REF   **Car Simulation**

$C\epsilon$ 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

CAR SIMULATION software is an immersive 3D simulation based on virtual reality technology, i.e. it allows a person to be immersed an artificial digitally created world. **CAR SIMULATION** software allows you to be a passenger (or a driver) in a car and to be subjected to the visual scrolling of a landscape.

INDICATIONS

Treatment of Motion Sickness (Kinetosis). Can be used for driving re-training (coordination, motor skills, visual controls) with the steering wheel and pedals supplied.

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 Centres: 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**

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1. GENERAL

1.1. General information on travel sickness

General information on the treatment of motion sickness:

The objective here is to provide some basics on motion sickness for those who would like to learn more about it.

These are simple recommendations for use, of course, everyone is free to use this software using their own protocols, to adapt them to their patients, etc... These are ideas, guidelines, that everyone can enrich by sharing them on the Virtualis website Forum.

Re-education principle: Habituation

Objective: to gradually reproduce the triggering conditions

Therefore, for each case, the triggering conditions must be identified in order to best apply our software on travel sickness (Sea Simulation, Waves (Sway Referenced), Reading (Sway Referenced), Car Simulation).

Trigger mechanism theories:

2 mechanisms:

- Unusual stimulation of peripheral sensors (Habituation without sensory conflicts)
- Sensory Conflicts (case of our software: Sea Simulation, Waves (Sway Referenced), Reading (Sway Referenced), Car Simulation).

Unusual stimulation of peripheral sensors depending on:

- **Type of movement**: roll, pitch etc.
- **Stimulation frequency:** movement amplitude

Protocol proposal:

At least reproduce fighter pilot training by using "Coriolis" accelerations, (greatly inspired by: "***The Italian Air Force rehabilitation program for air sickness***", M. Lucertini, V. Lugli, *Acta Otorhinolaryngol Ital* 24, 181-187, 2004).

- Rotations in the chair at different speeds (from 40 to 120°/s), eyes closed, adding head movements in the 3 planes (Coriolis effect).
- We measure the time withstood for each speed in the Clockwise and Anticlockwise directions, and for each movement (Flexion/Extension, Tilts, Rotations)
- The objective is to withstand 2 min. of clockwise and anticlockwise before moving to a higher speed

For example, you can start with slow flexion extension (less than 1 mvt/sec), eyes closed, combined with rotations in the chair, at a constant speed of 40°/s in the clockwise direction. Patients, for example, will withstand one minute and 40 seconds. You can wait a few minutes and, depending on their condition, start again in the anticlockwise direction, where, for example, patients will withstand 48s.

TIP: *To try to maintain a constant speed in the chair without an instrument, convert the angular speed into "how long for ½ a rotation" and readjust, stopwatch in hand, every ½ turn*
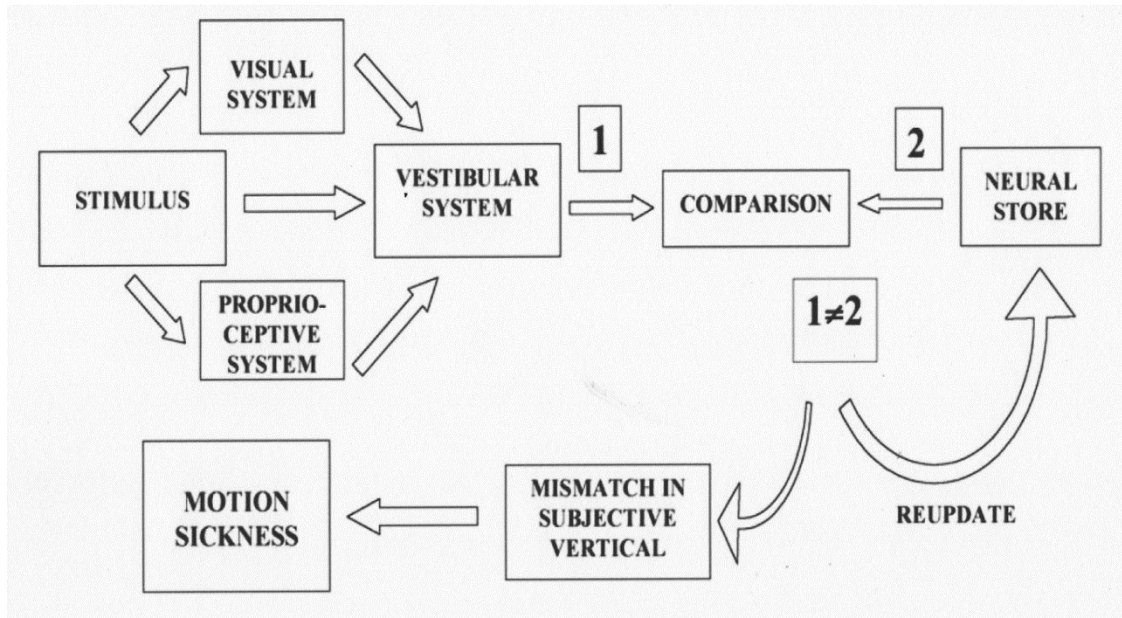
40°/s = 9 sec per turn (360/40=9) => 4.5s per ½ turn, so passages at 4.5, 9, 13.5, 18 etc.

60°/s = 6 sec per turn (360/60=6) => 3s per ½ turn, so passages at 3,6,9,12, etc.

	40 °/S	60 °/S	90 °/S	120 °/C
Rotations Right / Left				
Clockwise				
Anticlockwise				
Tilts				
Clockwise				
Anticlockwise				
Flex° / Ext°				
Clockwise	1 min40			
Anticlockwise	48s			

Sensory Conflicts

There are at least 2 categories of conflicts depending on the systems involved and 2 types of conflict for each category.

2 Main Conflict Categories

Depending on the sensory systems involved:

Visual / Vestibular

- the most often described in the literature

SC Canals / Otolithic System

- Vision is not involved (Blind people, eyes closed, may be sensitive)

In each category, there are 2 types of conflict

- **Type 1:**

The 2 sensory systems continuously send contradictory or uncorrelated information

For example: Head movements with visual distortion (binoculars, prism), watching waves from a boat.

- **Type 2:**

One system sends information while the signal expected by the other system is absent

For example: Optokinetics, Imax Cinema, Simulator Sickness (fixed base), etc.

Most highly triggering environments involve more than one type of conflict:

TYPE	CATEGORY	
	VISUAL (A)/VESTIBULAR (B)	**CANAL (A) / OTOLITH (B)**
1 : A and B signals simultaneously give contradictory information	Watching waves from a ship Use of binoculars in a moving vehicle - Making head movements when vision is distorted by an optical device Reading hand-held material in a moving vehicle	Making head movements while rotating about another axis (Coriolis) / Making head movements in an abnormal acceleration environment, (eg, hyper- or hypogravity) Vestibular disorders (eg, Ménière's disease, acute labyrinthitis, trauma)
2a: A signals are received but expected B signals are absent	**OptoKiNetics**, Simulator sickness (fixed base) / VIMS / VR Sickness 3D Cinema/Imax sickness/ Circular linear vection	Space sickness Pressure (alternobaric) vertigo Caloric stimulation of semicircular Canals
2b: B signals are received but expected A signals are absent	Looking inside a moving vehicle without external visual reference (cabin of a boat) Reading in a moving vehicle	Low-frequency (< 0.5 Hz) translational oscillation OVAR

Summary table for protocols:

	CATEGORY	
TYPE	**VISUAL (A)/VESTIBULAR (B)**	**CANAL (A) / OTOLITH (B)**
1 : A and B signals simultaneously give contradictory information	**Waves (sway referenced)**	**Coriolis Protocol**
2a: A signals are received but expected B signals are absent	**Sea Simulation Car Simulation**	**Non-physiological condition**
2b: B signals are received but expected A signals are absent	**Reading (sway referenced)**	**Non-physiological condition**

1.2. Advice for use

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

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 "powerful".

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.

The treatment of motion sickness is by "habituation", so symptoms felt during transport must be re-created very gradually. It is absolutely essential to interrupt the session when the first symptoms

appear, usually "sweating". Accepting that some motivated patients wish to go further would be counter-productive. It is up to the healthcare professional to "dose" the immersion to avoid causing neurovegetative symptoms. This type of symptom may intensify during the hour following the session.
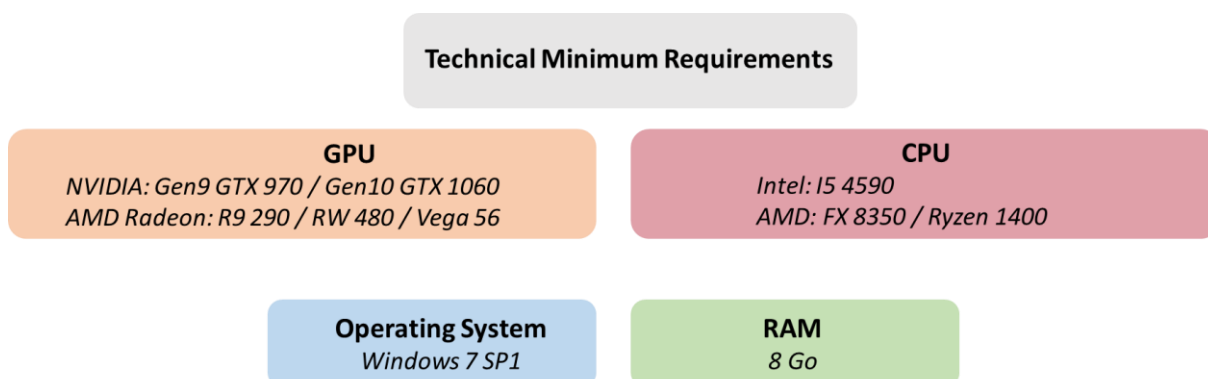
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

1.3. 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)
- 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:

Technical Minimum Requirements

GPU
NVIDIA: Gen9 GTX 970 / Gen10 GTX 1060
AMD Radeon: R9 290 / RW 480 / Vega 56

CPU
Intel: I5 4590
AMD: FX 8350 / Ryzen 1400

Operating System
Windows 7 SP1

RAM
8 Go

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 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.

CINETO VR software contains the following modules: Lift, Reading (sway referenced), Car Simulation, Sea Simulation and Waves (sway referenced).
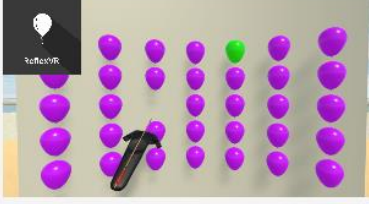
You can start or switch from one software to another from the home page by clicking the corresponding "Start" or "Protocols" button.
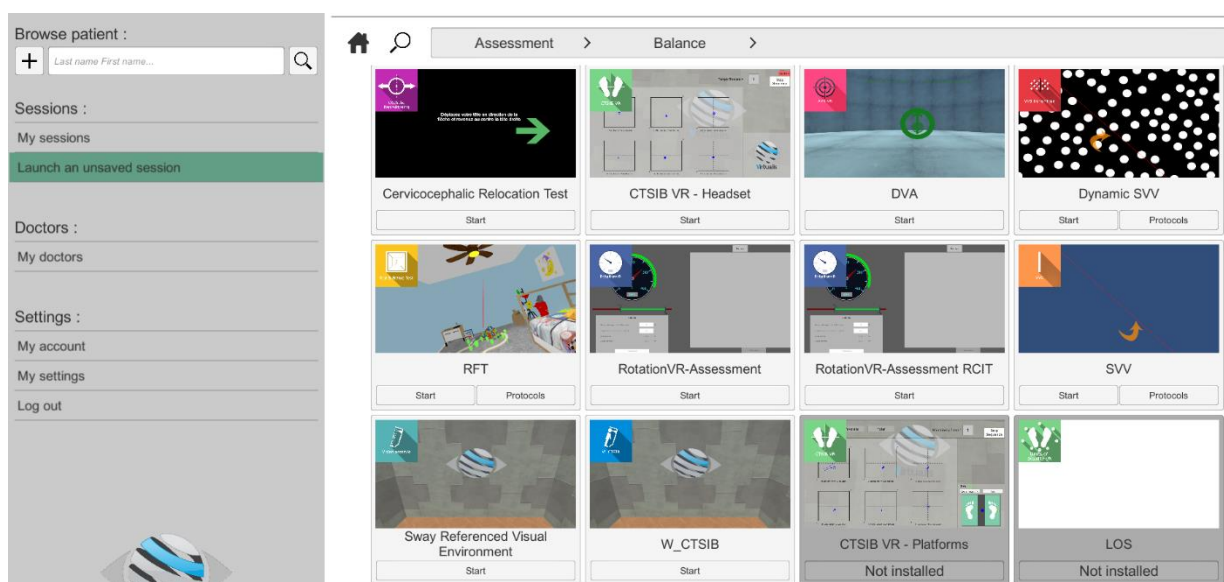
Some software can be started either in *manual mode*, by directly clicking the "Start" button, or in *protocol mode* by clicking the "Protocols" button.

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. CAR SIMULATION

3.1. Start interface

When starting the software in *manual mode* ("Start" button), 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.
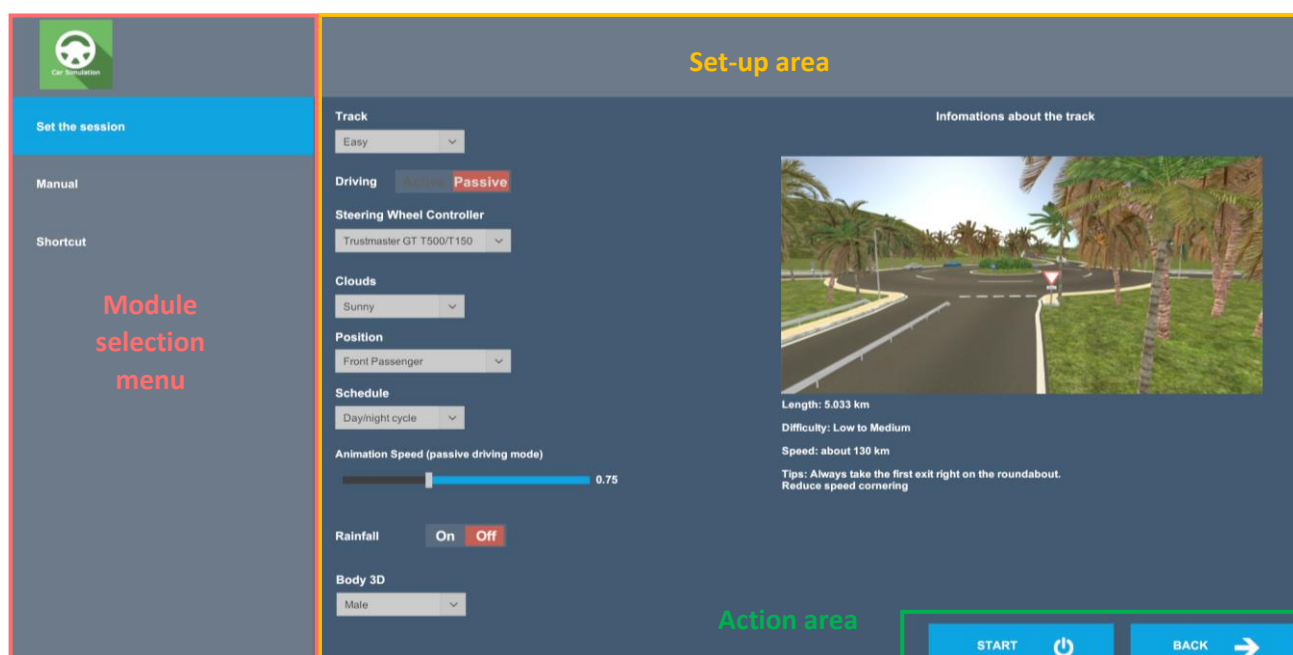
Once this button is pressed, the module starts by taking into account the specified settings. You also have the possibility to modify some settings when the module has been launched, using the mouse.

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

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

Specific module for car motion sickness.

The aim here is to reproduce the "Optokinetic" type Visual-Vestibular conflict, i.e. when Vision perceives a movement and the vestibular apparatus does not, but in a familiar environment reminiscent of motion sickness in a car.

This module has many adjustable options: leave the mouse on the question marks in front of each option to display detailed explanations.

Visual-Vestibular Conflict

- Visual Information: Present
- Vestibular Information: Absent

3.3. Installing the patient

Patients must be seated to reproduce the "sitting in the car" situation. During the first session, it is recommended to use the "Active Driving" mode to get patients to drive. (Steering wheel accessory required). Once patients "tolerate" the chosen circuit, they can switch to "Passive Driving" mode, namely passenger mode, for their treatment.

3.4. Session settings

The variable settings for this module are as follows:

Circuit

Environment selection according to difficulty. The selection is made directly from a drop-down menu**.**

Driving

Two types of driving are possible: active or passive. The selection is made by simply clicking on the chosen button. For more information, leave the mouse on the question mark.

Choice of steering wheel

Possibility of selecting steering wheel types

Clouds

Used to select the weather

Position

Used to choose the passenger seat in the car

Time

Used to select the time of day

Animation speed

The animation speed in passenger mode is fully configurable by direct adjustment of the corresponding cursor using the mouse.

Rain

Activates or deactivates rain

3D Body

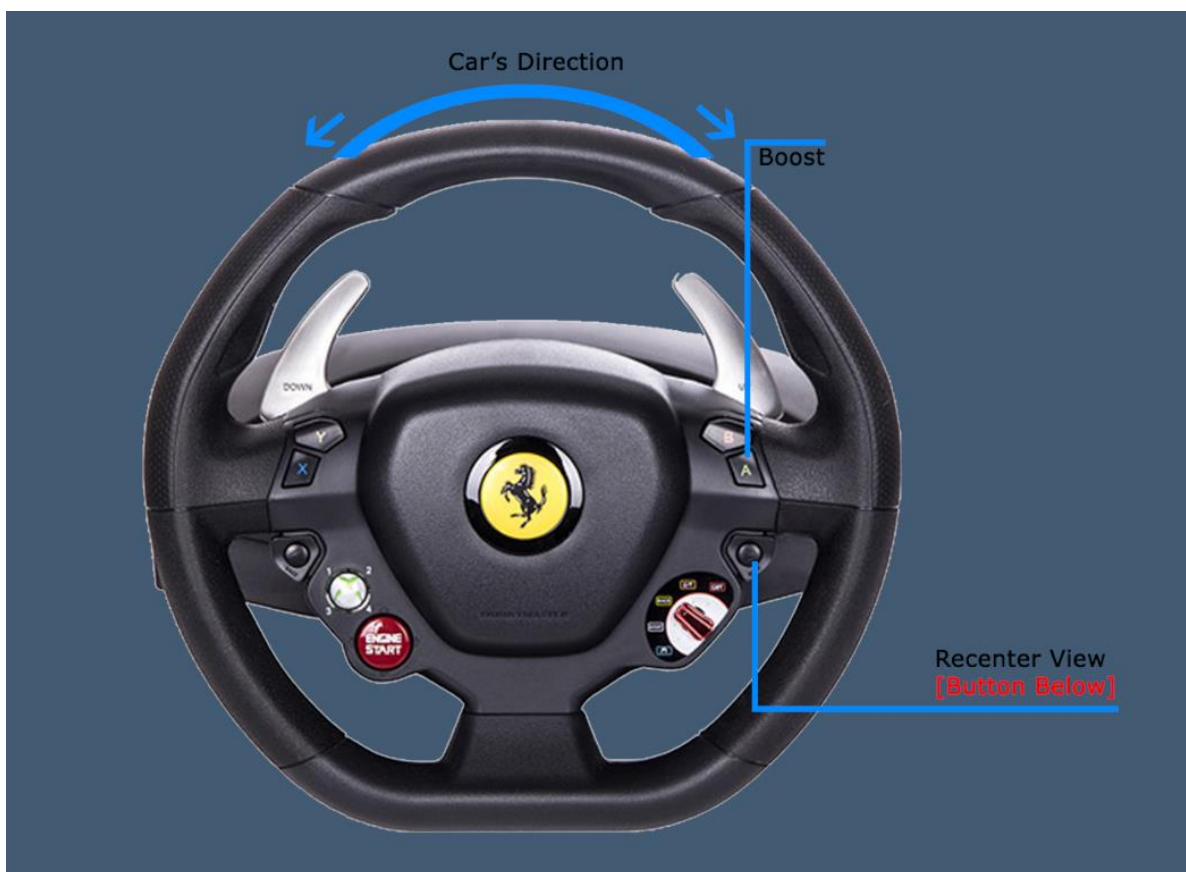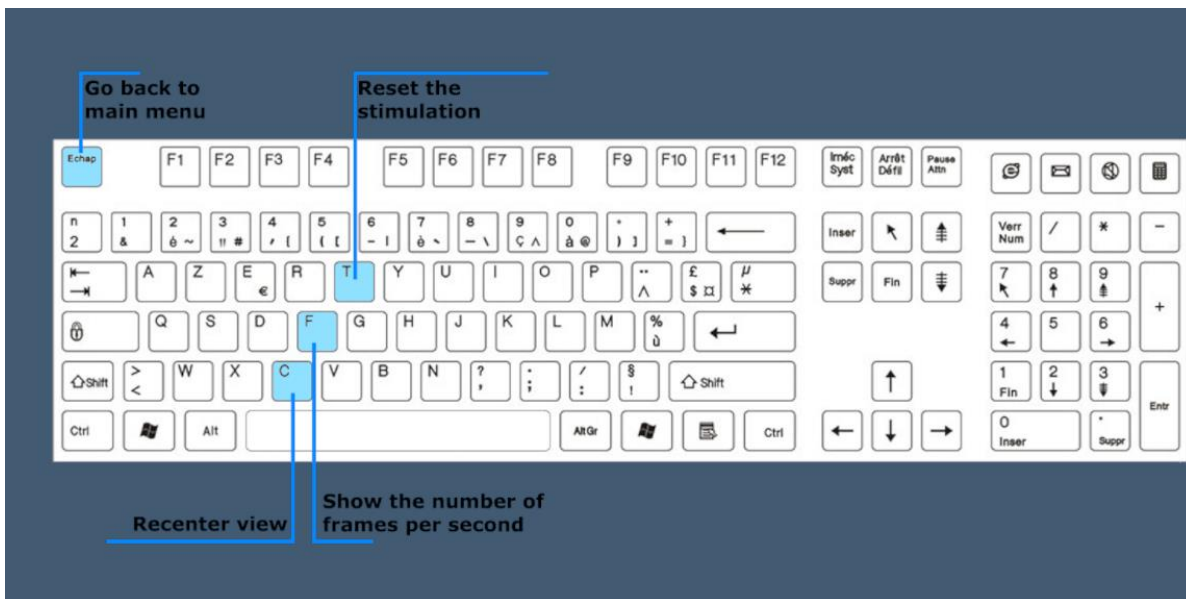Choice of the body according to users' gender

Example of an ongoing session.

3.5. Shortcuts

The keyboard or steering wheel shortcuts can be accessed in two ways:

- on the "Shortcuts" tab available at the start interface level
- within the module, by clicking on the joystick icon in the upper right corner of the screen

3.6. Data processing

Data retrieval and analysis uses the Patient Management software.