REF **DVA VR**

CE Class I Medical Device

User manual

Distribution mode

Available for direct download at

http://virtualisvr.com/espace-client/

Use under licence

VIRTUALIS

Avenue de l'Europe - 34830 CLAPIERS - Tel. 09 80 80 92 91

DESCRIPTION

DVA VR software is an immersive 3D simulation based on virtual reality technology, which allows a person to be immersed in an artificial digitally created world. **DVA VR** software is complete software for the assessment and re-education of image stabilization during high frequency head movements (oscillopsia).

INDICATIONS

Assessment, functional re-education and balance disorders.

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 Centers: 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 software, i.e. 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

Table of Contents

1. GENERAL

1.1. Advice for use

This type of re-education must be undertaken progressively, especially in Virtual Reality where the stimulation is much more "powerful" than the traditional optokinetic stimulators.

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)

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.

Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

1.2. 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)
- HTC VIVE Controller
- XBOX 360 Controllers
- USB HUB
- Screen clamp
- Two trackers

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

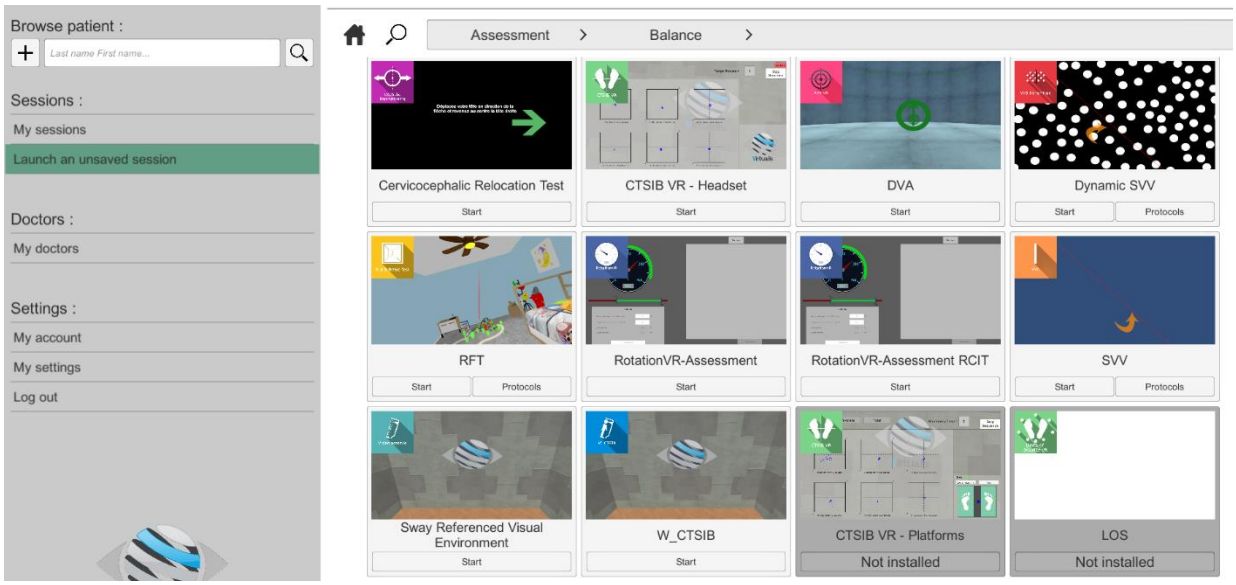
RAM
8 Go

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.

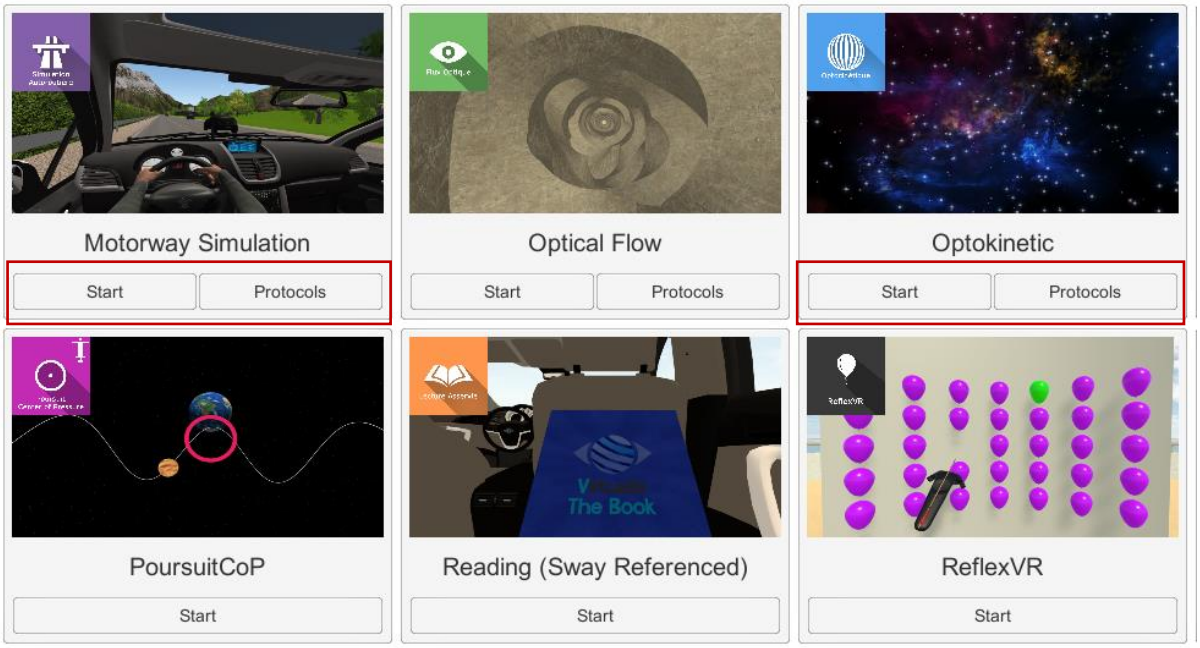
The software can be grouped according to criteria such as "Assessment" or "Re-education" and then by pathology type: Neurology, Balance, Functional or Travel sickness.

You can start or switch from one software to another from the home page by clicking the corresponding "Start" or "Protocols" button.

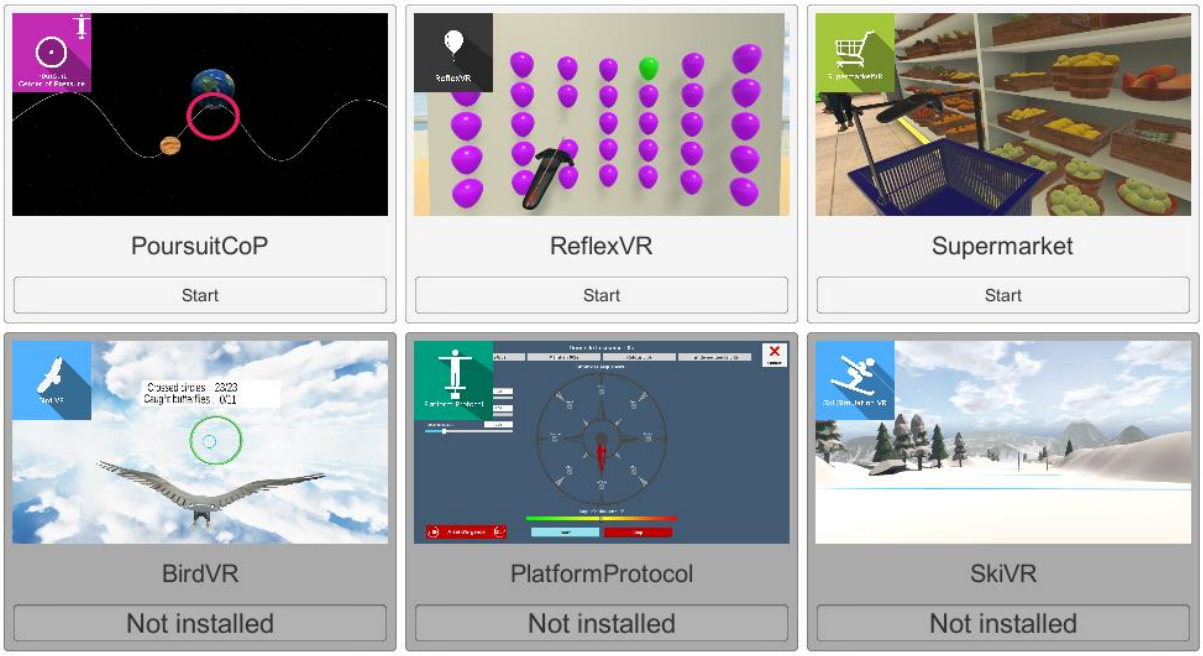


Some software can be started either in ***manual mode***, by directly clicking the "Start" button, or in ***protocol mode*** by clicking the "Protocols" button.

Manual mode allows users to choose the settings for each environment. ***Protocol mode*** offers several sessions with different difficulty levels to test and gradually accustom patients to the VR environment.

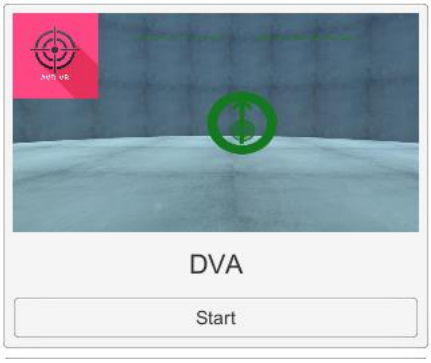


Software that is not part of your subscription package is greyed out. If you want to use it, please contact our sales department.



3. DVA VR

3.1. Start interface

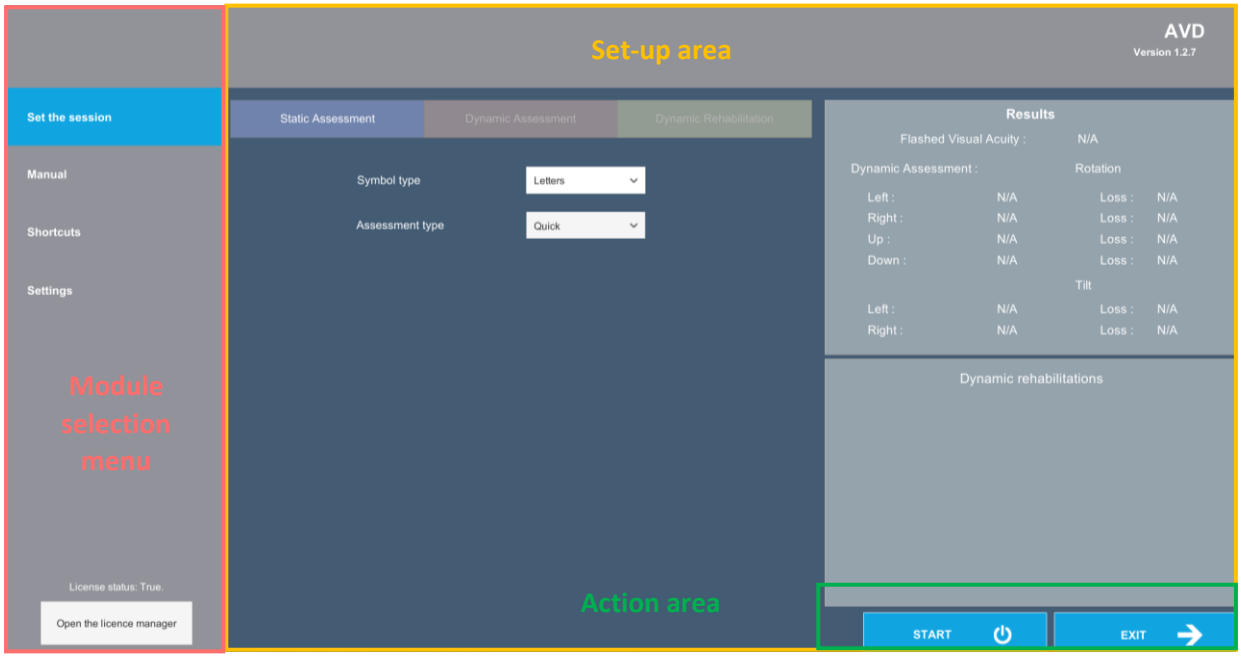


When starting the software in ***manual mode*** ("Start" button) from Patient Management, the software is opened in a start interface consisting of a module selection menu on the left, a set up area on the right, and an action area at the bottom right.

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.

3.2. Module field of application

Revised Dynamic Visual Acuity is used to carry out:

- accurate on-screen assessment: patient/screen distance measured automatically at each assessment
- on-screen re-education or using the virtual reality mask
- 360° physiological movements, anticipatory saccade work

3.3. Installing the patient

Patients must be seated at least 1m from the screen during assessments (static or dynamic).

Re-education can be carried out seated or standing (to add the vestibular-spinal reflex component)

3.4. Session settings

To carry out a **Static Assessment**, click the corresponding tab. You can then choose the graphic design of the optotypes to be displayed and start the assessment.

For a **Dynamic Assessment**, you can choose the graphic design of the optotypes to be displayed as well as the type of movement to be carried out. If you wish to assess all types of movement, check the "Automatic Assessment" box. The assessments will then follow one after the other for the different movements.

By starting the software from Patient Management, the software will communicate the last known Static Assessment.

For **Dynamic re-education**, choose the size of the optotypes by specifying the visual acuity to be worked on. You can choose one or more different movements to carry out. Similarly, you can specify one or more categories for the optotypes to be displayed.

The Amplitude Mode option consists of making a target appear opposite to where the optotype appears.

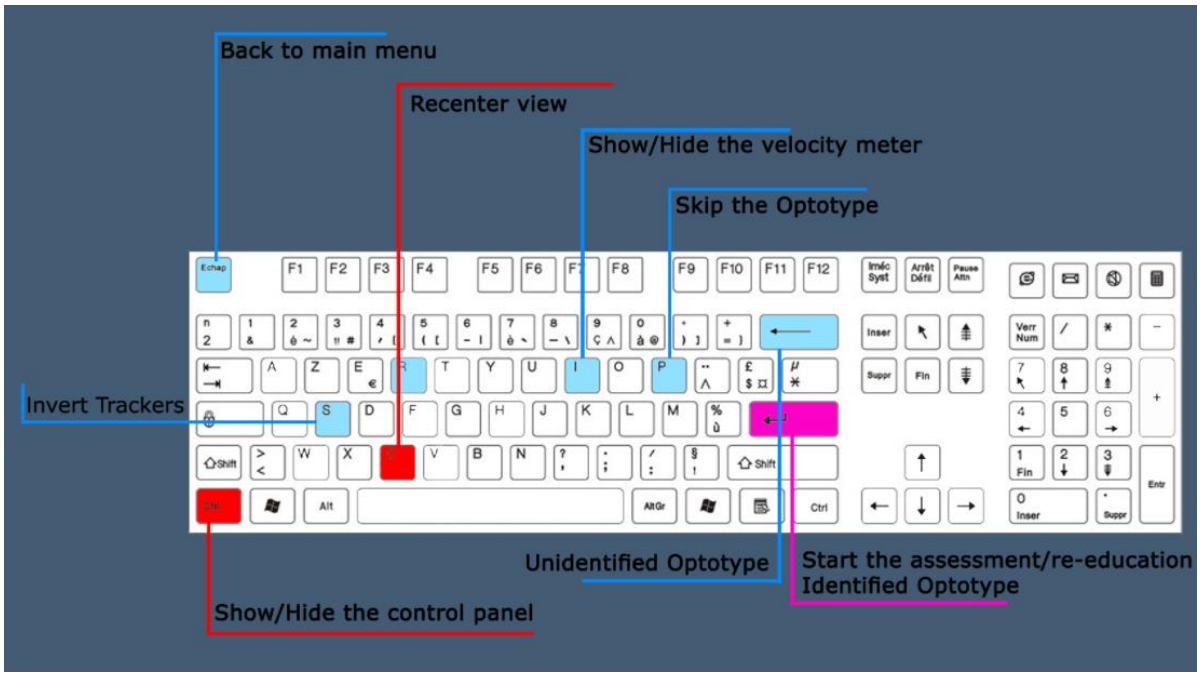
Users must then position the aiming circle on the target until it disappears. They can then carry out the movement to display the optotype.

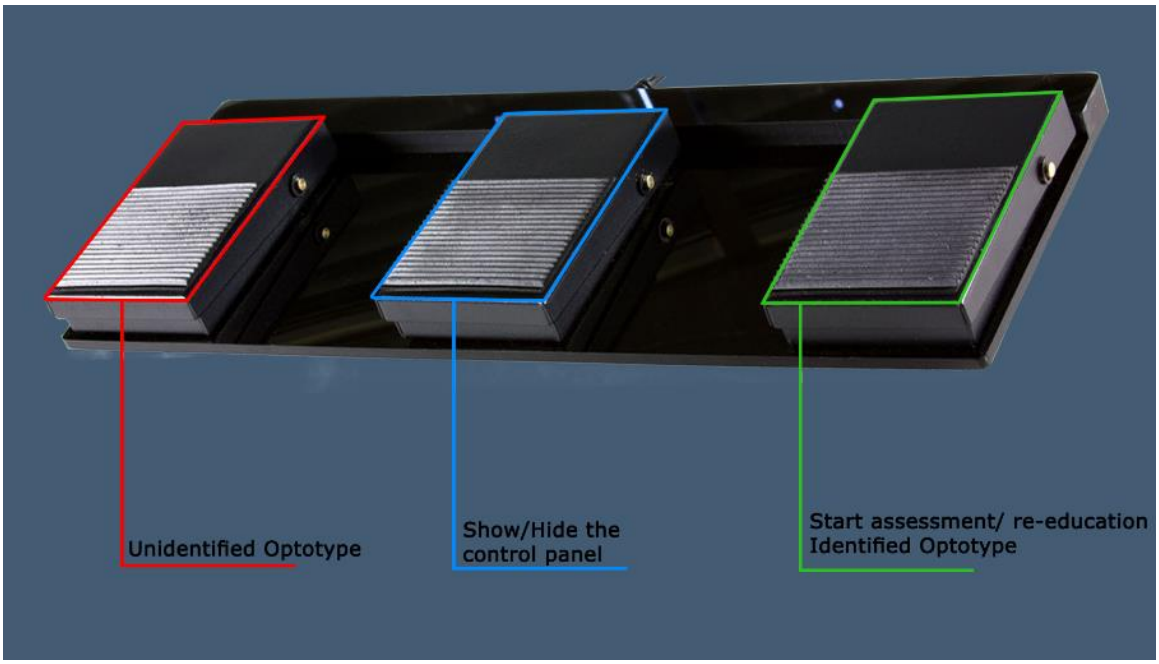
You can also add or remove words by modifying the "Word_List1.txt" and "Word_List2.txt" files located in the directory: "C:\ "Users\USERNAME\Documents".

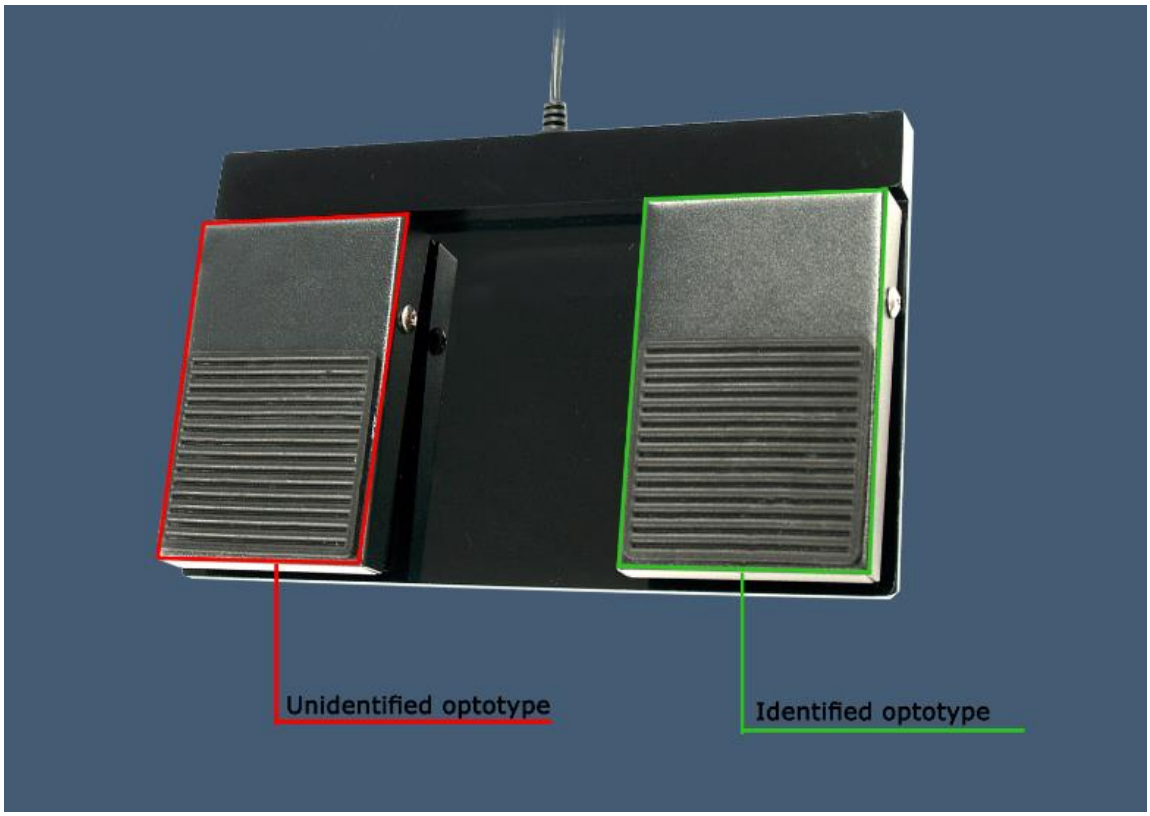
3.5. Shortcuts

Keyboard, joystick or pedal 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.