REF | **Shoulder Rotation**

CE   Class I Medical Device

User manual

Distribution mode

Available for direct download at

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

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1. GENERAL

1.1. Description

Shoulder Rotation software is an immersive 3D simulation based on virtual reality technology, immersing a person in a digitally created artificial world.

It is a functional shoulder re-education software program for any shoulder rotation pathology.

The patient controls a crank that reloads two cannons.

When the patient performs the required shoulder rotations, he or she reloads and pulls the cannons toward a castle.

1.2. Indications

Medial and lateral shoulder rotations in anatomical positions of the upper limb.

1.3. Contraindications

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

1.4. Software field of application

Any musculoskeletal pathology related to shoulder rotations.

1.5. Intended user

Healthcare professionals: physiotherapists; occupational therapists; neuropsychologists; ENT doctors; neurologists; PMR doctors (physical medicine and rehabilitation), etc.

Research Centers: CNRS, CHU, INSERM, etc.

1.6. Warnings and caution

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".

The contraindications are identical: Mainly epilepsy and migraines.

> **RECOMMENDATION**
>
> As postural reactions can be spectacular, we STRONGLY recommend that you place the patient in a secure environment and stay close to him/her throughout the session to anticipate any loss of balance or discomfort caused by the use of virtual reality.

> **RECOMMENDATION**
>
> It is also recommended to 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

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

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

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.

It would be counterproductive to take into account the fact that some motivated patients may wish to go further. 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.

Nor can Virtualis be held responsible for any disturbances suffered by patients during or use of their software.

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.
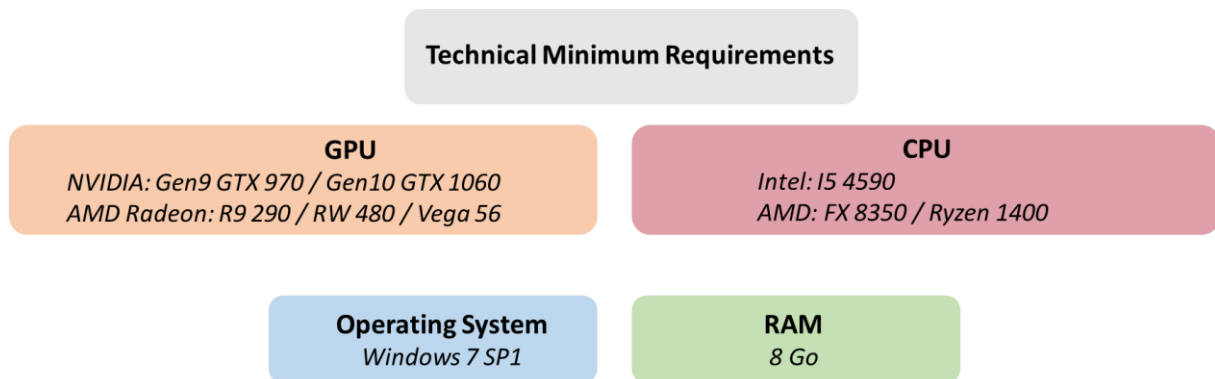
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⚠️ *Any serious incident should be notified in writing to* <u>qualite@virtualisvr.com</u>

1.7. 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)

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	**CPU**
NVIDIA: Gen9 GTX 970 / Gen10 GTX 1060 AMD Radeon: R9 290 / RW 480 / Vega 56	Intel: I5 4590 AMD: FX 8350 / Ryzen 1400

Operating System	**RAM**
Windows 7 SP1	8 Go

1.8. Required accessories

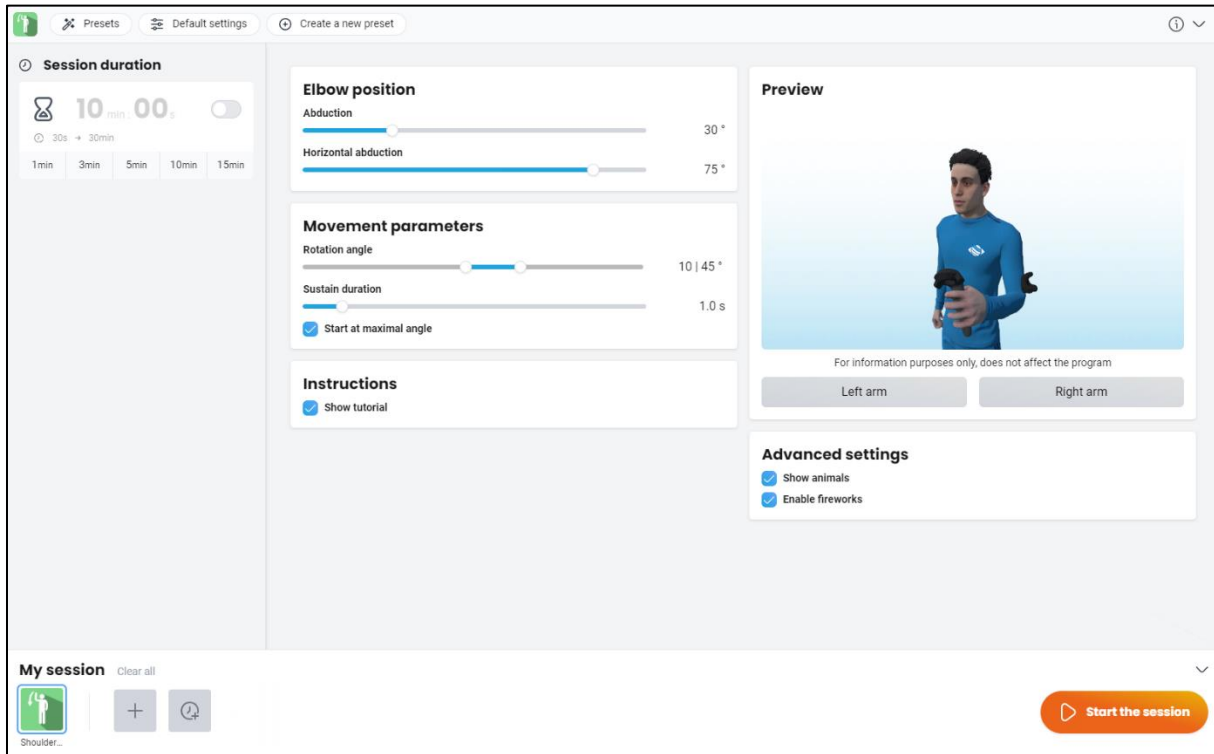VR headset, 1 or 2 controllers, and 1 tracker strapped to the patient's elbow.

2. SOFTWARE USE

2.1. Patient setup
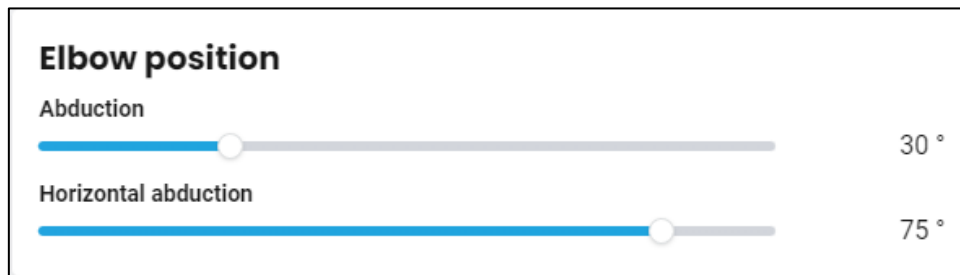
The patient can be standing or sitting.

2.2. Session settings

The following settings can be changed before or during the session:

2.2.1. Elbow position

Abduction:

Value: 10 to 90°.

Horizontal abduction:

Value: -15 to 90°.

2.2.2. Movement parameters

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Rotation angle:

Defines the patient's range of motion.

Value: -90 to 120°.

Sustain duration:

Value: de 0,0 à 10,0 s.

Start at maximal angle:

If the option is checked, the exercise starts at the maximum angle instead of the minimum.
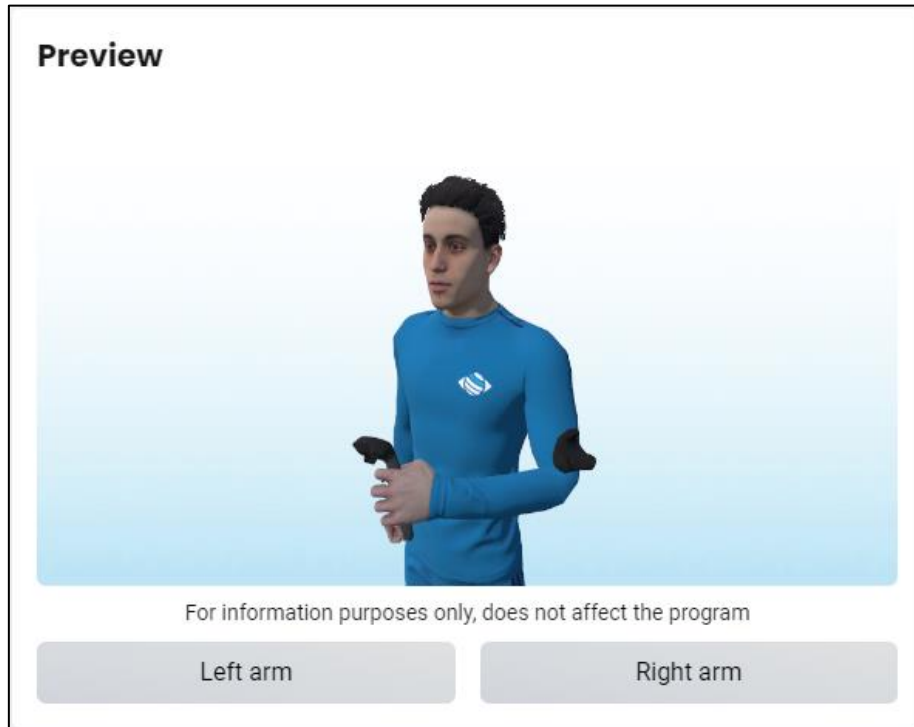
2.2.3. Instructions

Show tutorial:

Displays the calibration tutorial.
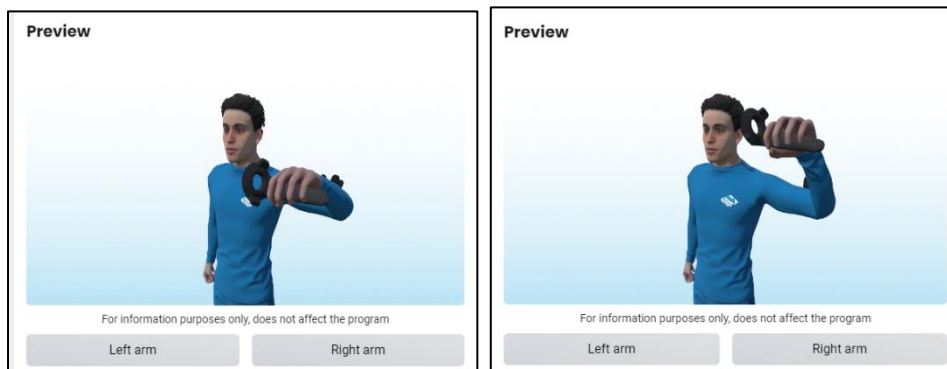
2.2.4. Preview

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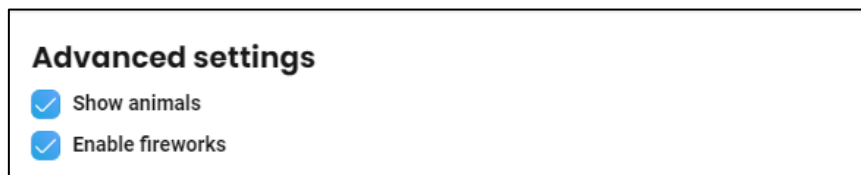
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Video preview showing movements according to the chosen settings. Choose to view the side you want to work on by clicking on "**Left arm**" or "**Right arm**". This does not affect the program.

2.2.5. Advanced settings
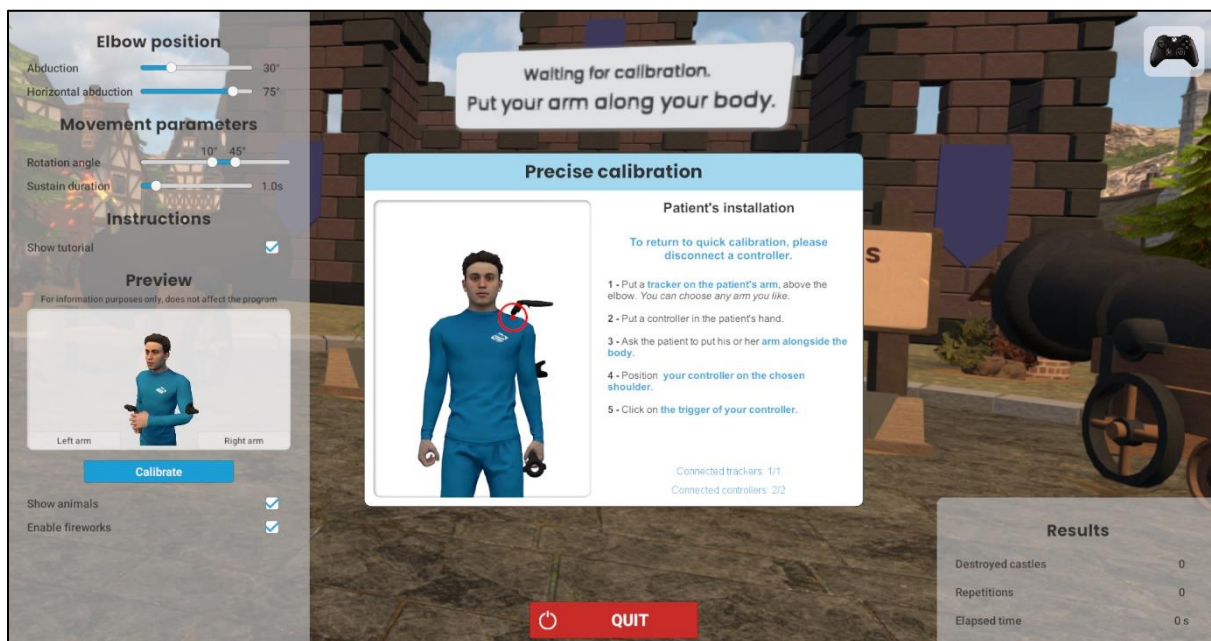

Choice of detail displayed:

- **Show animals**.

- **Enable fireworks** (when a castle is destroyed).

2.3. Session

Une fois les préréglages définis, lancez l'interface virtuelle en cliquant sur « **Démarrer la séance** », en bas à droite de l'écran.

Once the session has started, a calibration phase is required to ensure the module is working properly. The software automatically detects which accessories are switched on.

The patient's arm should be at their side, with 1 controller in their hand and 1 tracker above their elbow.

- **Quick calibration: 1 controller and 1 tracker switched on:** follow the instructions and click on "calibrate".
- **Precise calibration: 2 controllers and 1 tracker switched on:** position the second controller at the joint center of the shoulder, then click on the trigger of the 2nd controller to confirm precise calibration.

Calibration

Patient's installation

To access precise calibration, please connect an additional controller.

1 - Put a **tracker on the patient arm**, above the elbow. *You can choose the arm you want.*

2 - Put a **controller in his hand**.

3 - Ask to patient to put his **arm alongside his body**.

4 - Click on **Calibrate**.

Connected trackers: 1/1
Connected controllers: 1/1

Calibrate
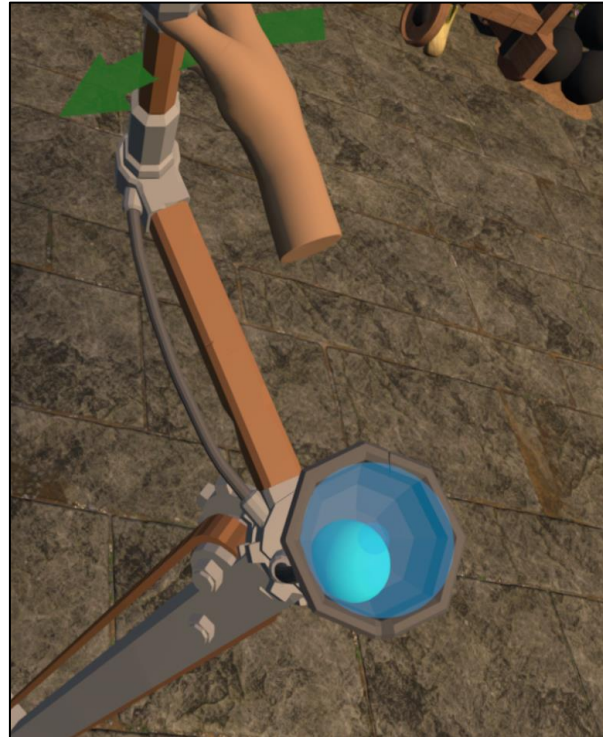

Precise calibration

Patient's installation

To return to quick calibration, please disconnect a controller.

1 - Put a **tracker on the patient's arm**, above the elbow. *You can choose any arm you like.*

2 - Put a controller in the patient's hand.

3 - Ask the patient to put his or her **arm alongside the body**.

4 - Position **your controller on the chosen shoulder**.

5 - Click on **the trigger of your controller**.

Connected trackers: 1/1
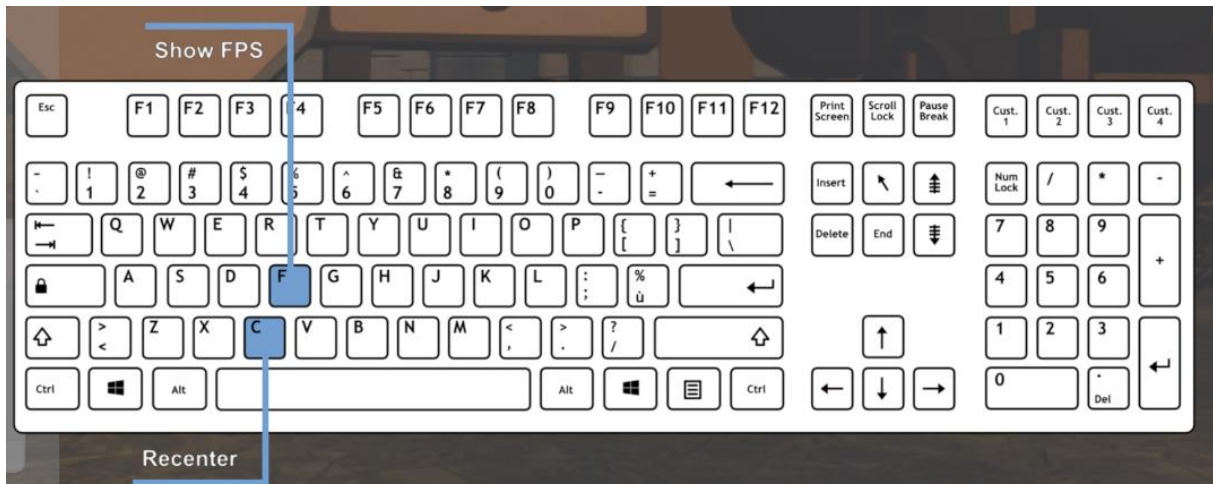Connected controllers: 2/2

To start the session, the patient must place their elbow in the blue zone and place their hand on the crank (green zone) which they will see in the virtual environment:
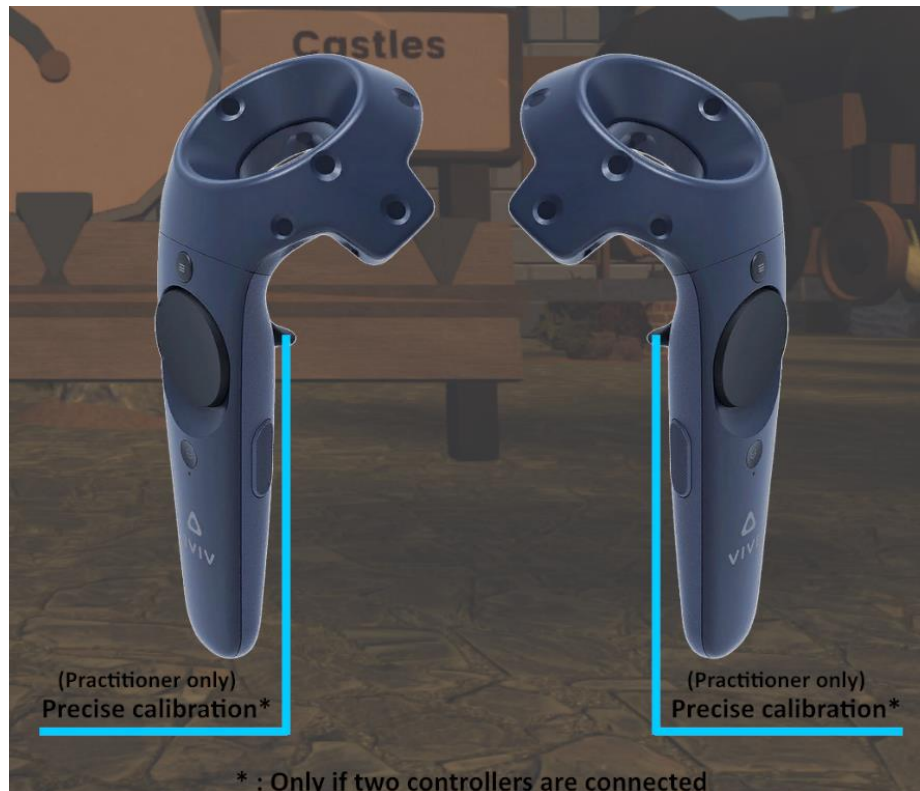
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2.4. Shortcuts

During the session, the shortcut list is found by clicking on the Xbox controller icon in the top right corner of the screen.

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2.5. Results

Once the session is over, you can access the results.

2.5.1. Summarized results

By default, the results are as follows:

- Repetitions
- Calibration side
- Min. Abduction
- Max. Abduction
- Min. Horizontal abduction
- Max. Horizontal abduction
- Min. Shoulder rotation – Achieved
- Min. Shoulder rotation – Reached
- Max. Shoulder rotation – Achieved
- Max. Shoulder rotation - Reached.

2.5.2. Report and graphs

Click on the histogram icon to access detailed results and the session report.

Name	Result
Repetitions	49
Calibration side	Right arm
Min. Abduction	30.00 °
Max. Abduction	30.00 °
Min. Horizontal abduction	75.00 °
Max. Horizontal abduction	75.00 °
Min. Shoulder rotation - Achieved	10.00 °
Min. Shoulder rotation - Reached	-25.00 °
Max. Shoulder rotation - Achieved	45.00 °
Max. Shoulder rotation - Reached	68.00 °

By default, you are shown the shoulder rotation angles (rotation and abduction angles)., but two display modes are available.
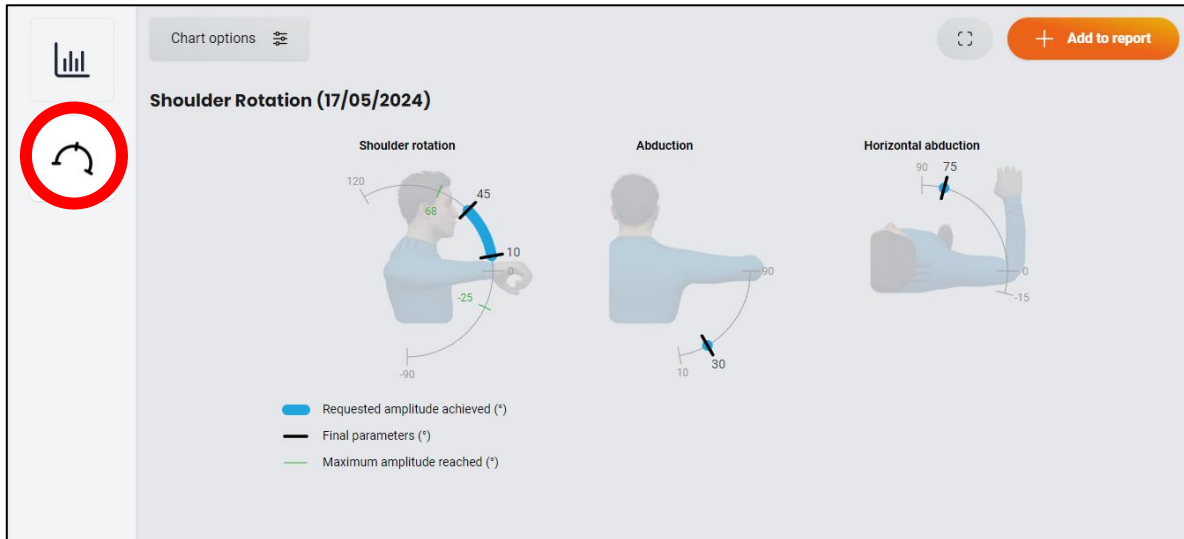
And:

By clicking on the "histogram" icon, you can access the all of the results.

2.6. Data processing

Data retrieval and analysis uses the Patient Management software (see dedicated user manual).

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