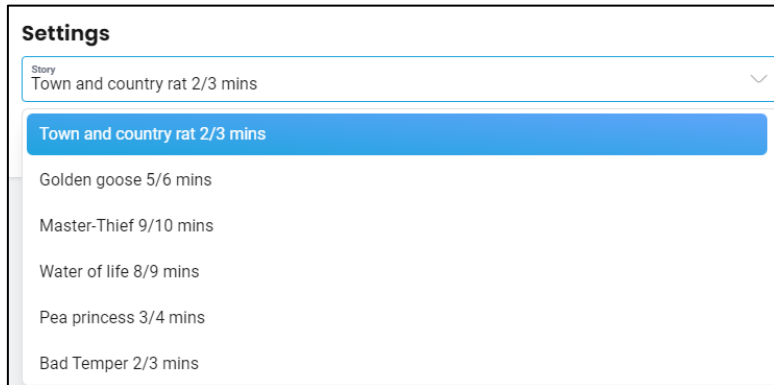
2.2. Session settings



The variable settings for this module are as follows:

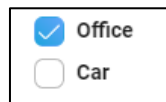
Choice of book:





Several books are available so that patients do not get bored too quickly. The durations are given for information purposes only.

Choice of environment



A choice between an **office** and a **car** environment is available.

2.3. Session

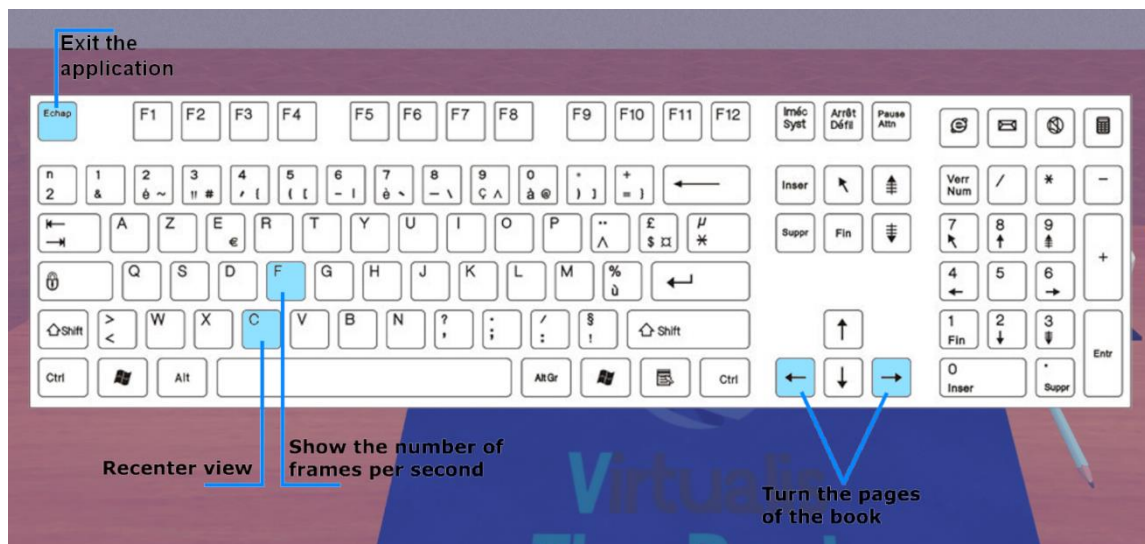
Once the presets have been selected, click on the "**Start the session**" button in the bottom right corner of the screen.



End the session by clicking on the “Exit” button in the bottom right of the screen.

2.4. Shortcuts

During the session, the shortcut list is found by clicking on the Xbox controller icon at the upper right corner of the screen.





2.5. Results

No results are displayed at the end of the session.

2.5.1. Data processing

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

