Instructions for Use

BalanceVR

Table of contents

1. Introduction

The system is fully installed and checked on site by authorized technicians.

Installation includes:

- System assembly
- Verification of main functionalities

1.1. About this IFU

Non-contractual photos.

Photos shown are for illustrative purposes only. Differences between photos and reality may occur as a result of updates or changes in equipment without impact on safety nor performances.

The abbreviation VR is used for Virtual Reality (VR).

1.1.1. Manufacturer

Virtualis is the legal manufacturer of the medical device software:

Manufactured by:	**CE marking's date of obtention: 2018**
VIRTUALIS Virtualis 78 All. John Napier Immeuble ATRIUM, 34000 Montpellier FRANCE ☎+33 9 80 80 92 91 🖃: contact@virtualisvr.com	CE

Virtualis is responsible for placing this system, composed of various devices, on the European market:

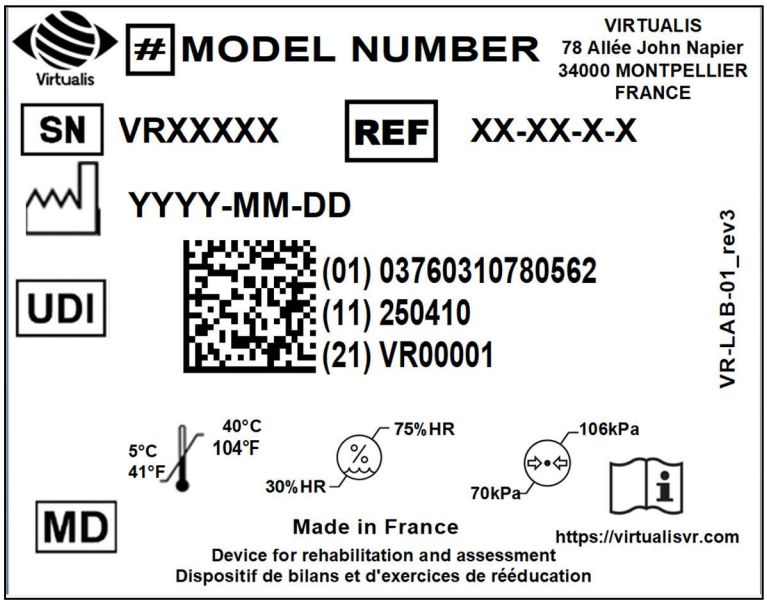
Virtualis
78 All. John Napier Immeuble ATRIUM,
34000 Montpellier
FRANCE
☎+33 9 80 80 92 91

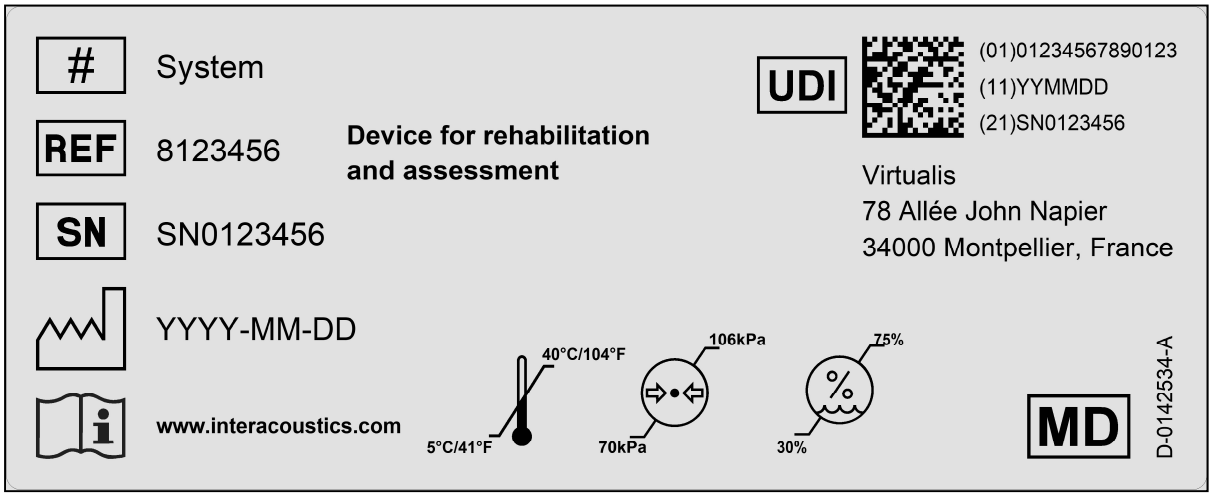
🖃: contact@virtualisvr.com

1.1.2. Label

1.1.2.1. System label

The system is identified with a label affixed to the computer. Depending on the manufacturing site, the system can be labeled with a label following these templates:





The system can be delivered in several configurations table:

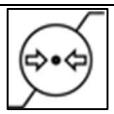
- Desktop
- Laptop
- Wired headset
- Wireless headset

1.1.2.2. Software label

The software is labeled as a medical device with the following label displayed on the Patient manager's home page (depending on the ordered variant):

1.1.2.3. Label symbols

Symbol	Description
	Manufacturer of the device
	Manufacturing date
	Part number
	Model number
	Serial number
 *Website*	Consult electronic instructions for use
	Reference to the warnings and/or precautions to take described in this document
	Unique Device Identifier
	Medical Device
	Humidity limitation

Symbol	Description
	Atmospheric pressure limitation
	Temperature limit
CE	The CE-mark indicates that the Virtualis product meets the requirements of the Medical Device Directive 93/42/CE.

1.2. Product description

BalanceVR consists of a software package installed on a computer paired with the necessary virtual reality accessories.

The BalanceVR range includes 2 variants: **BalanceVR** and **BalanceVR access** (which contains fewer modules than **BalanceVR**).

The range includes both assessment and rehabilitation software.

Some **BalanceVR** and **BalanceVR** Access modules can be compatible with the static rehab force plates and dynamic rehab platforms provided by Virtualis. If you would like to know more about how to use them, please refer to the documents supplied with your platform.

The modules and their availability (depending on the chosen variant) can be found in **Annex 1**.

The software is intended to be used for patient assessment and rehabilitation.

1.3. Principle of operation of the device

The solution developed by Virtualis is based on virtual reality technology, the principle of which is to visualize images in a 3D environment using a headset, and to use positioning sensors.

Virtualis develops software to create a virtual environment conducive to patient rehabilitation, thanks to the virtual reality products available on the market.

The software ‘s functionalities (called modules) provide to the practitioner exercises that he/she chooses and configures according to the rehabilitation program he/she needs for the patient.

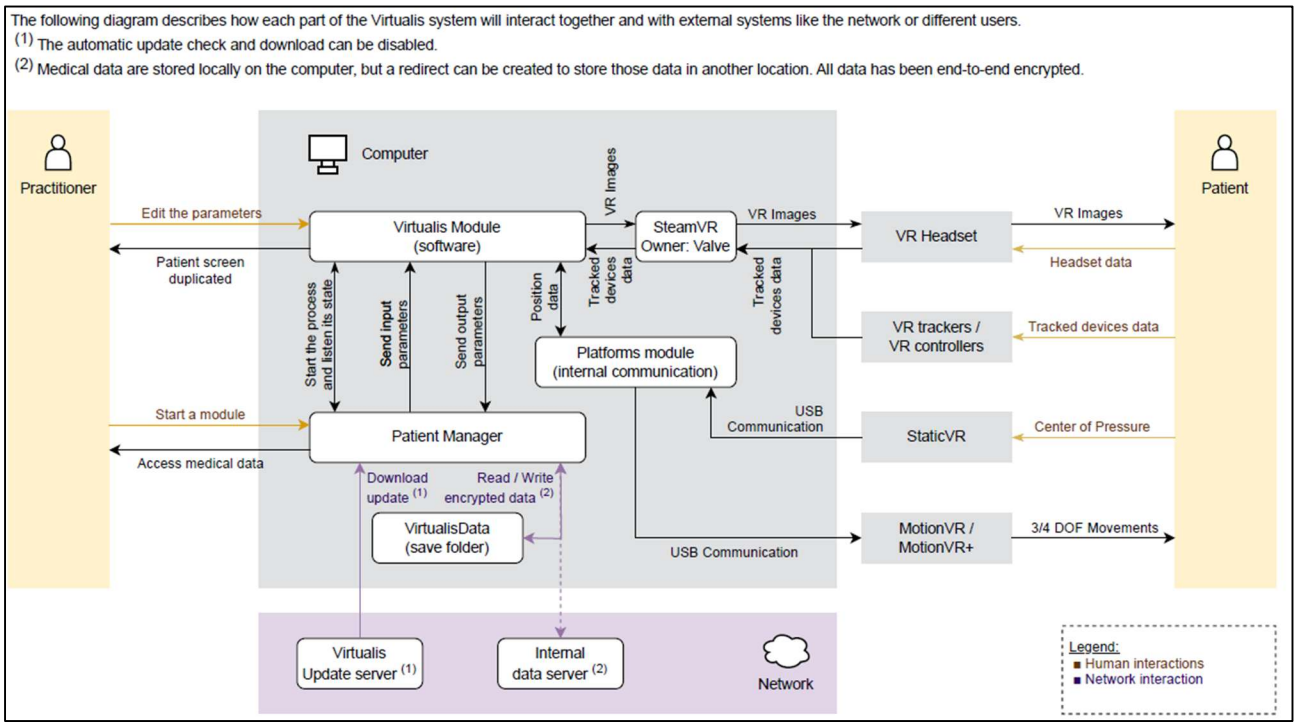
The Virtualis solution contains also Patient manager software enables practitioners to save patient data, to use Virtualis modules through parameterized sessions, and to store the results of these sessions. Once saved, these sessions can be consulted or displayed in printable reports.

The practitioner starts a module/exercise via the Patient Manager and set the parameters according to his/her intended rehabilitation program. These inputs parameters are sent to the Module.

Once the practitioner launches the session/exercise, the virtual reality images are displayed in the headset thanks to the virtual reality software (SteamVR) provided with the virtual reality accessories. Then the patient can see the image displayed in the headset. This image is also available for the practitioner on the screen.

During the session/exercise, the virtual reality accessories send data (position, range of motion) to the virtual reality software (SteamVR) in accordance with their intended use. This data is sent to the module which uses them to provide output parameters and calculated results.

At the end of the session, the output parameters and the results are sent to the Patient Manager.



In addition, remote controls are available by the practitioner to adapt the parameters of the exercise/module while remaining at the patient side during the session.

1.4. Intended use

The device provides quantified assessments of rehabilitation and exercises to enable the healthcare professional to adapt the rehabilitation protocol to the patient's needs.

1.5. Clinical benefits

· Reduction of dizziness symptoms as measured by the Dizziness Handicap Index (DHI).

· Reduction of visual vertigo symptoms as measured by the Visual Vertical Analogue Scale (VVAS).

· Reduction of anxiety and/or depression as measured by the Beck Anxiety Inventory (BAI) or Hospital Depression and Anxiety Scale (HADS).

· Improvement of balance performance in patients with vestibular disorders, demonstrated by improvement on the Limits of Stability (LOS) Test.

1.6. Indications for use

Assessment and rehabilitation, including:

- Balance and vestibular.

1.7. Contraindications

Contraindications for the use of virtual reality are not limited to, but may include:

- Patients with photosensitive epilepsy
- Pregnancy
- Per HTC Vive hardware manufacturer: young children are not recommended to use the product, however, there is no age limit recommendation.
- Patients with long-lasting cyber malaise or motion sickness.

The use of virtual reality for therapeutic purposes is not recommended for patients who have not undergone a prior vestibular assessment.

1.8. Intended user

Any Healthcare Professionals involved in rehabilitation/assessments including but not limited to physiotherapists, occupational therapists, speech and language therapists and audiologists, orthotists and prosthetists, clinical psychologists, physical medicine and rehabilitation doctors, and rehabilitation nurses.

The target patient population includes individuals of 15 years and above, excluding epileptic patients and pregnant women.

1.9. Caution symbols

WARNING

This symbol precedes a warning about conditions or practices that may present danger to the patient and/or user.

CAUTION

This symbol precedes a warning about conditions or practices that could result in damage to the equipment.

RECOMMENDATION

This symbol indicates advice on the use of the system, with no impact on the health or safety of users, patients or the environment.

1.10. Warnings and precautions

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".

WARNING

In case of a software malfunction, the screen could flash in the headset and potentially cause epileptic seizures: **do not use VR with epileptic patients.**

WARNING

Monitor the patient to prevent falls.

WARNING

It is recommended that the clinicians who administer test to consider the learning effect.

RECOMMENDATION

As postural reactions can be intense, place the patient in a secure environment and stay close to them throughout the session to anticipate any loss of balance or discomfort caused by the use of virtual reality.

RECOMMENDATION

Increase the duration and intensity of stimulation very gradually after an initial short session to ensure the patient's tolerance to this type of type of stimulation.

The use of virtual reality must respect the neurosensory capacities of the patient being treated.

RECOMMENDATION

Virtual reality for therapeutic purposes can be offered as a complement to conventional vestibular rehabilitation. In current available evidence, virtual reality rehabilitation has not shown to be superior to conventional vestibular rehabilitation.

Motion sickness is treated by "habituation", so you need to recreate the symptoms experienced during daily activities.

RECOMMENDATION

Monitor the patient for symptoms of cyber discomfort or motion sickness and their reaction to the virtual reality simulation.

WARNING

It is essential to stop the session when the first symptoms appear, generally "sweating".

Define a working area of about 4 m² to allow for risk-free movements.

Take a 10-to-15-minutes break every 30 minutes of use.

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.

According to HTC VIVE, the VR 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 https://virtualis-us-dgs.happyfox.com **for the USA or** service@interacoustics.com **and the Member State in which the user and/or patient is established.**

1.11. Side effects and residual risks

WARNING

Transient increase in symptoms including nausea, emesis, dizziness, imbalance, motion sickness, musculoskeletal discomfort, symptoms of hypotension, headache and fatigue.

WARNING

Falls or near falls resulting in injury including fractures.

WARNING

Some physicians may want to delay exercises during the early postoperative stage because of risk of bleeding or cerebrospinal fluid leak.

WARNING

Dizziness and imbalance as side effects of the exercises could increase psychological distress in some individuals.

WARNING

If the software has some performance issues, the patient could experience motion sickness as a result.

1.12. Training

Before using the device, training is recommended.

The provided flyer by the customer service, gives you a QR code for online training.

2. General technical specifications

2.1. Deployed configuration

- Computer workstation with Windows 11
- Windows configuration with a single local user account with administrative rights
- IT security tools are integrated into Windows: Windows Defender.
- Administrator account for interface access: username and password to be defined by the customer, required on the day of installation.
- Software Bill Of Material installed on the computer are listed in Annex 3.

2.2. Required configuration for operation

WARNING

Do not change the PC NAME (in System), as software licenses are “attached” to the PC ID. If the NAME is changed, the software will stop working.

- Full access rights (read and write) and exclusion (whitelist) from the antivirus for the following folders and all their subfolders and contents:
- C:\Virtualis
- C:\Virtualis\Software
- C:\Program Files (x86)\Steam
- C:\Program Files (x86)\Steam\steamapps\common\SteamVR
- C:\Users\Virtualis(or user name)\Appdata\Local\Virtualis
- C:\Users\Virtualis(or user name)\Appdata\LocalLow\Virtualis

2.3. Network requirements

The software is intended to be used on an IT network that is outside the control of the software or update purpose only.

For streaming headset configuration, the software is intended to be used on a local controlled and restricted IT network created during the system preparation.

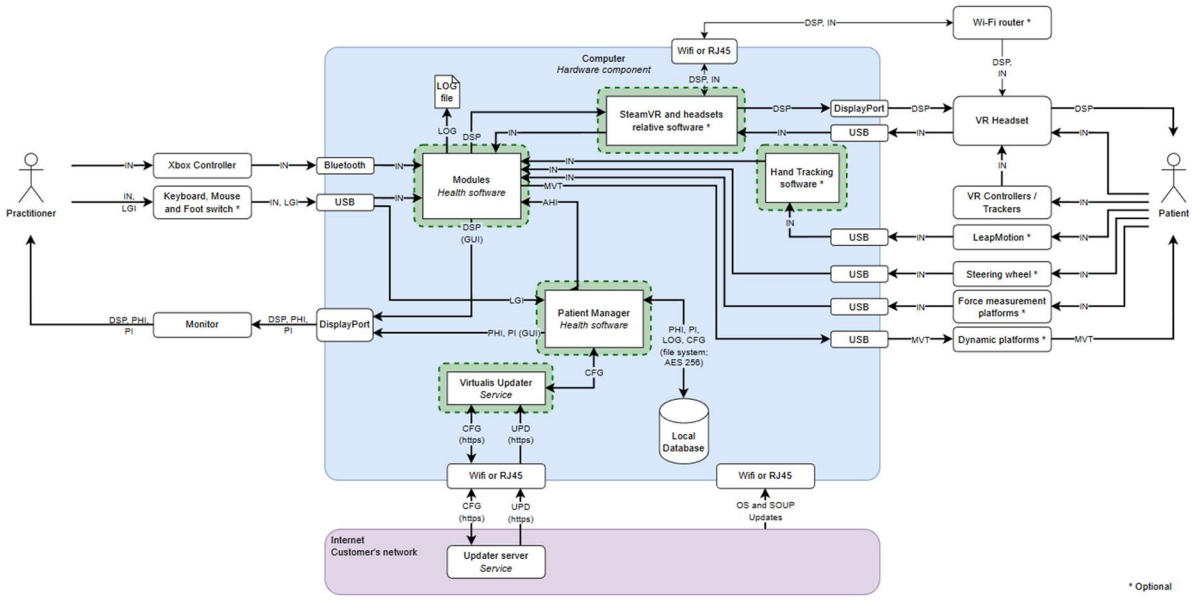
WARNING

If this network is connected to internet by the customer, it’s become uncontrolled.

Interface and protocols:

Interface		Between	Protocol
Ethernet (RJ45)	Computer	Customer's network	IEEE 802.3 + TCP/IP + HTTPS (for Updater server)
Ethernet (RJ45)	Computer	Router	IEEE 802.3 + TCP/IP
Wi-Fi	Computer	Customer's network	IEEE 802.11 + WPA2/WPA3 + HTTPS (for Updater server)
Wi-Fi	Computer	Router	IEEE 802.11 + WPA2/WPA3 + TCP/IP
Wi-Fi	Router	VR Headset	IEEE 802.11 + WPA2/WPA3 + TCP/IP

Data-flow diagram



F Thrust boundary

Acronym	Type
LGI	Login information
PI	Personal Information
PHI	Personal Health Information
AHI	Anonymized Health Information
LOG	Log file

Acronym	Type
CFG	Configuration file
DSP	Display
IN	Input, Therapeutic commands
UPD	Updates
MVT	Physical movement

Hazardous situation resulting from a failure of the IT Network

- The network is down, so the customer will not receive corrective updates and security patches.
- The local network is down, so the VR Headset will not work, and it will not be possible to perform the exercise until it is restored.

As the local network is not connected to internet and only provides a Wi-Fi connection, the main risk is to have an intruder that is close to the system and access this network from an external device.

Requirements: This network must be secured by a strong password.

WARNING

If connected to a network (to perform system's update), the system may be vulnerable to external attacks that may lead to data exposure or system corruption.

RECOMMENDATION

To prevent these risks, the security components of the system must be updated, and all security patches must be applied as soon as they are available. Security components update is performed by (but not limited to): Windows update, Virtualis software update, Anti-malware update and firewall update. In addition, anti-malware and firewall service must be activated and run in background.

2.4. Minimum computer requirements

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 – Computer	
CPU	i7-9700 (3.5GHz) or greater
GPU	Nvidia GTX 2060 or greater
Operating system	Windows 11
VRAM	6 Go minimum
RAM	16 Go minimum
Storage	512 Go minimum

Technical Minimum Requirements – Other	
Screen	Resolution: 1920x1080 or greater
VR headset	HTC Vive series
Workstation	64 x 60 x 170 cm (W x L x H)

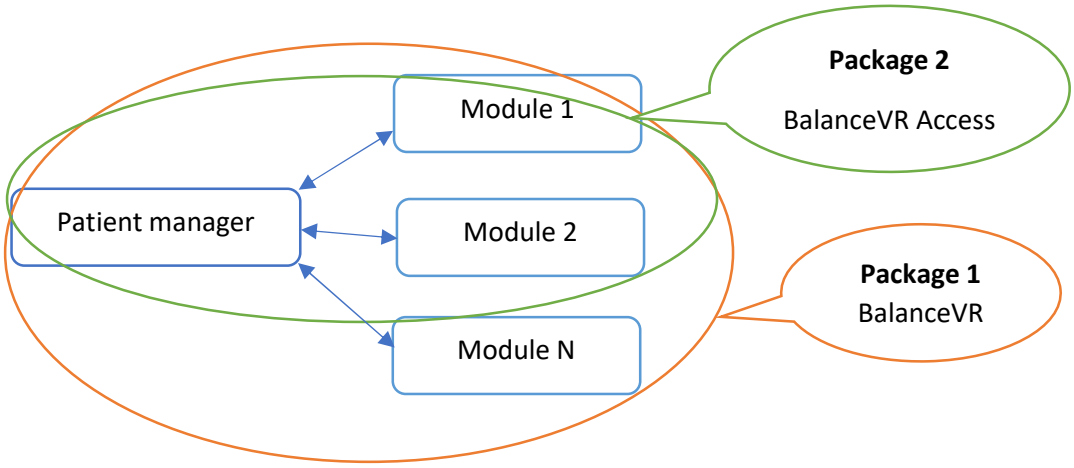
2.5. System performance

System performances are:

- Immerse the patient in a virtual environment.
- Run a module adapted to the patient using editable parameters.
- Provide data corresponding to the module completed by the patient.

2.6. BalanceVR key functional elements

The medical device software consists of an application (called “Patient Manager”) which enables the use of software modules that the therapist selects according to his/her assessment or rehabilitation needs. Software modules are marketed in packages as illustrated in the following figure:



The key functional elements of the device are:

- **Patient manager that includes:**

- Create patient file
- Set the modules parameters
- Start a module
- Provide results
- Generate reports
- Create chaining
- Administrative management

- **Modules:**

- Display VR images
- Edit parameters
- Start the exercice
- End and exit the exercise
- Calculate and display results

2.7. Module compatible accessories

Compatible accessories vary depending on the selected module. They are the following:

- VR headset
- Handheld controllers
- Trackers
- Xbox controller
- Steering wheel (optional)
- Straps
- Clamp for VR tracker
- Headgear for VR tracker
- Footswitch
- Airex Balance pad Elite foam pad or similar models.

CAUTION

Do not use any other devices than the ones provided by Virtualis.

The accessories and equipment may vary depending on the chosen package variant or the options you may have purchased. See **Annex 2** for more information on the equipment available and which modules they are compatible with.

The software runs on a computer and screen with adequate performances to support virtual reality.

The interactive virtual reality software modules use head mounted display virtual reality hardware with a virtual reality- ready PC, to deliver the Virtualis VR Software to the patient.

The computer can be installed on a cart to provide the user with a control station, composed of:

- Computer Monitor or laptop
- Storage Basket
- Virtual Reality-Ready Computer Tower
- 4-Port USB Hub
- Link Box

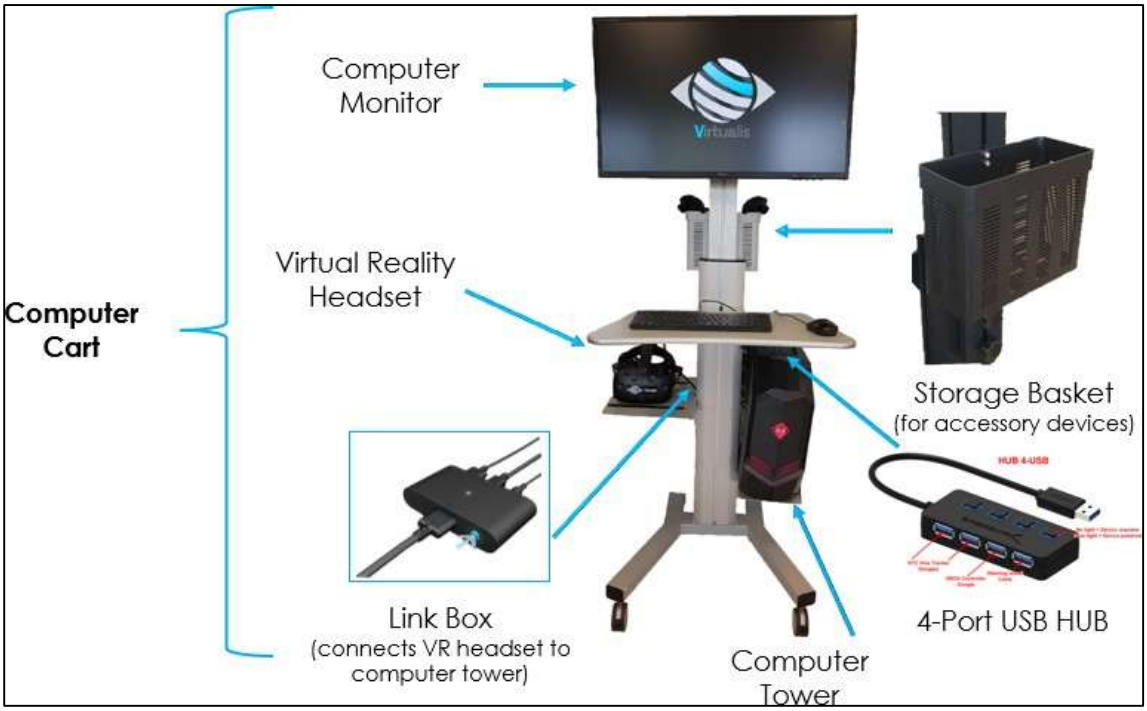


FIGURE 1 - COMPUTER CART EXAMPLE

CAUTION

Prevent the accessories from falling by setting them in the storage basket, or on a sufficiently large table. For setups without a cart, reserve a space of 90 x 60 cm minimum to store the accessories.

CAUTION

The computer provided is only intended for professional use of the Virtualis software. Do not install unauthorized software or modify the computer's initial configuration.

Remote controllers are supplied to be used by the practitioner as a remote control to navigate software menus from a distance while at the patient's side:

- A wireless Xbox controller:

FIGURE 2 - XBOX CONTROLLER

- A footswitch wired to the computer:

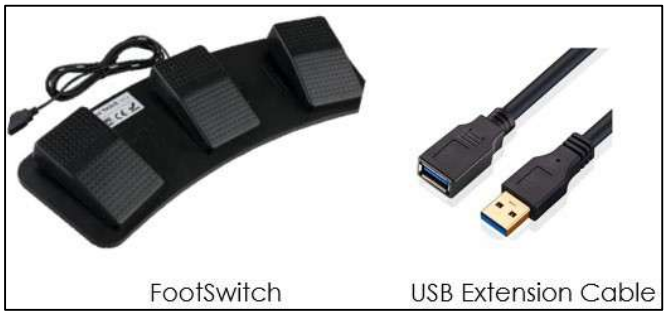


FIGURE 3 – FOOTSWITCH

The software package is intended to operate with compatible virtual reality accessories verified and validated by Virtualis. These virtual reality accessories are intended to be held by the patient while they perform the exercises displayed by the software. The choice of accessories depends on the software module and its intended purpose.

Virtual Reality Headset:

- Headset Strap (adjustable)
- Headset Adjustment Dial
- VR Lenses
- VR Headset and Face Cushions, that are in direct contact with the patient
- Earphones

FIGURE 4 - VIRTUAL REALITY HEADSET AND CONTROLLERS

2 controllers are provided with their charging cables.

2 trackers are provided with their charging cables (n*ot pictured).*

FIGURE 6 - TRACKERS

Some software modules (like **Dynamic Visual Acuity (DVA)**) require the patient to be equipped with a head tracker that communicates with another tracker mounted on the computer.

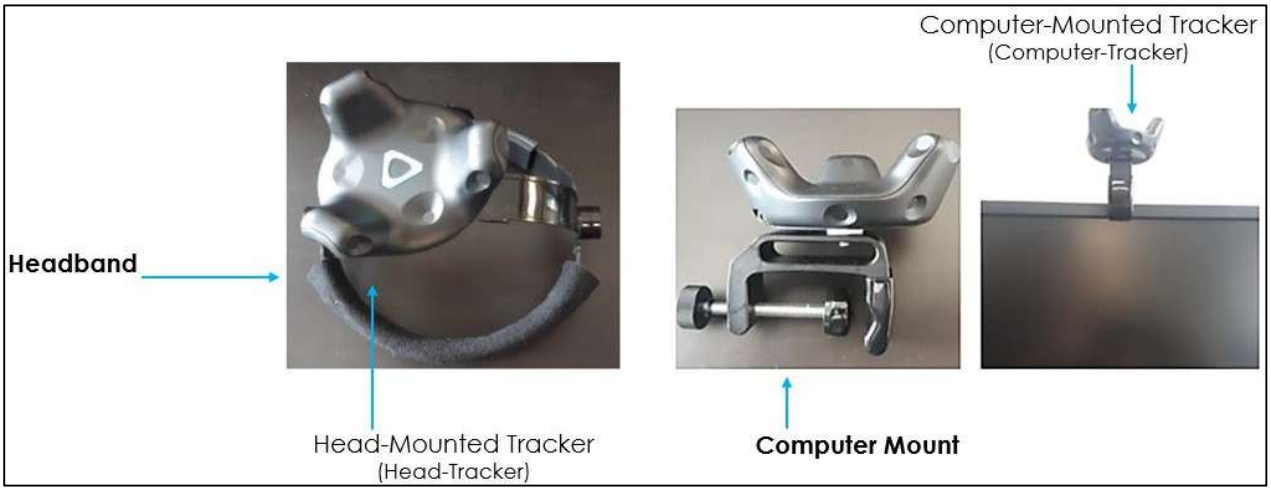


FIGURE 7 - HEAD TRACKER EXAMPLE

Some modules destined to work on motion sickness require the patient to be equipped with a steering wheel.

FIGURE 8 – STEERING WHEEL EXAMPLE

The steering wheels compatible with Virtualis modules are the following:

- T128
- GT cockpit 458 / Ferrari 458
- T150
- TMX

CAUTION

The steering wheel must be unplugged after used the modules that require it.

Leaving it connected can interfere with the operation of other modules that don't require it.

Some software modules can be used by the patient without the VR headset, viewing the environment via a screen.

According to your configuration the systems are delivered with 2 base stations to be used with the headset (HTC Pro versions) or not (HTC Focus Vision series).

- Power cables (2)
- Tripods (2)
- Wall Mounts (2) that can be used for permanent installation.

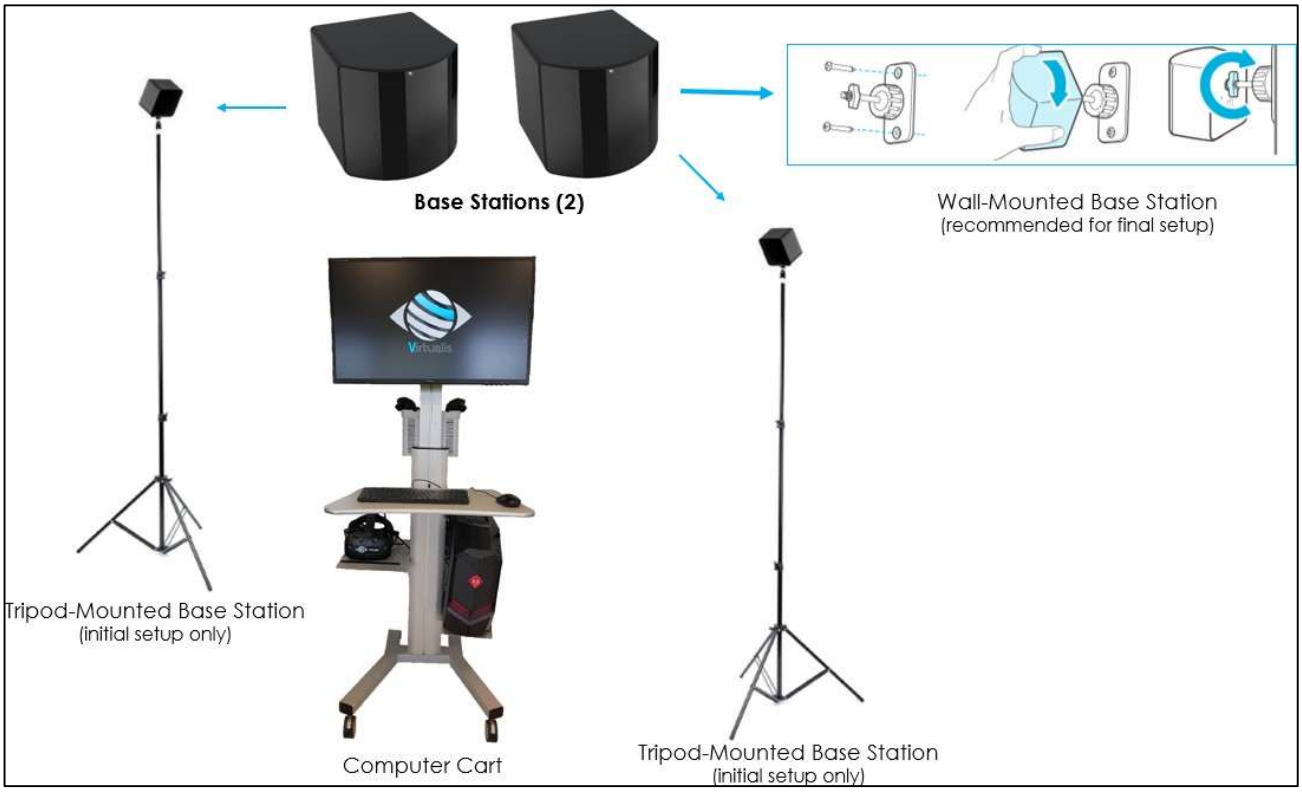


FIGURE 9 – EXAMPLE HTC VIVE PRO VERSION BASE STATIONS WITH COMPUTER CART

Some software modules are intended to be used with **memory foam blocks** (see Annex 2 for more information). We recommend the use of **Airex Balance Pad elite** foam blocks, or products with similar characteristics.

Some modules are compatible with static force platforms and with another Virtualis device called Dynamic Rehabilitation Platform for the MotionVR package (see **Annex 2**).

3. Operating instructions

3.1. System start / stop

3.1.1. Start

Follow the steps below:

1) Connect the main plug to the main socket.

2) Turn ON the computer

3) Start the link box in order to connect the headset to the computer or turn ON the router and turn ON the headset (depending on your configuration).

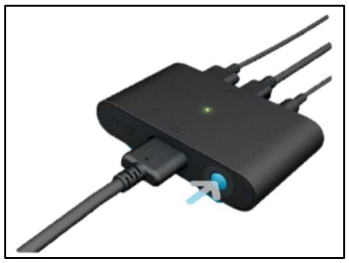
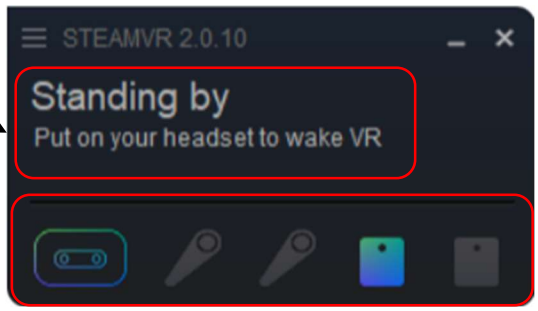


FIGURE10: EXAMPLE: HTC VIVE PRO AND HTC FOCUS VISION HEADSET'S "POWER" BUTTON

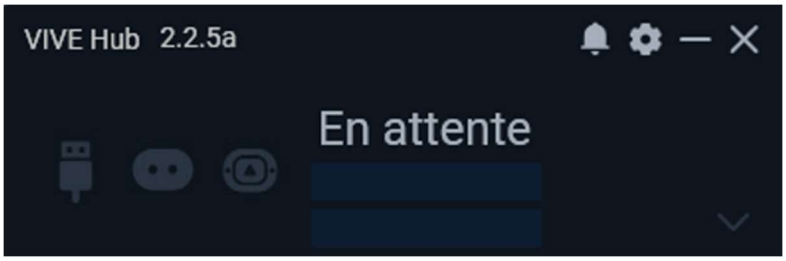
4) The system starts up and displays the SteamVR software or Vive Hub on the screen:

Virtual reality accessory state

List of virtual reality accessories



Virtual reality accessory state



CAUTION

If the system is connected to the Internet, SteamVR software can be updated automatically.

If the update affects the Virtualis software operation, please contact the customer service:
USA: https://virtualis-us-dgs.happyfox.com
Other countries: service@interacoustics.com .

RECOMMENDATION

A configuration of the virtual space was carried out during the initial installation of the Virtualis system.

If you are having trouble setting up this space, especially if you have changed the initial location of the system, please contact Customer Service.

USA: https://virtualis-us-dgs.happyfox.com
Other countries: service@interacoustics.com .

3.1.2. Verify successful installation of the system

Verifying that the system is ready for use consists in checking that the 3D environment is displayed correctly in the virtual reality headset according to the following steps:

- Turn ON the system
- Turn ON the headset
- Turn ON controllers
- Select the Test Patient :
    - Please refer to the Patient Manager User Manual, sections “Creating a patient,” “Selecting a patient,” and “Selecting a module”.
- Launch a module, example « Cervical Range of Motion »
- Look into the headset to check that the 3D environment is displayed and that the images correspond to your head movements
- Hold the controllers and verify that you can see the controllers in this 3D environment

Once the checks have been completed:

- Exit the module
- Exit Patient Test to return to the patient selection interface.

The system is now ready to start your virtual reality sessions with your patients.

3.1.3. Stop

CAUTION

To avoid any risk of data loss, always switch off the system and wait for it to come to a complete standstill before disconnecting the power cable.

RECOMMENDATION

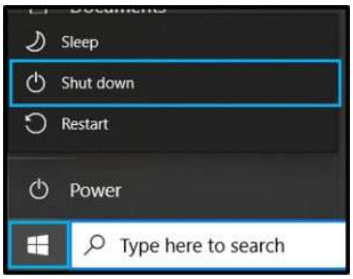
Make sure the computer is properly turned off at the end of each day.

Follow the steps below:

1) Close/ Exit Virtualis Patient Manager software.

2) Close/ Exit SteamVR.

3) Turn off system from Windows menu.



4) Turn off the screen.

5) Turn off the link box.

6) Disconnect the main plug to the main socket.

3.2. Before starting a session

RECOMMENDATION

Familiarize yourself with the modules before using them with a patient.

RECOMMENDATION

Check the battery level of the VR accessories and charge them if need be.

1) Launch the Virtualis software. 

2) Launch the SteamVR application. 

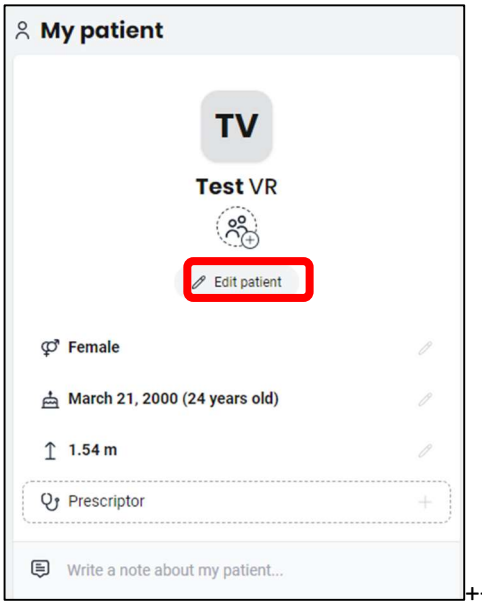
3) Check that the headset and the base stations are detected by the SteamVR application.

The accessories appear in blue if they are properly detected.

FIGURE 11: VR ACCESSORIES PROPERLY DETECTED BY STEAMVR

4) Select a patient in the Virtualis Patient Manager.

5) Check that the patient information displayed matches your patient's. Edit it if necessary.



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3.3. Patient setup

3.3.1. General patient setup

RECOMMENDATION

The patient setup differs depending on the module you have chosen. Check the module's tutorial to find it.

1) Ensure the patient is properly situated and has enough room to move freely without risk (a minimum of 4 m^2 is required).

2) Always stay nearby to prevent them from losing their balance or falling.

3) Help the patient put on the VR headset. It should be tightly but comfortably fixed on the patient's head. It can be worn with glasses.

4) Help the patient equip any required accessory depending on the module you have chosen.

5) Show the patient how to hold the controller(s) to ensure they will not fall.

6) Give them all the necessary indications prior to starting the session:
   - The module you have chosen,
   - Its objective(s),
   - The movements they will have to perform.
7) Ensure the patient keeps their hands off the headset's sensors.

RECOMMENDATION

Ensure the patient keeps their hands off the headset's sensors.

3.3.2. Holding the controllers

Show the patient how to hold the controller(s) to ensure they will not fall.

- **Vive Pro controllers:**

Make sure the patient keeps their fingers off the system button  , which can quit a module.

- **Vive Focus series controllers:**

Make sure the patient keeps their fingers off the Menu button  and the VIVE button  , which can quit a module.

3.3.3. Equipping the trackers

RECOMMANDATION

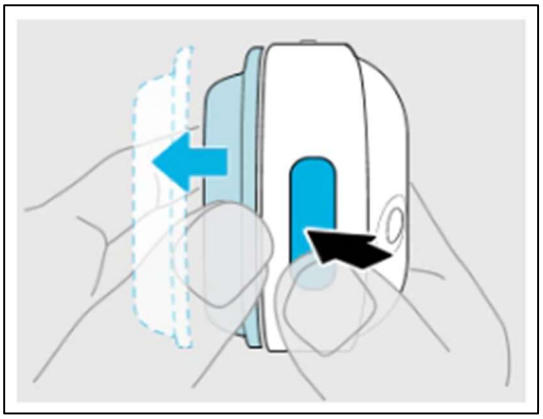
Switch off the trackers after each session.

3.3.3.1. VIVE Tracker

Please refer to the information on 2.3 section.

3.3.3.2. VIVE Ultimate Tracker

Please refer to the information on 2.3 section.



3.3.4. Airex Balance pad Elite

Use an Airex Balance pad Elite or similar models cushion if the module requires this.

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, position the patient either directly on the force plates or the Airex cushion as follows:

1. Help the patient step onto the force place or Airex cushion, facing forward
2. Center the patient's feet on the force plate or Airex cushion. The medial malleolus of each foot should be centered directly over the center horizontal (wide) line on the force plates or aligned with the horizontal lines on the Airex cushion.

Feet on cushion

3.4. Starting a module

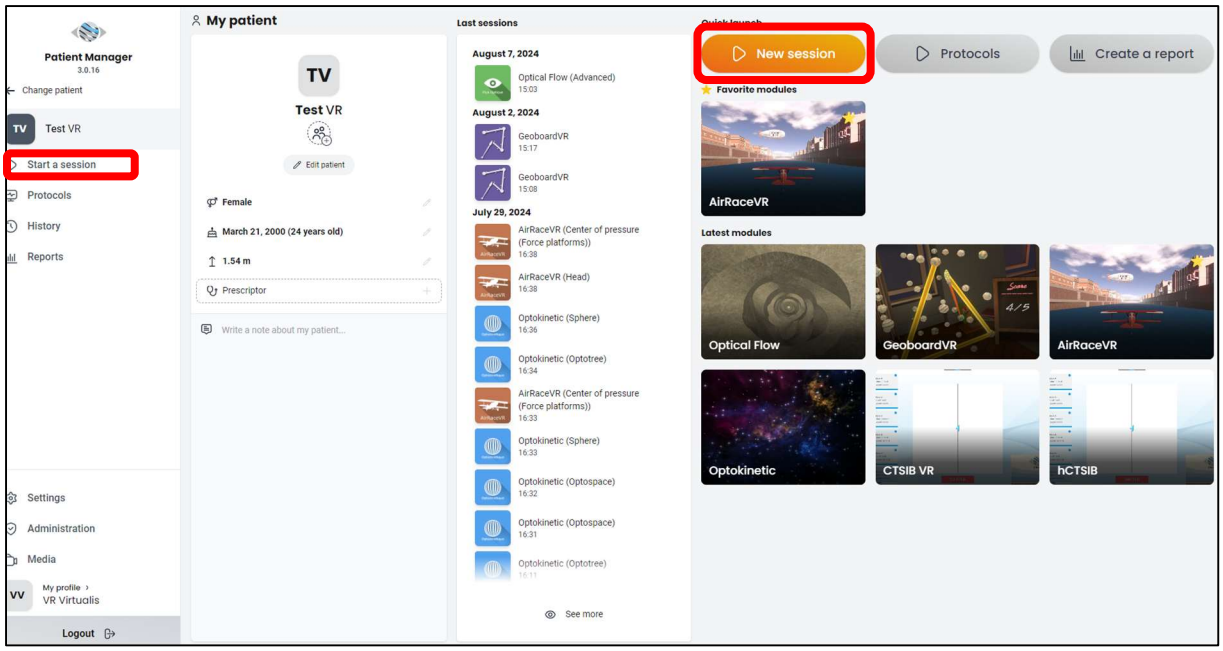
Refer to the Patient Manager's User manual for more information.

RECOMMENDATION

If you are unable to log in, contact the administrator to unlock the account and/or change the password.

Once the patient is selected in the Patient manager, properly set up in the room and the VR accessories are properly detected:

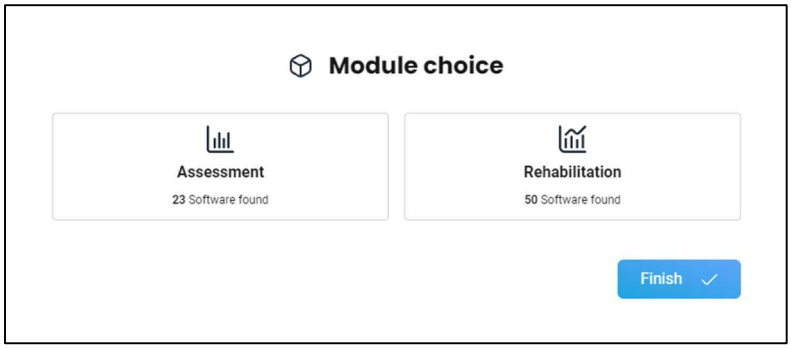
1) Click on "**New session**" or "**Start a session**" in the Virtualis software.



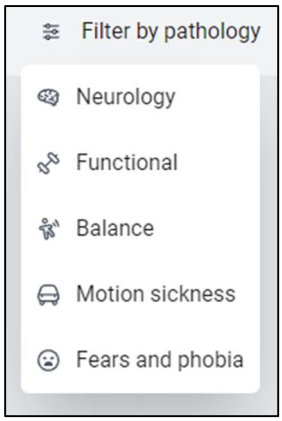
2) Choose a module in the list.

- Use the "**Search**" bar to find a specific module.

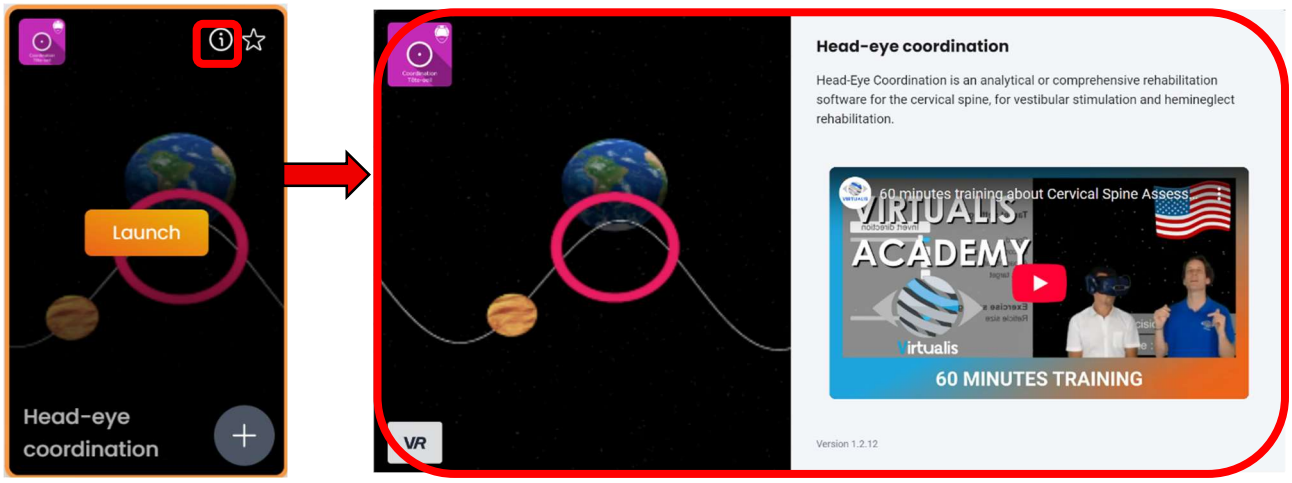
- Click on "**Module choice**" to filter assessment or rehabilitation modules.



- You can also filter the modules by pathology.

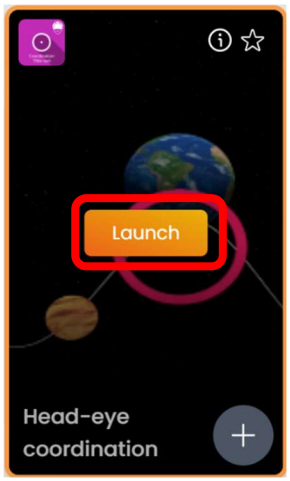


3) Read the module's description by clicking on the **(i)** icon and check out the tutorials (video and document). The written documentation can be found in a dedicated folder on the computer.



THE MODULE HEAD-EYE COORDINATION IS USED AS AN EXAMPLE

4) Quit the module description
5) Click on "**Launch**".



3.5. Session settings

Once a module has been selected:

- You can adapt the session to your patient's needs and to your objectives by adjusting the settings.
- The number of parameters available varies depending on the chosen module.

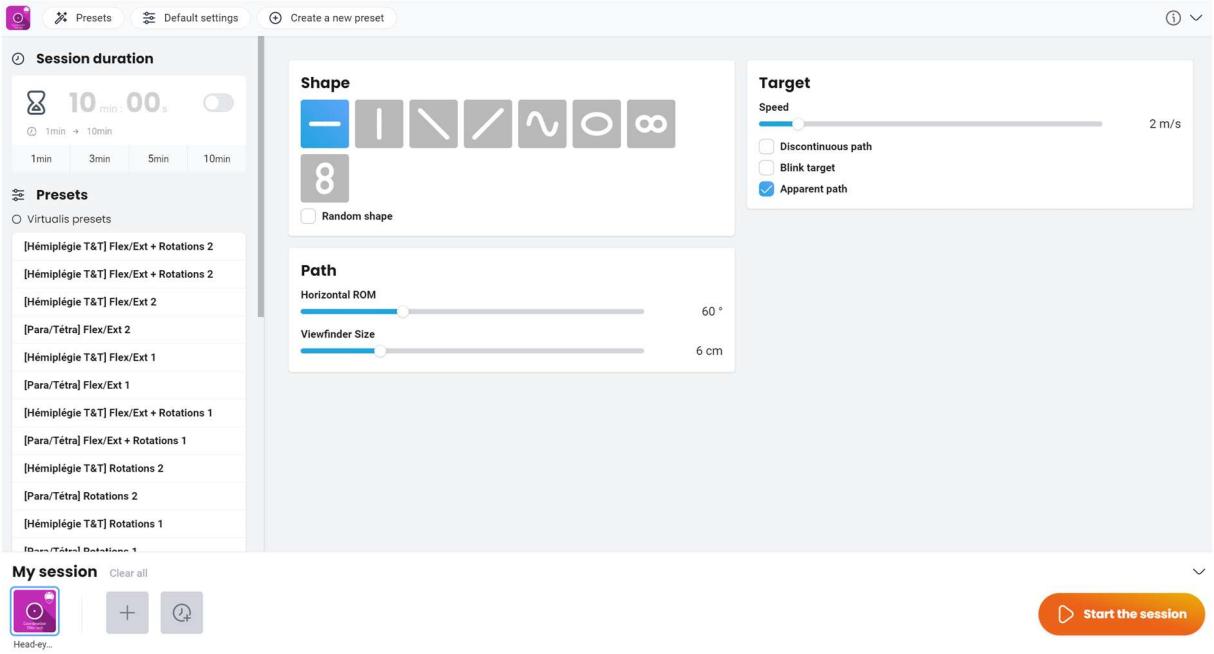
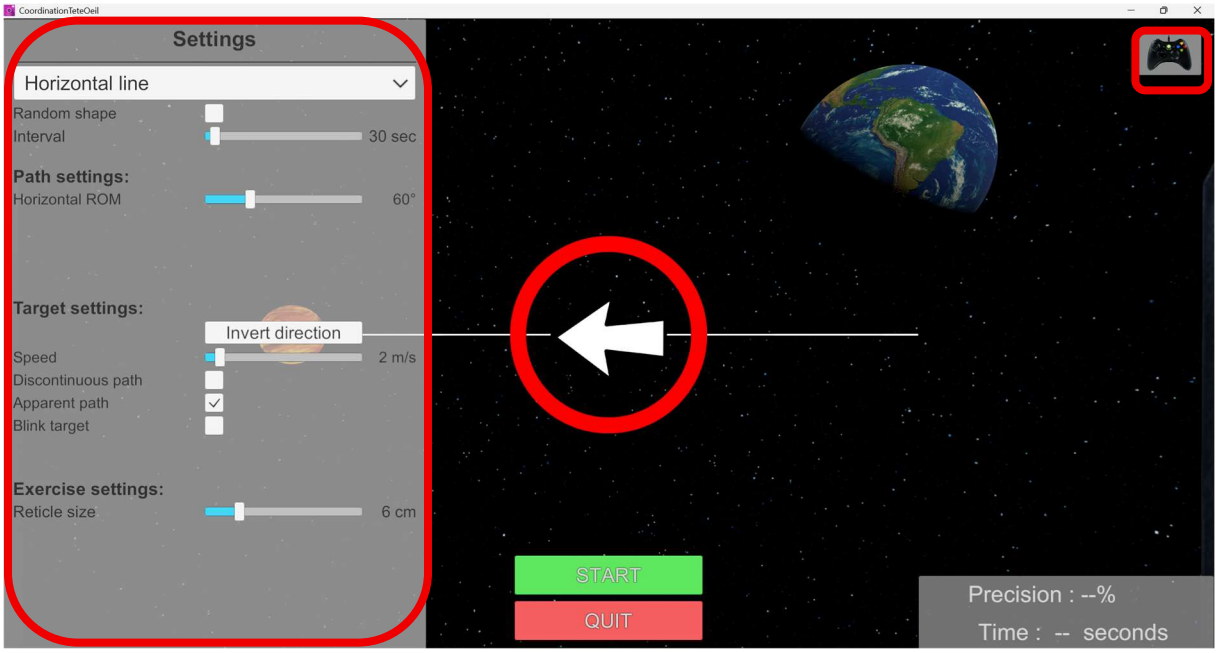


FIGURE 5 : EXAMPLE OF THE SETTINGS AVAILABLE FOR THE MODULE "HEAD-EYE COORDINATION"

3.6. During a session



A list of **shortcuts** can be found in most of the modules by clicking on the keyboard or Xbox controller icon  **in the top right corner of the screen**. You can scroll through different shortcuts options by clicking on the arrows:  .

In most modules, some settings are available and can be adjusted from the **left side of the screen**.

You can have access to remote controls using the Xbox controller, the footswitch, the controllers, etc.

CAUTION

The patient could leave the session by themselves by pressing the wrong button on the controllers. **Make sure the patient is holding the accessories properly**.

The module pauses and a window offers to confirm or cancel the requested action. The patient must cancel the action by clicking on “cancel” to return to the virtual reality environment

3.7. Accessing the results

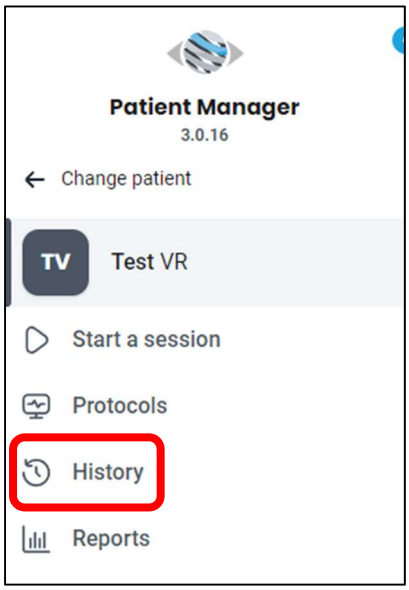
At the end of a session:

RECOMMENDATION

Not all modules have results to access (summarized or detailed ones).

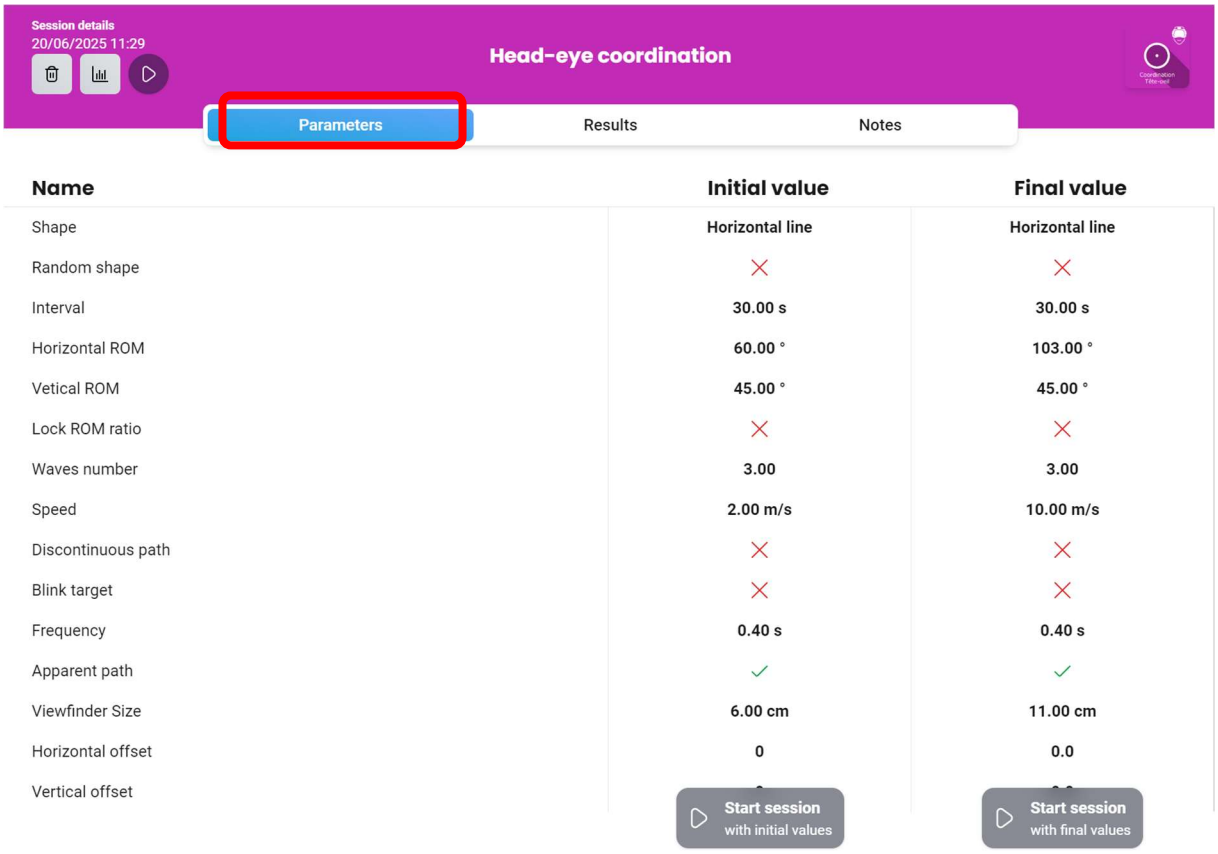
- **Accessing the summarized results:**

1) Access the session's summarized results by clicking on "**History**" in the Patient Manager.

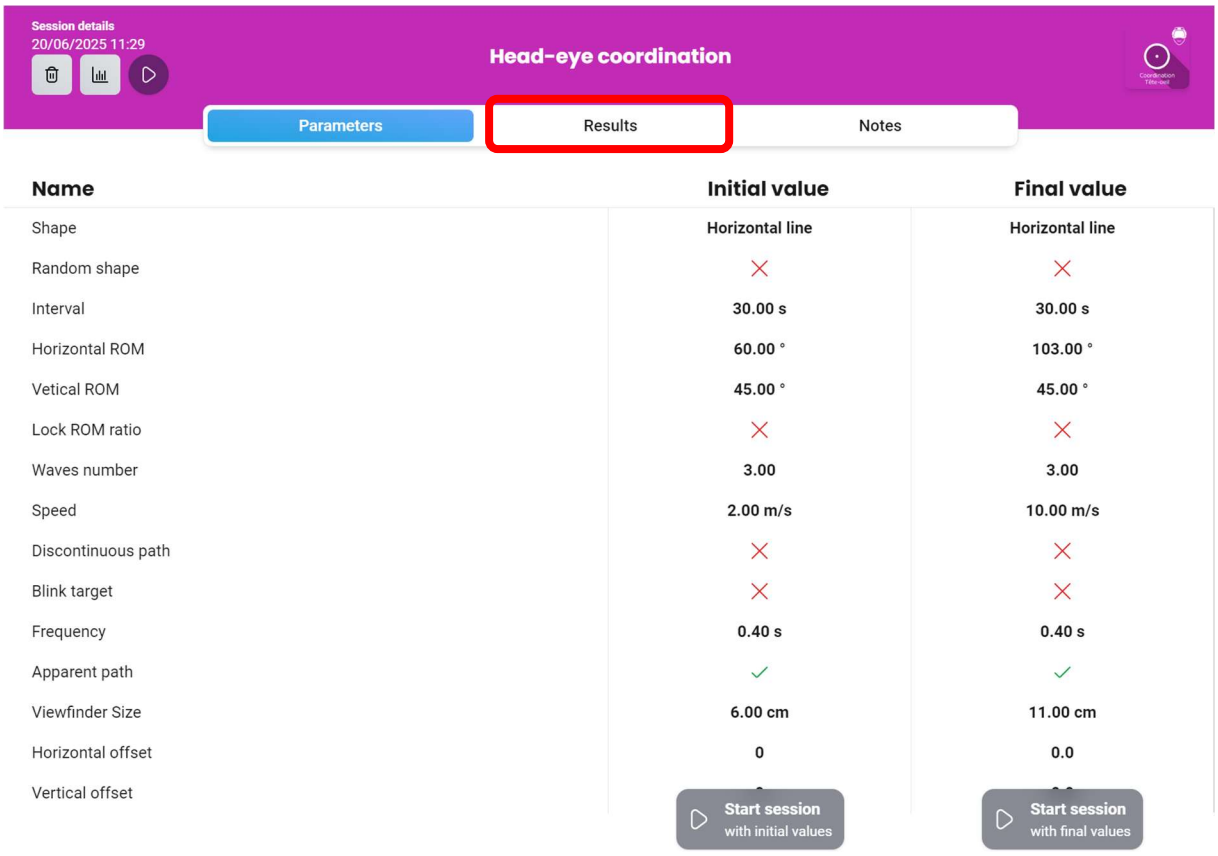


2) Select the session whose results you wish to see.

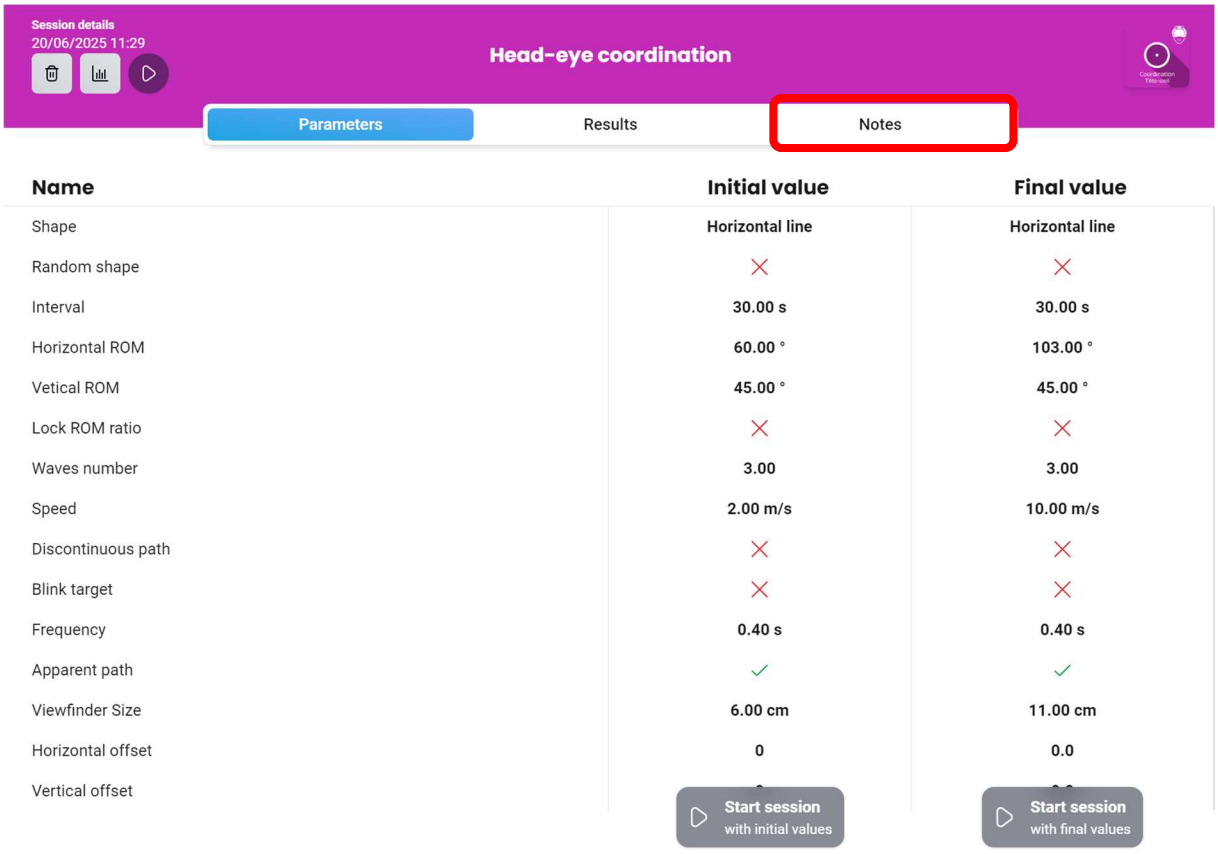
3) You access a page showing the initial and final parameters.



4) Click on "**Results**". (Some modules do not have summarized results).

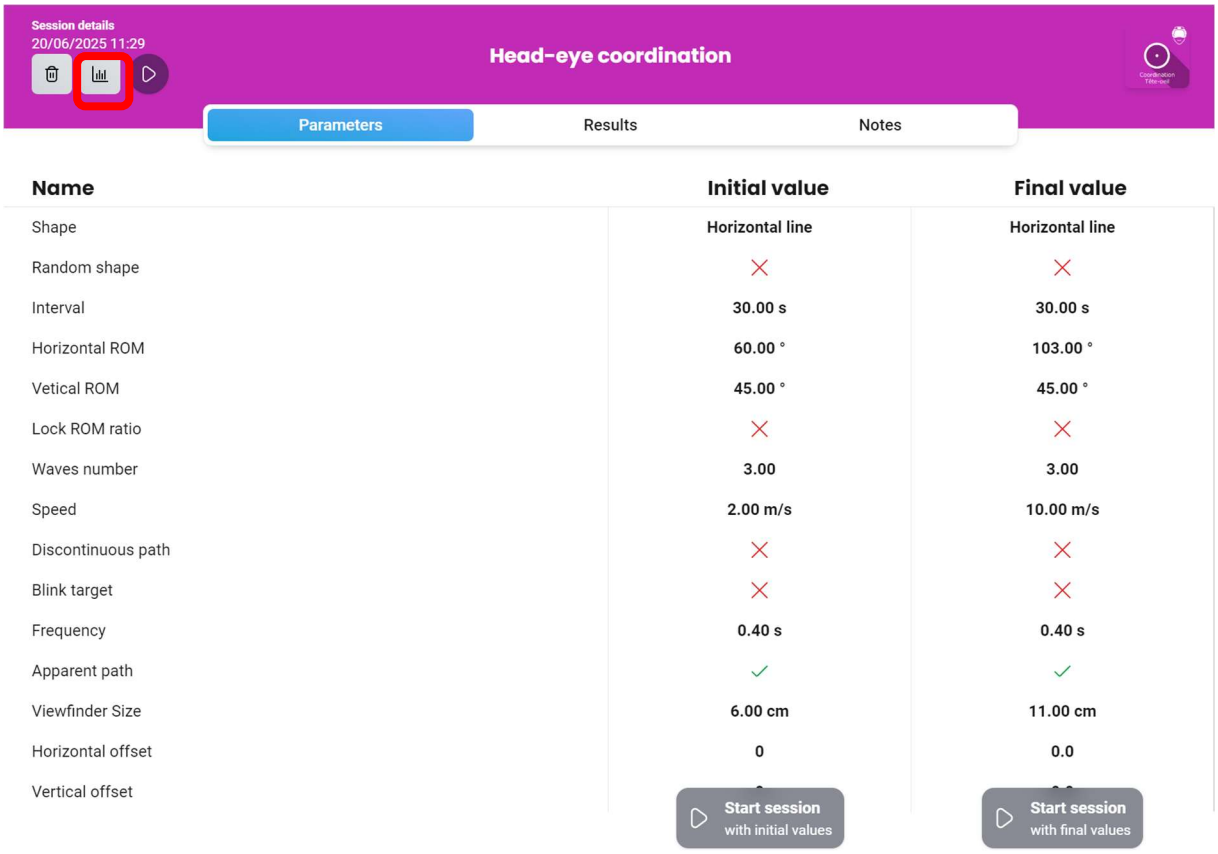


5) Click on "**Notes**" if you want to keep Notes

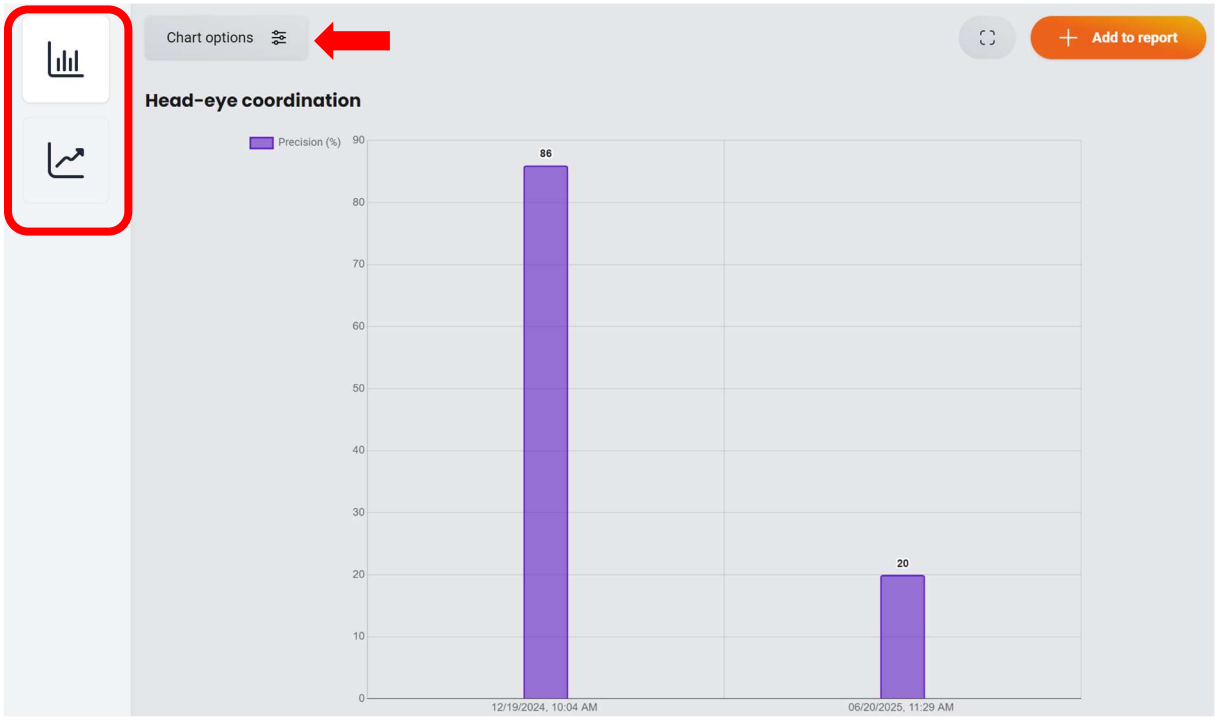


- **Accessing the detailed results and the report:**

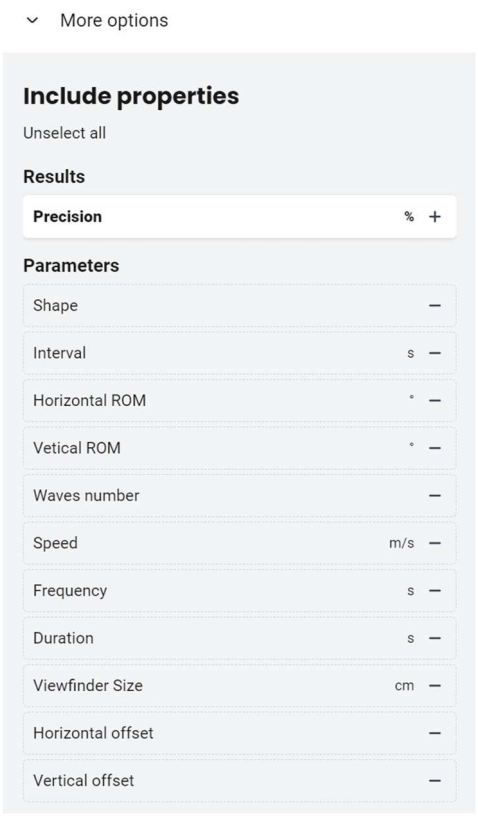
1) Click on the graph icon  .



2) Select a type of graph.



3) Click on "**Chart options**" to choose which information to display on the graph.



4) Click on "**Add to report**" to add the graph to a report.

5) Click on "**PDF**" to see the generated document.

3.8. Daily maintenance

- Clean the headset and accessories daily, following the instructions in the product manufacturer guide.

- After each session with a patient, it should be ensured that there is no contamination on the equipment and accessories. General precautions must be observed to avoid the transmission of infections and diseases between patients. **Sanitize the accessories between each patient, including the headset's lenses**. (See 4.1 Cleaning procedure for more information).

- Perform a check each morning and evening to make sure the equipment is clean, working properly and fully charged.

Icon	Status	Description
	Low battery	The accessory's battery is low.

TABLEAU 1: LOW BATTERY ICON IN STEAMVR

- Charge all the accessories at the end of each day.

4. Care and maintenance

WARNING

To prevent data loss or theft, choose a secure Patient Manager password and make sure to keep it private.

See the Patient Manager's manual for more information.

RECOMMENDATION

Perform updates as soon as they are available.

4.1. Cleaning procedure

CAUTION

The following points are to be used as general guidelines; **always refer to product manufacturer guide for cleaning instructions for specific products or components**.

WARNING

Always use protective gloves when cleaning and disinfecting equipment.

RECOMMENDATION

Dust the station regularly, using a soft, damp antistatic cloth soaked in cleaning solution.

4.1.1. Computer cart

WARNING

Switch off and disconnect the system from the main power supply before cleaning it.

4.1.2. Computer tower

WARNING

Do not spray or pour liquid cleaners on the central unit. Liquid may penetrate the ventilation holes. Use only a soft cloth dampened with cleaning solution.

The central unit can be cleaned with a soft cloth soaked in cleaning and disinfectant products commonly used in hospitals, including isopropyl alcohol and neutral cleaning solutions.

Substances not to be used:
1. thinner, benzine, alcohol
2. insecticides or other volatile elements
3. organic solvents such as acetone and toluene

4.1.3. Other components

WARNING

Avoid splashing liquids on electrical components.

Do not use abrasive products.

Use isopropyl alcohol or neutral cleaning solutions.

4.1.3.1. Screen

WARNING

Do not spray or pour liquid cleaners onto the screen vents.

WARNING

When cleaning the screen, take care not to spill any liquid on the central unit.

Lightly wipe dirt from the screen surface with a soft cloth soaked in a neutral cleaning solution.

Substances not to be used:

- Thinner, benzine, alcohol
- Insecticides or other volatile elements
- Organic solvents such as acetone and toluene
- Avoid long-term contact with rubber or vinyl products.

Do not rub the surface of the LCD panel with a rough object, and do not press hard on the surface of the LCD panel.

4.1.3.2. Virtual reality accessories

RECOMMENDATION

Please refer to the instructions provided with the accessories.

Headset cushion:

Clean with a nonabrasive antibacterial/disinfecting wipe between uses *or* per your facility and institutional policy for cleaning non-porous foam. It is also possible to use an additional protective barrier between the patient and VR headset components.

4.1.3.2.1. Headset

RECOMMENDATION

Clean the headset between each patient.

a) Cleaning the face cushion

See: https://www.vive.com/us/support/vive-pro2/category_howto/cleaning-the-face-cushion.html and https://www.vive.com/us/support/vive-pro2/category_howto/replacing-the-face-cushion.html#replacing-the-face-cushion for more information.

1) To remove the face cushion, peel off starting from both ends of the face cushion until it detaches from the headset.

2) When cleaning the face cushion, remember to:

- Dampen a clean smooth cloth with cold water and gently wipe the area you want to clean.
- Air dry it at room temperature. Don't tumble dry, iron, or expose it to direct sunlight.
- Don't scrub, wring, or bleach it.
- Don’t dip or soak it in water.

3) To replace the face cushion, insert the tab on the face cushion into the slot on the headset.

4) Align the hook and loop strips.

b) Cleaning the exterior of the headset and the controllers

See: https://www.vive.com/us/support/vive-pro2/category_howto/caring-for-your-vive.html for more information.

Wipe them down using a clean microfiber cloth.

c) Cleaning the headset lenses

See: https://www.vive.com/us/support/vive-pro2/category_howto/cleaning-the-headset-lens.html for more information.

1) Make sure the cleaning cloth provided in the box is dry.

2) Wipe the lenses in a circular motion from the center to the outer edges of the lenses.

CAUTION

Do not scratch the lenses or disassemble other parts of the headset.

RECOMMENDATION

You can use an air pump to blow away dust and particles from the headset lenses.

4.1.3.2.2. Other accessories

Refer to the manufacturer's care instructions for more information.

4.2. Caring for the headset

Refer to the VIVE care instructions:

https://www.vive.com/us/support/vive-pro2/category_howto/caring-for-your-vive.html

4.3. Maintenance requirements

For any maintenance inquiry, such as log files to be checked or possibly cleared, contact authorized personnel.

4.4. Decommissioning and disposal

If decommissioning or disposal of the software is necessary, the medical data should be exported as PDF files from the Patient Manager.

Then, the software should be uninstalled, and the local data folder should be removed from the computer.

To ensure that the data is completely deleted, it is recommended to format the hard drive.

5. Annexes

5.1. Annex 1: Modules included in the BalanceVR and BalanceVR Access packages

Table legend:
I: Included
X: Excluded

Modules	BALANCEVR ACCESS (France)	BALANCEVR	Assessment / Rehabilitation	Clinical application
Cervical Range of Motion	**I**	**I**	Assessment	Any cervical troubles.
Lift	**I**	**I**	Rehabilitation	Realistic elevator simulation software used to actively desensitize patients, who must move forward and face their fears.
DVA Test	**X**	**I**	Assessment	Dynamic Visual Acuity assessment, any condition affecting balance
DVA VR	**X**	**I**	Assessment and Rehabilitation	Dynamic visual acuity assessment, rehabilitation of oscillopsia, work on image stabilization during rapid head movements.

Modules	BALANCEVR ACCESS (France)	BALANCEVR	Assessment / Rehabilitation	Clinical application
Head-eye coordination	**I**	**I**	Rehabilitation	”Oculocephalic” type cervical spine rehabilitation and balance disorders.
EscalatorVR	**X**	**I**	Rehabilitation	Software used to reintegrate everyday activities, the treatment of scrolling syndrome and acrophobia as well as work on parachute reflexes.
Optical flow	**I**	**I**	Rehabilitation	Optical Flow is a software used for balance disorder rehabilitation using linear or curved visual scrolling.
CrowdVR	**X**	**I**	Rehabilitation	Treatment of scrolling syndrome, visual vertigo, reintegration of everyday activities, ochlophobia, claustrophobia and agoraphobia.
hCTSIB	**I**	**I**	Assessment	Balance troubles.
Reading (Sway Referenced)	**I**	**I**	Rehabilitation	This software aims to help desensitize kinetosis related to reading in a moving car.
Optokinetic	**I**	**I**	Rehabilitation	Disorders of the global balance. Fight against visual dependence. Vestibular, neurology, (heminglect).

Modules	BALANCEVR ACCESS (France)	BALANCEVR	Assessment / Rehabilitation	Clinical application
RelaxationVR	I	I	Rehabilitation	Relaxation sessions. Painful syndromes. Isolation of a patient from the real environment during treatment.
Cervical Joint Position Error Test	I	I	Assessment	Neck pain, balance troubles, neurology.
RFT	I	I	Assessment	Evaluation of the perception of verticality and the influence of the visual field in the context of balance disorders or neurological conditions (stroke, for example).
RotationVR-Assessment	I	I	Assessment	Rotating chair assistant to simplify the recording of complex data. Software to support assessment using a rotating chair. Measurement of chair rotation speeds and number of revolutions.
RotationVR-Assessment RCIT	I	I	Assessment	Rotating chair assistant to simplify the recording of complex data. Computerized RCIT assistant.
RotationVR-Rehabilitation	I	I	Rehabilitation	Rotating chair assistant to simplify the recording of complex data.

Modules	BALANCEVR ACCESS (France)	BALANCEVR	Assessment / Rehabilitation	Clinical application
Car Simulation	I	I	Rehabilitation	Treatment of Motion Sickness (Kinetosis). Can be used for driving situations (coordination, traction, visual controls) with the steering wheel and pedals provided.
Motorway Simulation	I	I	Rehabilitation	Motorway Simulation is a software used for rehabilitation of the "syndrome de l'autoroute" - a disorder occurring when the left and right visual hemifields move at different speeds.
Sea Simulation	I	I	Rehabilitation	Sea Simulation is used for desensitization in cases of naupathia (sea sickness).
Waves (Sway Referenced)	I	I	Rehabilitation	The software is used for desensitization in cases of naupathia (sea sickness).
Target Tracking	I	I	Rehabilitation	Software used for the rehabilitation of the cervical spine, an upper limb, balance, hemineglect, ataxias…
SVV	I	I	Assessment	Balance disorders, Spatial disorganization.
Dynamic SVV	I	I	Assessment	Balance troubles, Spatial disorganization.

5.2. Annex 2: BalanceVR modules and their accessories

Table legend:
I: Included
X: Excluded
A: Alternative

Modules	Patient required VR Accessories										Partient optional VR Accessories	Platforms	Other accessories
	VR Headset	VR Headset and Controller(s)	VR Headset and Tracker(s)	VR Headset and Controller(s) and Tracker(s)	VR Headset and Xbox controller	VR Headset and keyboard	VR Headset or TV screen and Platform	VR Headset and Leap Motion	Tracker(s)	VR Headset and Steering wheel			
Cervical Range of Motion	**I**	**A**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**Controller**	**X**	**X**
Lift	**I**	**A**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**Controller**	**X**	**X**
DVA Test	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**I**	**X**	**Xbox Controller**	**X**	**DVA headgear and screen clamp** (used with Trackers)
DVA VR	**I**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**A**	**X**	**Xbox Controller**	**X**	**DVA headgear and screen clamp** (used with Trackers))
Head-eye coordination	**I**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
EscalatorVR	**I**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**

Modules	Patient required VR Accessories										Partient optional VR Accessories	Platforms	Other accessories
	VR Headset	VR Headset and Controller(s)	VR Headset and Tracker(s)	VR Headset and Controller(s) and Tracker(s)	VR Headset and Xbox controller	VR Headset and keyboard	VR Headset or TV screen and Platform	VR Headset and Leap Motion	Tracker(s)	VR Headset and Steering wheel			
Optical flow	**I**	**X**	**X**	**X**	**X**	**X**	**A**	**X**	**X**	**X**	**X**	**StaticVR** (optional) OR **MotionVR** (optional)	**X**
CrowdVR	**X**	**I**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
hCTSIB	**I**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**Airex Balance Pad elite memory foam**
Reading (Sway Referenced)	**X**	**X**	**X**	**X**	**I**	**A**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Optokinetic	**I**	**X**	**X**	**X**	**X**	**X**	**A**	**X**	**X**	**X**	**X**	**StaticVR** (optional) OR **MotionVR** (optional)	**X**
RelaxationVR	**I**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Cervical Joint Position Error Test	**I**	**X**	**X**	**X**	**I**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
RFT	**I**	**A**	**X**	**X**	**A**	**A**	**X**	**X**	**X**	**X**	**Xbox Controller** OR **Controller(s)** OR **Keyboard**	**X**	**X**
RotationVR-Assessment	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**I**	**X**	**X**	**X**	**DVA headgear and rotatory chair**

Modules	Patient required VR Accessories										Partient optional VR Accessories	Platforms	Other accessories
	VR Headset	VR Headset and Controller(s)	VR Headset and Tracker(s)	VR Headset and Controller(s) and Tracker(s)	VR Headset and Xbox controller	VR Headset and keyboard	VR Headset or TV screen and Platform	VR Headset and Leap Motion	Tracker(s)	VR Headset and Steering wheel			
RotationVR-Assessment RCIT	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**I**	**X**	**X**	**X**	**DVA headgear and rotatory chair**
RotationVR-Rehabilitation	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**I**	**X**	**X**	**X**	**DVA headgearand rotatory chair**
Car Simulation	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**I**	**X**	**X**	**X**
Motorway Simulation	**X**	**X**	**X**	**X**	**I**	**X**	**X**	**X**	**X**	**A**	**X**	**X**	**X**
Sea Simulation	**I**	**X**	**X**	**X**	**X**	**X**	**A**	**X**	**X**	**X**	**X**	**MotionVR** (optional)	**X**
Waves (Sway Referenced)	**I**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Target Tracking	**I**	**A**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**Controller**	**X**	**X**
SVV	**I**	**A**	**X**	**X**	**A**	**A**	**X**	**X**	**X**	**X**	**Xbox Controller** OR **Controller(s)** OR **Keyboard**	**X**	**X**
Dynamic SVV	**I**	**A**	**X**	**X**	**A**	**A**	**X**	**X**	**X**	**X**	**Xbox Controller** OR **Controller(s)** OR **Keyboard**	**X**	**X**

5.3. Annex 3: Software Bill Of Material installed on computer

Name	Type	Installation required on the customer computer ("-" for "No")	Description	Manufacturer / Author / Open source project	Version	Dependencies
Windows	OS	Yes	Operating system	Microsoft	10 Home or greater	-
Ultraleap Tracking*	SOUP	Yes	Link between the UltraLeap Tracking SDK and the LeapMotion camera	Ultraleap	5.16.0	LeapMotion camera
Nvidia driver	SOUP (Driver)	Yes	Control the computer GPU	NVidia	535.98 or greater	Windows, Computer GPU (hw)
2016_TTRS_4	SOUP (Driver)	Yes	Steering wheel driver	Thrustmaster	4.TTRS.2016	Windows, Steering wheel (hw)
SteamVR	SOUP	Yes	Link between all VR headsets and the Virtualis' software	Valve Corporation	1.25.8 or greater	Windows, VR Headset (hw)
QLM Wizard	SOUP	Yes	Manage the license keys on the computer	Soraco	12.1.199331.5	Windows
Vive hub	SOUP	For streaming headsets only	Additional link between streaming VR headsets and the SteamVR SOUP	Vive	1.5.11	Windows, Streaming headset (hw)
Silicon Labs CP210x USB to UART Bridge	SOUP (Driver)	For MotionVR+ only	Controls the MotionVR+ option of the MotionVR platfrom	Silicon Laboratories Inc.	11.2.0.167	Windows, MotionVR+ (hw)

Name	Type	Installation required on the customer computer ("-" for "No")	Description	Manufacturer / Author / Open source project	Version	Dependencies
CDM20802	SOUP (Driver)	For MotionVR and MotionVR+ only	Controls the MotionVR platform	FTDI	2.12.36.4	Windows, MotionVR (hw)
Vive Console	SOUP	For HTC Vive pro 2 heasets only	Additional link between Vive Pro 2 headsets and the SteamVR SOUP	Vive	2.1.24.9 or greater	Windows, VR Headset (hw)
VIVE Business Streaming	SOUP	For business streaming headsets only	Additional link between business streaming VR headsets and the SteamVR SOUP	Vive	2.2.4 or greater	Windows, Streaming headset (hw)

* including or not, depending on your configuration