REF **LOS Rehab**

CE Class I Medical Device

User manual

Distribution mode

Available for direct download at

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

Use under license

VIRTUALIS

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DESCRIPTION

LOS Rehab (Limits of Stability Rehabilitation) is an immersive 3D simulation software based on virtual reality technology, meaning a person can be immersed in a digitally created artificial world. **LOS Rehab** works on the rehabilitation of patients' stability limits, based or not on the results of the previously established LOS assessment.

INDICATIONS

Rehabilitation of the patient's balancing strategy according to the limits of the angle of his oscillating cone.

CONTRAINDICATIONS

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

FOR USE BY

Healthcare professionals: Physiotherapists; Ergotherapists; Neuropsychologists; ENT doctors; Neurologists; PM&R physicians (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 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. Advice for use

Virtual Reality Immersion is a powerful tool, especially for optokinetic stimulation, optical flow, motorway simulations, dynamic SVV etc.

These stimulations have the potential to cause a number of 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 rehabilitation must be undertaken progressively, especially in Virtual Reality where the stimulation is much more "powerful" than with traditional optokinetic stimulators.

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 check the patient's tolerance to this type of stimulation.

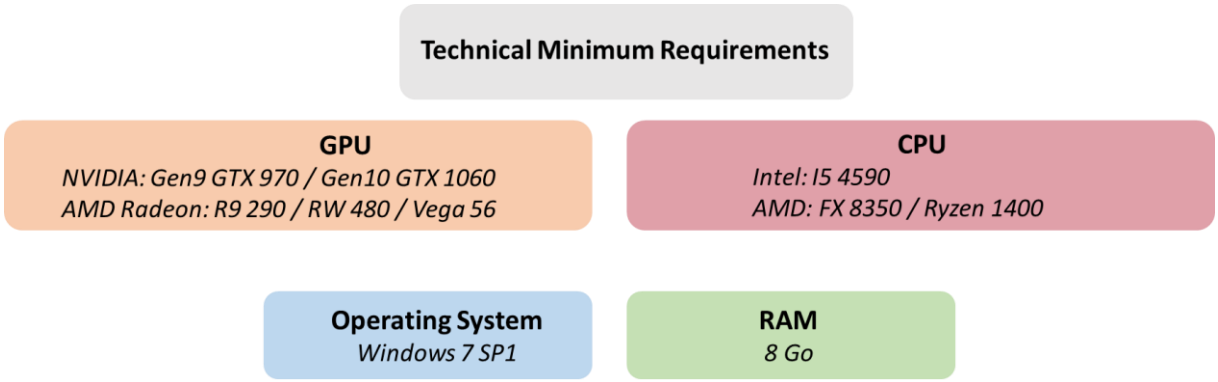
Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

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)
- Posturography platforms (StaticVR or MotionVR)

In order to install and use our virtual reality applications, we recommend a configuration equal to or higher than the following system requirements:

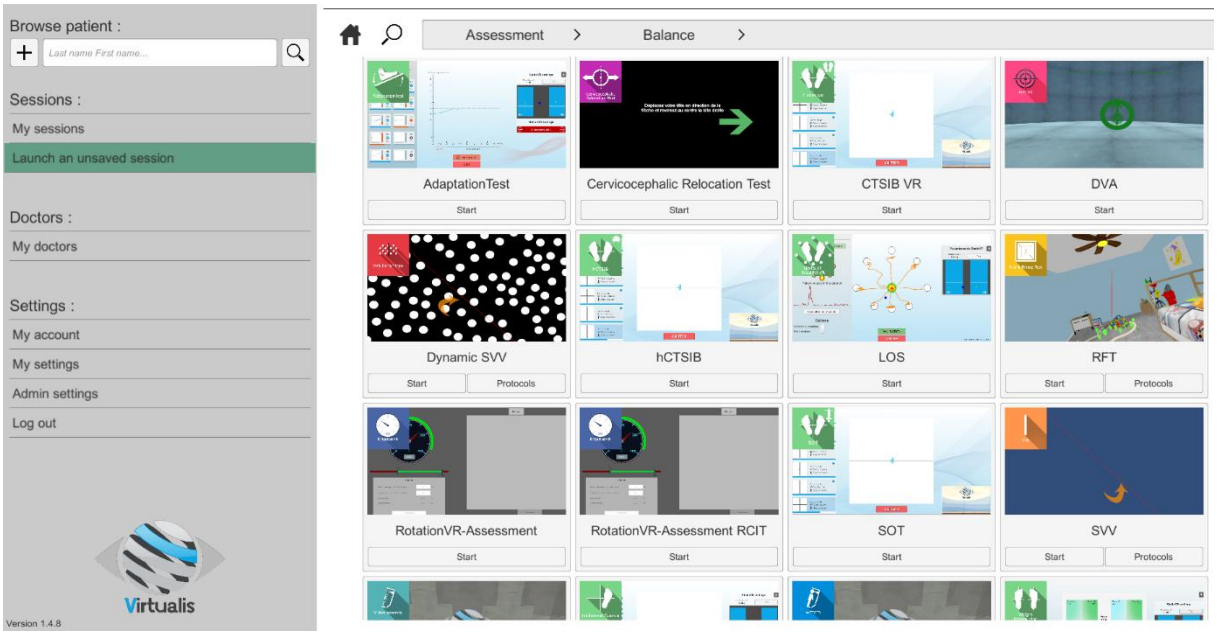


2. USE of PATIENT MANAGEMENT

Once connected to the Patient Management software, you get to the home page. It is from this home page that you will be able to start your VR software as well as other Patient Management features.

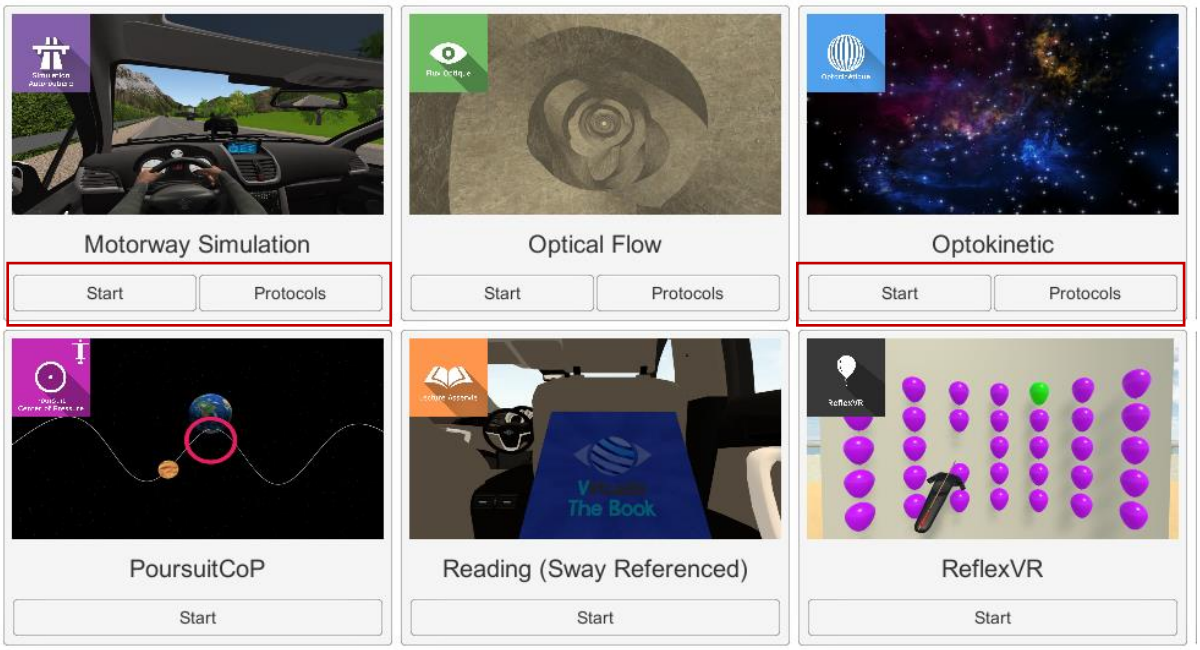
The softwares can be grouped according to criteria such as "Assessment" or "Rehabilitation" and then by pathology type: Neurology, Balance, Functional or Motion sickness.

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

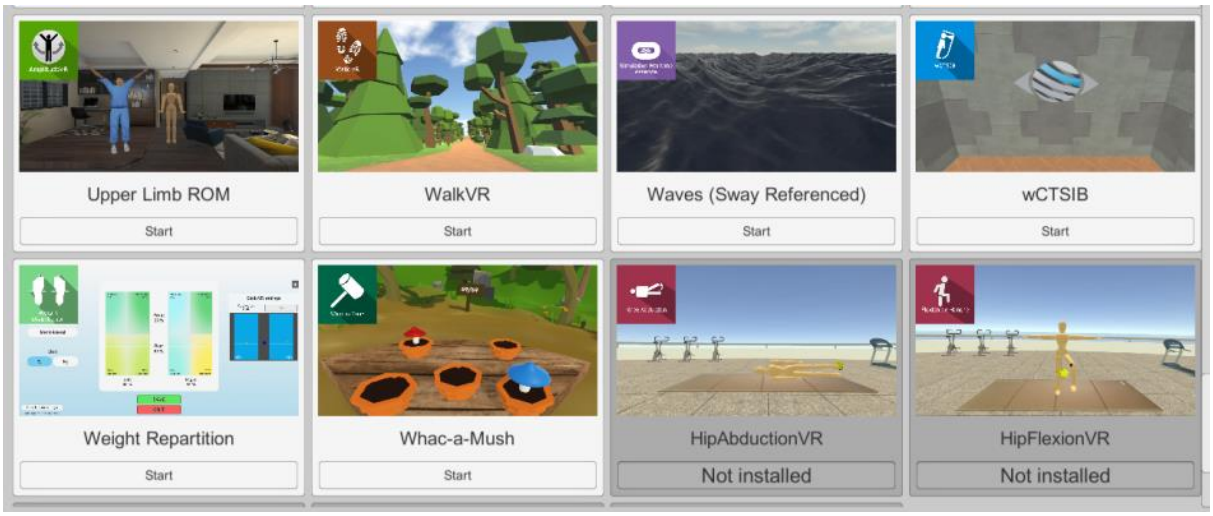


A number of softwares can be started either in ***manual mode***, by directly clicking the "Start" button, or in ***protocol mode*** by clicking the "Protocols" button.

The ***manual mode*** allows users to select settings for each environment. The ***protocol mode*** offers several sessions with different difficulty levels to test and gradually accustom patients to the VR environment.

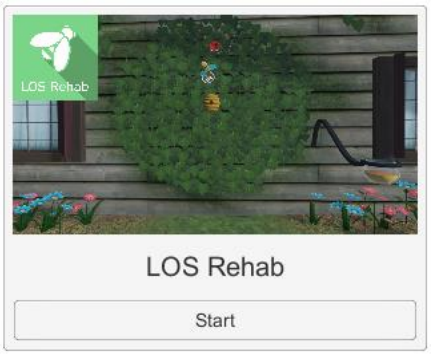


Softwares which are not included in your subscription package are grayed out. If you want to use them, please contact our sales department.



3. LOS Rehab

3.1. Start interface

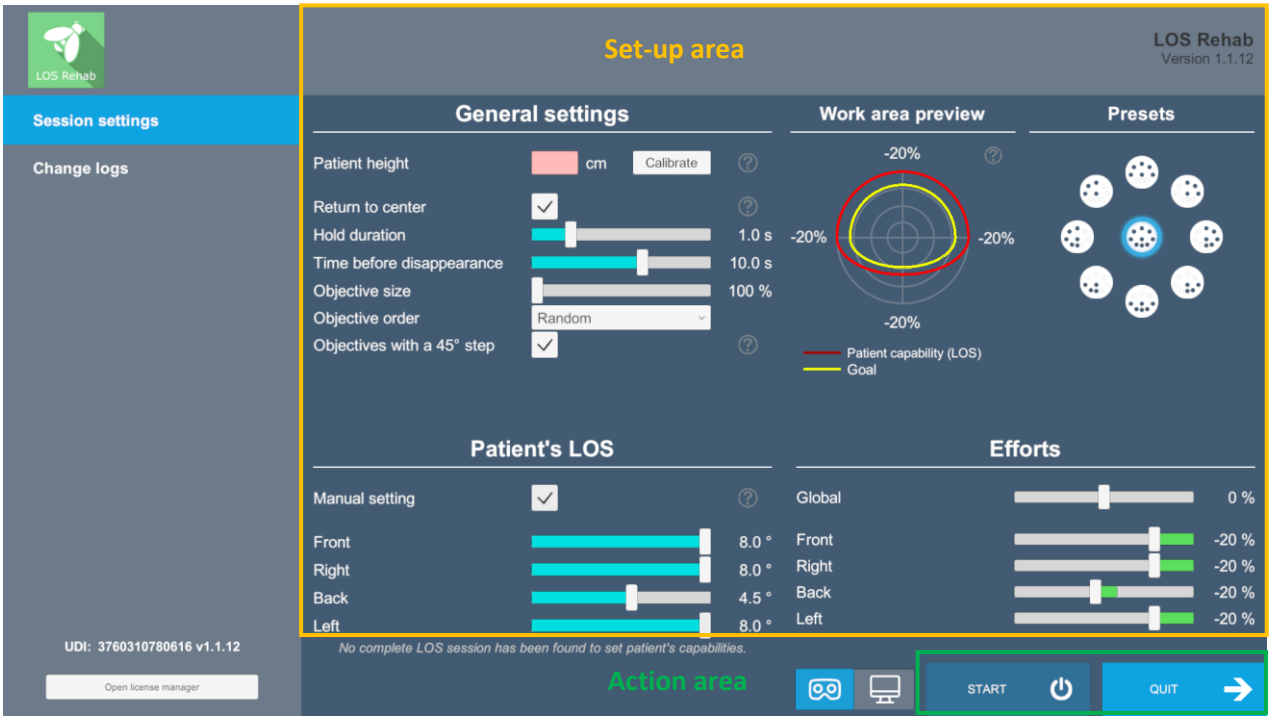


When launching the software in ***manual mode*** (Start button), it opens a launch interface consisting of a set up area and an action area (“start” and “quit” buttons).

The general Patient Management menu can be accessed from the start interface by simply clicking the "quit" button or by pressing the "escape" key on the keyboard.

The software is launched by simply clicking the "start" button in the action area.

Once this button has been pressed, the software is launched, taking into account the specified settings.



The selected environment launches in the headset, and you can see and track what is happening in your patient’s headset using the software window.

Action area

3.2. Software field of application

LOS Rehab is a rehabilitation software, complementary to the LOS evaluation software, for the patient's balancing strategy according to the limits of the angle of his oscillating cone.

The health care professional can use the data in the LOS assessment to set aims.

3.3. Installing the patient

Patient standing on StaticVR or MotionVR force platform.

Positioning the patient on the platform:

- Center the patient's feet on the force platform.
- The medial malleolus of each foot should be directly centered on the horizontal line of the force platform.

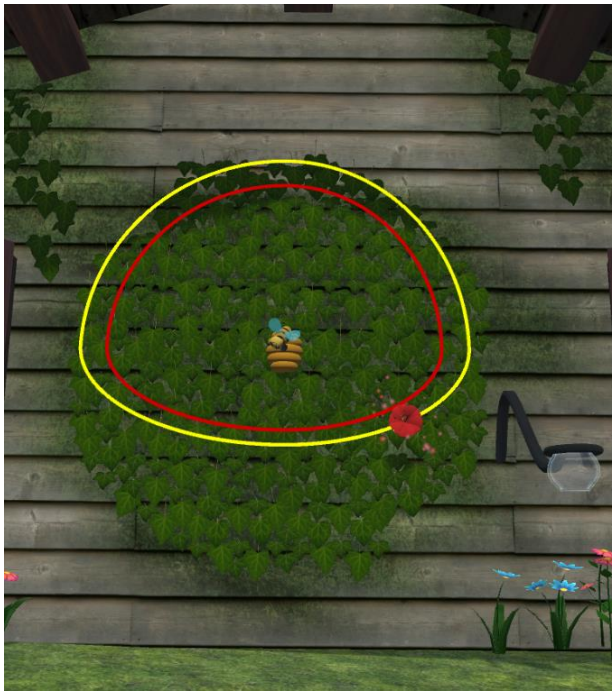
Warning: It is recommended that all tests be performed with shoes removed, in order to get a standardized input of somatosensory system signals and to compare with the standard data set.

3.4. Session settings

To carry out this test, the patient, standing on the platform, must voluntarily move his center of pressure, which is depicted as a bee, by leaning towards a target depicted as a flower. He must lean his body in a given direction without losing his balance, walking or looking for help.

Once the target has been reached, the position will have to be maintained until the target disappears.

Between each movement, the patient must return to the center if the "return to center" option is activated.



The software's variable settings are as follows:

General settings

Patient height

This value can be entered manually or automatically by pressing the "calibrate" button.

Note: For accurate calibration, please have the patient stand with the VR headset correctly positioned. The feet should be on the floor and the patient should be looking straight ahead.

Return to center

If this option is activated, the patient must return to the center between each movement

Hold duration

Time during which the patient has to touch the target.

Time before disappearance

Time during which the target appears

Objective size

This is used to increase or decrease the size of the target (flower)

Objective order

This is used to select the direction in which the target appears: clockwise, anticlockwise or random

Objectives with a 45° step

If this option is activated, the objectives will only appear on standard LOS angles (spaced 45° apart).

Sway-referenced support

Once this option has been activated, the MotionVR dynamic posturography platform will tilt according to the movements of the patient's CoP (center of pressure).

Display mode

Two possibilities: Headset or Screen Mode

You can choose between "headset" or "screen" mode simply by clicking the corresponding icon; the selected icon switches to blue.

Headset mode: Instructions will be communicated to the patient visually through the virtual reality headset.

Screen mode: Instructions will be communicated to the patient visually on an external screen. This mode requires a second screen connected to the computer

Warning: in this mode the headset should not be used and the patient should be facing the second screen.

Work area preview

This is used to visualize the patient's capabilities (red line) and the patient's effort goal (yellow line) relating to his capabilities. Targets will appear along the yellow line.

Presets

This is used to select the work area (yellow line) following a given direction or in all directions by simply clicking the corresponding circle

Patient's LOS

The patient's capabilities can be determined from a LOS session.

It is also possible to edit the patient's LOS manually by checking the "manual setting" box.

Efforts

This is used to set the effort the patient will have to make according to his LOS assessment.

Positive values indicate the patient must go beyond his capabilities.

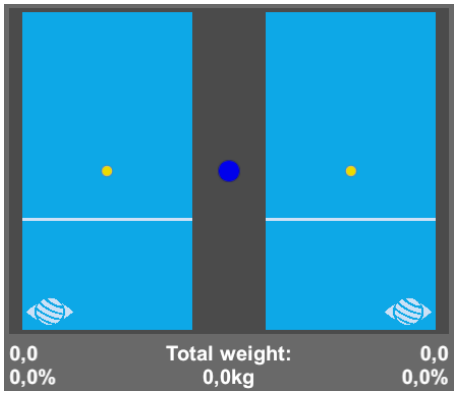
StaticVR settings

Raw data sent by the platforms

Yellow dots: Center of Pressure (CoP) of each foot

Blue dot: Overall Center of Pressure (CoP)

The weight distribution for each foot is displayed



Smoothed data & settings:

Tare

Platform reset (must be carried out when empty)

Smoothing

Smoothing force applied to the data

Sensitivity

Multiplier applied to the data received

Decrease to reduce motion sensitivity

MotionVR settings

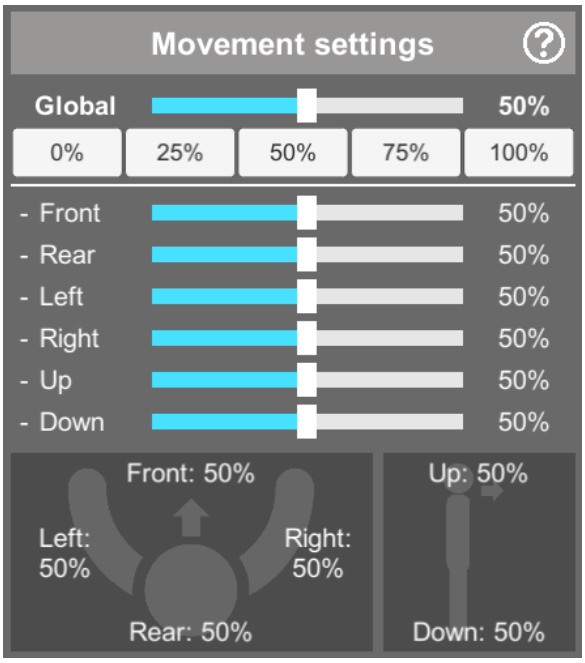
Movement settings

Platform amplitude values can be defined either by using the cursor or by selecting one of the proposed values by simply clicking on the corresponding button.

You can select an overall or per-axis movement amplitude, the presets provide a smooth transition.

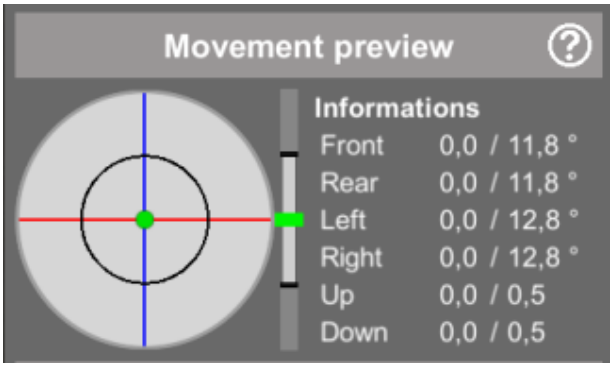
For example:

- To work in anteroposterior mode, reduce the left and right amplitude
- To work in mid-lateral mode, reduce the front and rear amplitude

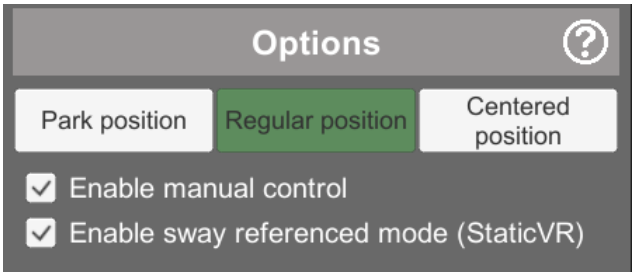


Movement preview

This is used to view the platform tilt, height and amplitude settings (the action area is delimited by a black circle).



Options



Platform positions

Park position: forces the platform to ground level. The height of the platform is set to the minimum.

Regular position: allows the platform to move normally, as provided for in the software

Centered position: forces the platform into a horizontal position at its operating height

Enable manual control

This is used to move around using the arrow keys on the keyboard and the "+ " and "-" keys on the numeric keypad (up and down).

Enable sway referenced mode (for StaticVR platforms)

The platform movement is coupled to the patient's center of gravity

If you press the emergency stop button, the platform will freeze in its current position.

A window opens and the following message appears

Warning:

Stopping the software or changing the window may cause the platform to reset to the default position and cause movement that could be dangerous for the patient. It is therefore advisable not to touch the computer again until you have secured the patient when the emergency stop is triggered.

Score

At the end of the exercise, results are shown in different forms: table, detailed and composite graph, statokinesigrams and ellipses compared to the standard.

Parameters measured are: reaction time, average velocity, directional control, initial excursion and maximum excursion.

3.5. Data processing

Data retrieval and analysis is done using the Patient Management software.