



REF **MotionVR**

CE Dispositif Médical de Classe I

User manual

Distribution mode

Available for direct download at
<http://virtualisvr.com/espace-client/>
Use under license

 **VIRTUALIS**

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

DESCRIPTION

MotionVR system is a clinical balance assessment device that collects and analyzes force and moment data from a balance /force plate. The balance plate is seated in a dynamic chassis that can move in up and down directions, under control of the Virtualis softwares. The Patient Manager software contains both assessment and training modules that can be used during each session. The system is intended to be used by trained clinicians in a hospital or clinical (physical therapy or ENT) environment who operate the device via a computer and dedicated software and ensure the safety of the patient. For use during dynamic training, MotionVR platform is fitted with a safety railing or the patient is placed in an optional harness.

INDICATIONS

Evaluation and Rehabilitation of balance and postural disorders of multiple origins: vestibular, neurologic, orthopaedic (lower limbs and spine)

FOR USE BY

Motion VR is to be used only by qualified and trained practitioners/ physicians.

Healthcare professionals: Physiotherapists; Ergotherapists; Neuropsychologists; ENT doctors; Neurologists; PMR doctors (physical medicine and rehabilitation), etc.

Research Centers: CNRS, CHU, INSERM, etc.

Read Carefully Before Proceeding

INTENDED USE :

Balance Evaluation and Rehabilitation

The MotionVR system is intended as an objective platform used for gathering and characterizing movement of subjects with balance disorders or instability.

MotionVR systems should only be operated by qualified personnel.



WARNING: To avoid risk of electrical shock, MotionVR system must only be connected to properly grounded power sources.

The successful use of the Virtualis technology requires an appropriate level of professional expertise to set-up proper treatment programs that are specific to the patient and their individual cases. The operators should be confident they understand the operation of the system, can properly administer test protocols, and interpret results.

The patient's center of gravity position (COG) can be monitored real time during all tests and measures.

NOTE: Virtualis equipment must only be serviced by qualified personnel. Please do not attempt to service equipment yourself.

Please contact Virtualis first for any service or support requests.



All protocols should be performed in stocking feet with hygienic foot covers.



WARNING: Do not modify Virtualis systems in any way. Modifications will void the warranty.

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



For additional product service or support, please contact: Virtualis Corporation Avenue de l'Europe – 34830 Clapiers, phone : 00 33 980 809 291 or contact@virtualisvr.com

General Maintenance

Virtualis MotionVR platform require basic maintenance, performed on an as-needed basis.

CLEANING INSTRUCTIONS :

- Wipe down the balance platform with damp cloth or standard cleaning solution.
- For good hygiene, patients should wear footies.

Table of Contents

05	Patient Considerations Prior To Testing
07	Getting Started
07	Fundamental Operations
07	Your MotionVR Balance System(S)
07	Turning The MotionVR System On/Off
08	Emergency Stop Button
09	Positioning The Patient
10	System Configuration
16	Entering the Patient Manager System
17	Clinician Home Screen
18	Establishing New Patient Files
18	Recalling Existing Patient Files
19	Starting A New Assesment or Rehabilitation Session
20	Particular Case : Launching an Unsaved Session
20	Patient Assessment
22	To View and Print Reports of Completed Assessments
22	Assesment Reports

PATIENT CONSIDERATIONS PRIOR TO TESTING

OPERATOR RESPONSIBILITIES

1. The clinician will be responsible at ALL TIMES for the safety of the patient while using the MotionVR platform.

BEFORE BEGINNING A SESSION MAKE SURE :

- The patient is standing on the platform with feet properly positioned and is facing into the visual surround (if present).

To help ensure patient safety :

- The MotionVR platform is fitted with the safety railing which can be adapted to each patient's needs regarding their height/ size.

Or

- The patient is properly fitted with the harness and the harness straps are attached to the overhead bar with the correct tension (for dynamic systems).

MECHANICAL PATIENT SAFETY SYSTEMS : SAFETY RAILING AND PATIENT HARNESS

If safety railing is used :

The safety railing must be used at all times : during static and dynamic use of the MotionVR system for evaluation or training.

Safety railing settings :

The safety railing of the platform must be securely closed and its height adapted to the patient's size.

The safety railing height can be modified in two ways (Figure 1): manually by pressing the **Up** and **Down** button or automatically by means of button **2**, **3** and **4** for a predefined position (buttons are located on the front side of the MotionVR platform). The height of the safety railing is displayed on the screen next to the buttons.

Button **2** : the height of the safety railing is 1.15 m

Button **3**: the height of the safety railing is 1.25 m

Button **4**: the height of the safety railing is 1.40 m

Button **1** : allows to go down the safety railing at 1 m

Button **S** : allows to stop the movement of the safety railing at any moment.

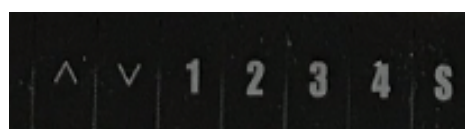


Figure 1. The safety railing control panel

Security harness settings :**If harness is used :**

Patient security can be provided during testing and training with the use of a harness. The patient must wear a securely fitted safety harness connected to the overhead bar by two suspension straps.



Warning: A harness appropriate for the weight of the patient shall be selected to ensure patient safety during use.

Included are:

- A complete harness – already assembled and ready to be worn. The maximum weight capacity is 300 lb.
- Two shoulder straps to connect the harness to the support structure

NOTICE!

Harness straps must be tight enough to stay in place if the patient should fall and therefore prevent injury. Tension should not trigger pain or physical or respiratory discomfort or restrict the required mobility for the correct progress of the evaluation or training.

GETTING STARTED

YOUR MOTIONVR BALANCE SYSTEM(S)

Identify all tests and measures that are available to you on your MotionVR system :

Sensory Organization Test (SOT), Adaptation Test (ADT), Limits of Stability (LOS), Unilateral Stance (US), Ski, Bird, MotionProgram, Sea Simulation

TURNING THE MOTIONVR SYSTEM ON/OFF

Do not stand (operator or patient) on the device during system switching on of off.

1. Turning the MotionvVR System ON correctly allows for proper initialization and operation :

MotionVR must be turned on prior to turning on the computer

- Locate the Power Box on your system and turn it on (Figure 2)



Figure 2. Base turned On

- Once done, turn ON the computer and start the **Patient Manager** software which allows you to access to all softwares and operational commands.
2. Turning the System OFF correctly allows for proper system back-up and protection of MOTIONVR operating systems.
- From the launch interface of the software you use, select **QUIT** button
 - The MotionVR system will systematically shut down its' operation.
 - After shutting down the computer completely, turn OFF the Power Box located on the system (Figure 3)



Figure 3. Base turned Off

EMERGENCY STOP BUTTON

The emergency stop button is located on the front of the device under the security railing (Figure 4).

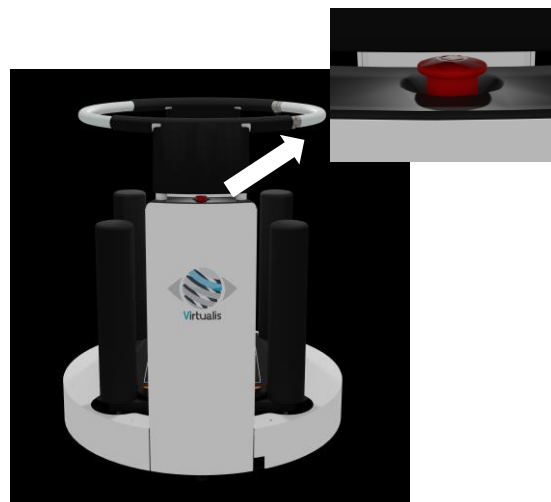


Figure 4. Emergency stop button

1. To stop the device press the button down.
2. To unblock the device after an emergency stop, release the button by turning it 1/4 turn to the right (clockwise rotation indicated by an arrow).

POSITIONING THE PATIENT

The device must be correctly turned on and initiated and computer software operational prior to patient positioning on the device.

When standard foot placement is required (applies to all force plates), position the patient as follows:

1. Help the patient step onto the platform base facing forward
2. Center the patients' feet on the force plate. The medial malleolus of each foot should be centered directly over the center horizontal (wide) line on the force plate and the lateral calcanei are aligned with the small (**S**), medium (**M**), or large lines (**L**). (Figure 5)

S = 30-55 inches/76-140 cm; **M** = 56-65 inches/141-165 cm; **L** = 66-80 inches/166-203 cm

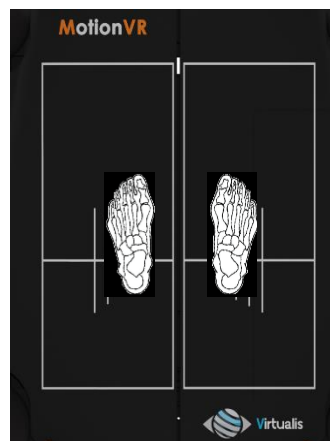


Figure 5. Proper foot placement

NOTICE! It is recommended that all testing be completed in non-slip socks to achieve standardized input from the somatosensory system cues and to compare to the normative data set.

The dynamic force platform performs linear tilting or impulse movements, depending on the chosen parameters.

During sessions, stay close to the patient in order to anticipate any loss of balance or discomfort caused by the use of virtual reality.

Sessions may be interrupted at any time (if the patient starts to fall, etc.) by selecting the **Pause** or **Stop** button on the control screen.

PAUSE

STOP

SYSTEM CONFIGURATION

REAL TIME VISUALISATION AND PARAMETER SETTINGS

Options Setup

The operator must select the icon in the upper right corner of the screen (**arrow**) to set-up the parameters for MotionVR system (from the clinician home screen of each software).

StaticVR settings

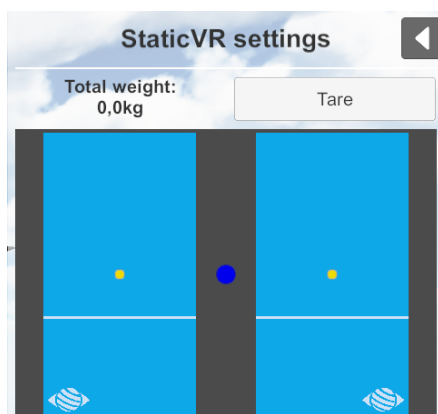
Real time feedback through control screen located top right of the control screen

Raw data sent by the platforms

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

Blue dot: Global Center of Pressure (COP)

The weight distribution for each foot is displayed



Tare

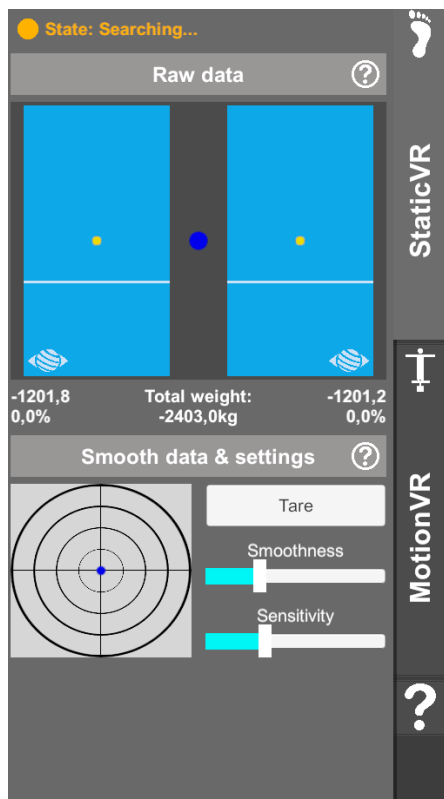
Platform reset (must be carried out when empty)

Advanced Settings

The grey triangle located on the top right of the previous diagram opens the optional settings menu.

STATICVR optional settings menu

Selection of the menu on right hand side of the screen.



Smoothed data & settings:

Smoothing

Smoothing force applied to the data

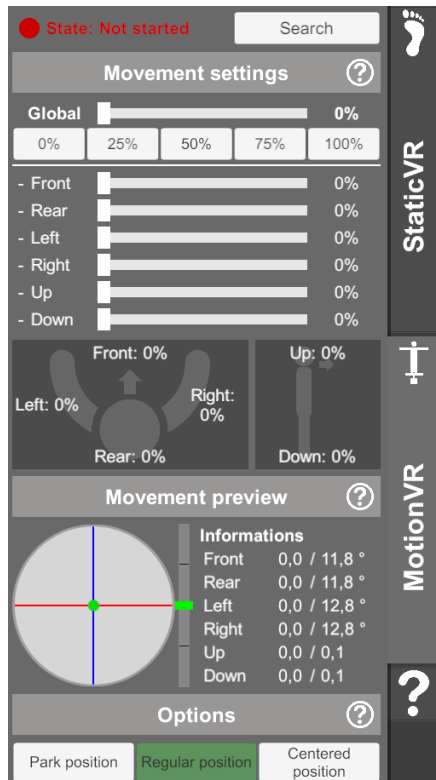
Sensitivity

Multiplier applied to received data

Decrease to reduce motion sensitivity

MotionVR settings

To activate the Motion VR settings menu, open the settings menu located on the right hand side of the screen.

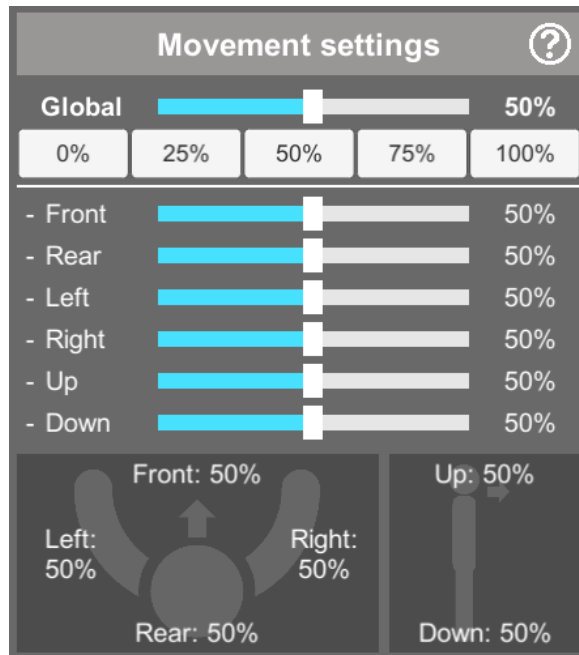


Movement settings

Platform movement amplitude values can be defined to an overall equivalent setting or independently per axis.

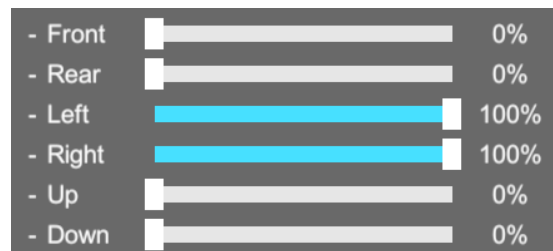
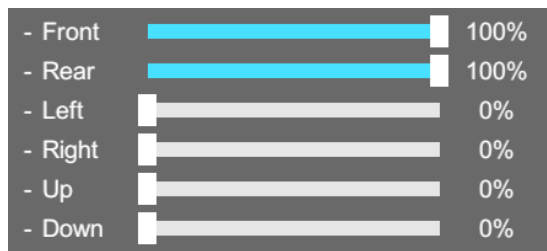
To set movement amplitude of all axes simultaneously the operator can use the "global" cursor or by choosing one of the proposed values by simply clicking on the button corresponding to the value. In this case all axes movement values will represent the same percentage of total amplitude possibilities

To set independently the movement amplitude values per axes the operator uses the specific cursors regarding the front, rear, left, right up and down settings.



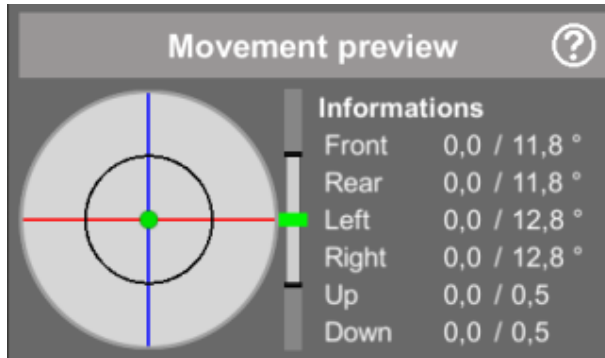
For example:

- To work in anteroposterior mode, reduce the left and right amplitude
- To work in the mid-lateral position, reduce the forward and backward amplitude

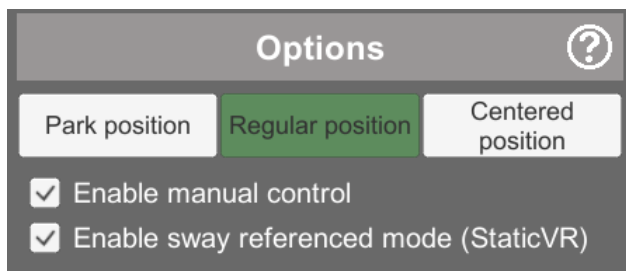


Movement preview

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 lowest level

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

Activate manual control

Use the arrow keys on the keyboard and the "+" and "-" keys on the numeric keypad (up and down) to move around.

Enable sway referenced mode (for StaticVR platforms)

The platform movement is controlled by the patient's center of gravity.

The  button on the launch interface at the bottom right provides access to other advanced

options:

Check the corresponding box to **"Enable development options"**

Two types of display are possible:

- [StaticVR] Display graphics
- [StaticVR] Display port status

These boxes are development options used to test and control the device and are reserved for maintenance purposes. It is not advisable to use them (slows down the software).

Recording Options:

You have the possibility of choosing the type of data to be recorded by ticking the corresponding box:

StaticVR:

- Raw data
- Smoothed data

MotionVR

- Gross position (pitch & height)

Select the location on the computer to save the data and press the "Start Recording" button

EMERGENCY STOPPAGE OF DEVICE

Through software/ manual Emergency Stop Button



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.

ENTERING THE PATIENT MANAGER SYSTEM

To Log into the Program:

1. Open **Patient Manager** software.
2. Opening the Patient Manager software will reveal the Login Screen shown in Figure 6
3. Click on the correct username within the User name box.
4. Type in the correct password.
5. Click the "Login" button, to arrive at the clinician home screen. Refer to the following page for information regarding the clinician home screen.

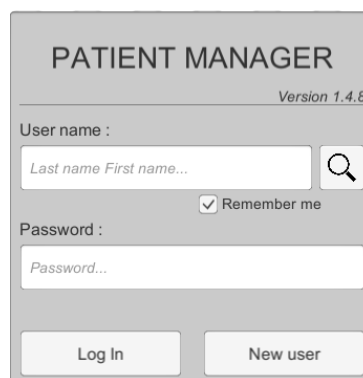
A screenshot of the Patient Manager login screen. The title "PATIENT MANAGER" is at the top, with "Version 1.4.8" in the top right corner. Below the title, there is a "User name :" label followed by a text input field containing "Last name First name..." and a search icon. A "Remember me" checkbox is checked. Below that is a "Password :" label followed by a password input field containing "Password...". At the bottom, there are two buttons: "Log In" and "New user".

Figure 6. Software Login Screen

New user Login to Patient Manager System for the First Time:

1. Open **Patient Manager** software. Arrive at the login screen, shown in Figure 6.
2. Click on the New user button.
3. Fill in all required fields (Figure 7)
4. Enter a password
5. Click the “Create” button, to arrive at the clinician home screen.



The screenshot shows a window titled "PATIENT MANAGER" with the version "0.4.1". It contains a form with the following fields: "Last Name*" with the value "Dupond", "First Name*" with the value "Jean", "Password:" with a masked input field, and "Password confirmation:" with another masked input field. A "* Required" label is positioned to the right of the confirmation field. At the bottom, there are two buttons: "Create" and "Cancel".

Figure 7. Creation of new Operator account

CLINICIAN HOME SCREEN

The clinician home screen is the first screen seen immediately after the operator (or administrator) logs in the Patient Manager software (Figure 8). All operational commands are listed here for easy navigation.

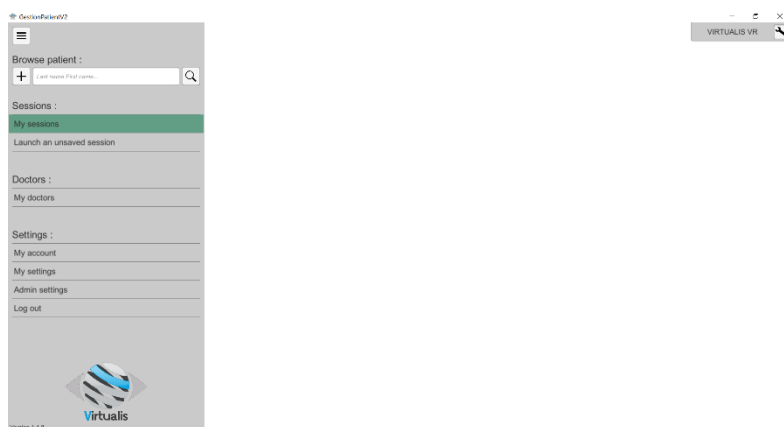


Figure 8. Virtualis Patient Manager System Main Page

The left side of the screen is split into three main regions, described below.

1. Patient Information : This is the primary interface for loading a patient, creating a patient, and viewing a patient's history.
2. Sessions : All of the software available with the system are located within the *Sessions* area. Each software is represented by an easily identifiable icon. A wide range of options are available to help rehabilitate a patient.
3. Settings: This is the interface for creating an account for operator and set-up some parameters of Patient Manager system.

ESTABLISHING NEW PATIENT FILES

To Create a New Patient:

1. From the system main page, click on « + » button (located in the upper left corner of the screen).
2. After clicking, the **Add a patient** page will appear with empty patient information fields. The popup window is illustrated in Figure 9.
3. Use the TAB key to change fields and enter the patient specific information. Fill in all required fields.
4. Click on the Create button to establish the new patient profile.





Figure 9. New Patient Data Entry page

RECALLING EXISTING PATIENT FILES

To Select a Patient who is already recorded in the System :

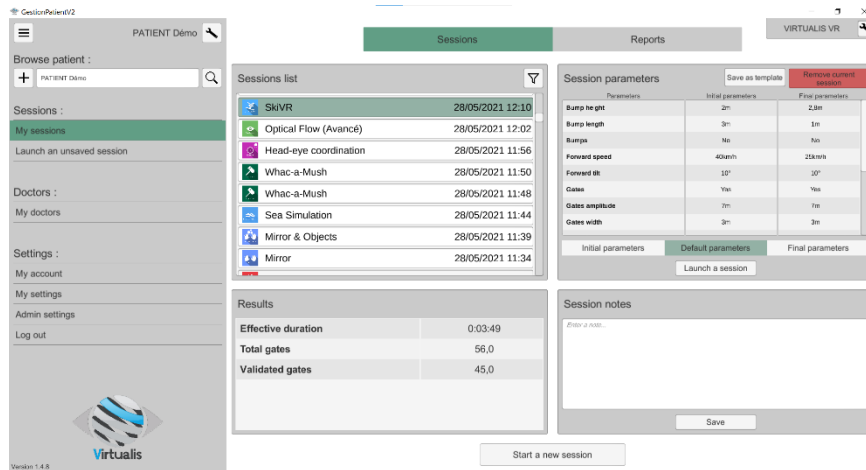
1. Click on the Browse *Patient* field and enter the patient's name or click on the  bouton. A list of patients will appear on the left side of the screen.

2. Click to select the patient. The patient’s information will appear in the center of the screen. Above the patient’s information are the dates of previous tests (if any were performed).

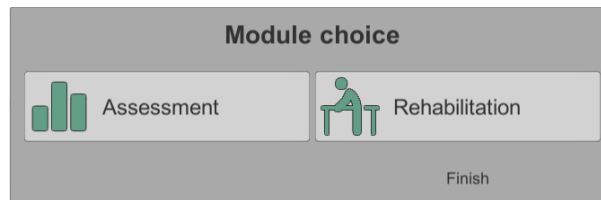
STARTING A NEW ASSESMENT OR REHABILITATION SESSION



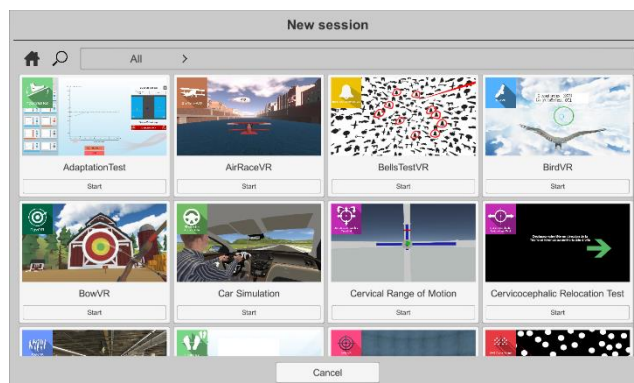
Once a patient is selected from the Patient Manager database, the operator may complete assessments or training by clicking on the « Start a new session » button at the center of the bottom of the screen.



This will open a new screen from which the operator may choose the desired program after running through the **Module choice menu**: the software can be grouped according to criteria such as "Assessment" or "Rehabilitation" and then by pathology type: Neurology, Balance, Functional, Motion Sickness.

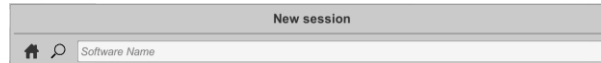


By choosing « finish » the operator will access directly the full list of programs presented by alphabetical order.



You can start any software by clicking on the corresponding "Start" button.

The operator may also click on the magnifying glass button in order to type the name of the required program.



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.

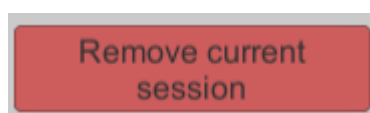
PARTICULAR CASE : LAUNCHING AN UNSAVED SESSION

Before conducting an assessment or treatment the operator may decide whether he will need to access the data later in time by recording the data in the patient folder or not

To perform an unsaved assessment or rehabilitation test click the *Launch an unsaved session button*, shown in figure 8.

By choosing an unsaved session there will be no recording of data and therefore it will not be possible to regain access to the results after the test or treatment.

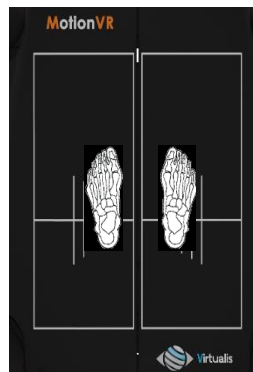
Advice is **do not to use this option** if you have any doubts on the need to regain access to session data. It is possible to remove a saved session through the session history screen after selecting the session to be discarded and clicking on the following button :



PATIENT ASSESSMENT

To Start a Patient Assessment :

1. Access an existing patient's session file or create a New Patient file
2. Decide whether to launch a Data Saved or Unsaved session
3. Properly position the patient's feet on the balance plate.



4. Choose the desired software you wish to perform (sensory tests, motor impairment tests and functional tests available on the system, example shown in Figure 10) and select **Start** to open the software.

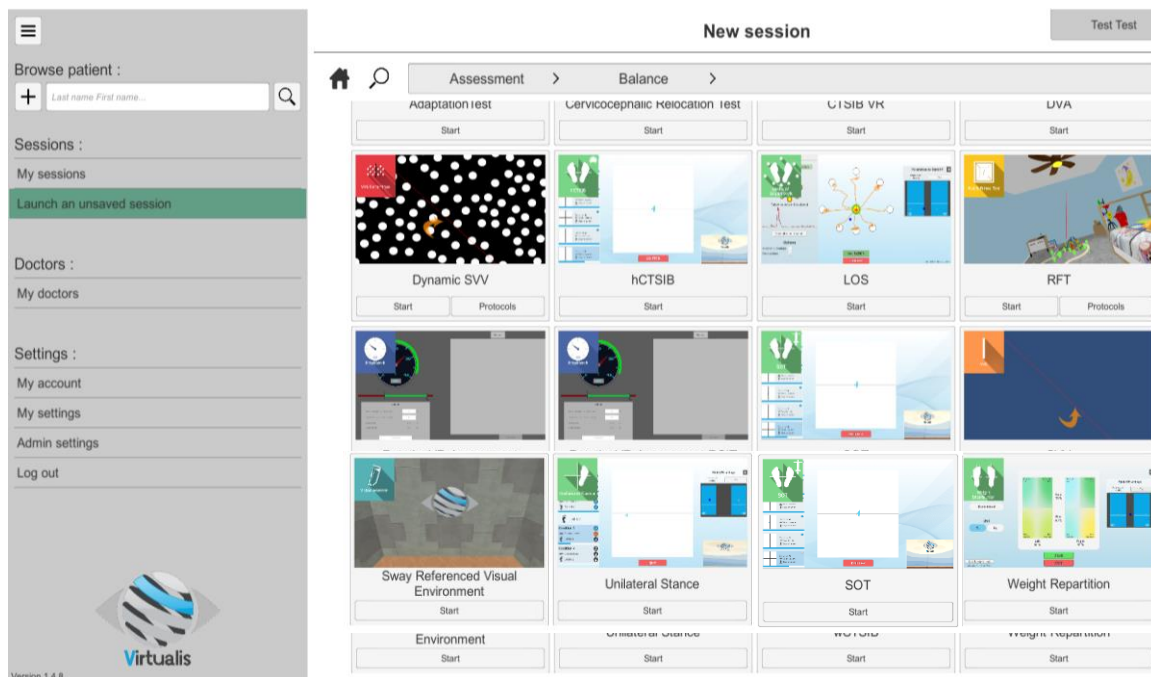


Figure 10. Clinician screen : assesment tab for balance

5. After setting up the parameters to perform the test, select **Start**, located in the bottom of the page.

For a description of an assessment or rehabilitation, refer to the appropriate user manual devoted to said assessment or rehabilitation.

6. Once tests are completed, return to the main menu of Patient Manager software, select **My sessions**.

Data retrieval and analysis uses the Patient Manager software.

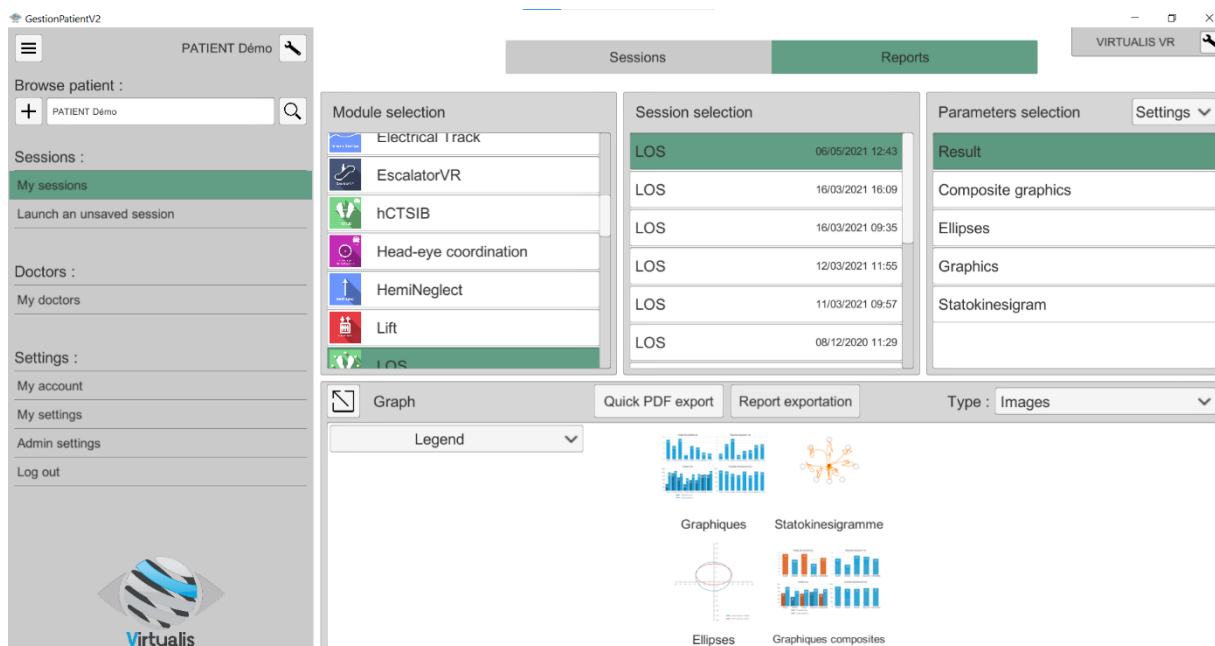
Assessment results are viewed directly from Reports.

TO VIEW AND PRINT REPORTS OF COMPLETED ASSESSMENTS :

- From the **main menu** screen of Patient Manager software, select **My sessions**.
- Navigate to the patient tab and confirm the correct patient is selected.
- The My sessions screen will be listing the completed tests for the current patient file under Sessions Test tab.
- View the numeric (or other data) reports by selecting the desired report under **Reports** tab (example shown in Figure 9)
- Once the desired assessment report is pulled up, click on the **Quick PDF export** located in the middle of the screen to export and print the report.

ASSESSMENT REPORTS

Individual Test Reports present the results from a single assessment performed on a specific day. An individual test report may be generated for any single assessment or training. The results may be presented through a variety of types graph (histogram, lines, radar) (Figure 11).



The screenshot displays the 'GestionPatientV2' software interface. On the left is a sidebar with a 'PATIENT Démo' header and a search icon. Below it are sections for 'Browse patient', 'Sessions' (with 'My sessions' selected), 'Doctors', and 'Settings'. The main content area has two tabs: 'Sessions' and 'Reports' (which is active). Under 'Reports', there are three panels: 'Module selection' listing various tests, 'Session selection' showing a table of sessions, and 'Parameters selection' with a 'Result' dropdown. At the bottom, there are buttons for 'Graph', 'Quick PDF export', and 'Report exportation', along with a 'Type' dropdown set to 'Images' and several graph icons.

Session selection	Date/Time
LOS	06/05/2021 12:43
LOS	16/03/2021 16:09
LOS	16/03/2021 09:35
LOS	12/03/2021 11:55
LOS	11/03/2021 09:57
LOS	08/12/2020 11:29

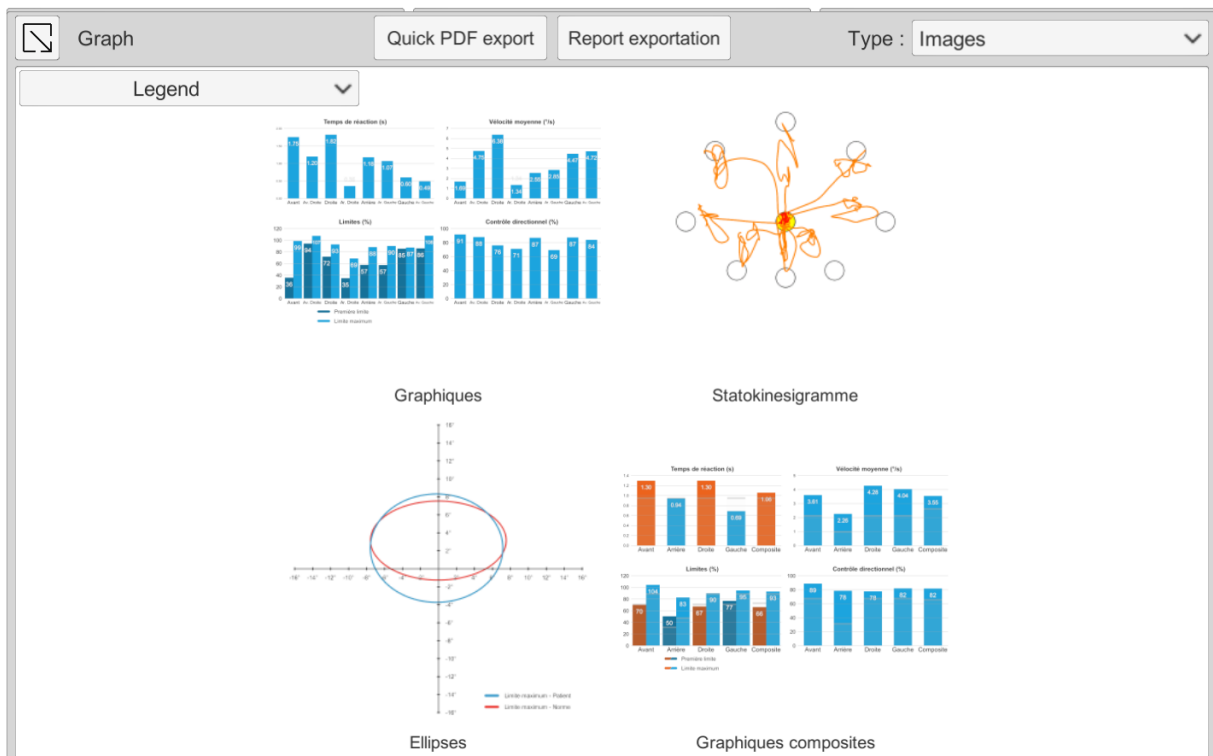


Figure 11. An example of a LOS Test Report