



WEARABLE ROBOTICS



## INSTRUCTIONS FOR USE

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#### Recipients of the Manual

This manual is intended to be a reference for physiatrists, physiotherapists, neurologists, support staff, and all rehabilitation professionals trained in the proper use of the **ALEX RS**. The user trained in the proper use of **the ALEX RS** is responsible for the patient and for all operational aspects of **the ALEX RS**.

#### Disclaimer

Improper use of **the ALEX RS** can cause serious personal injury. Wearable Robotics Srl will not be liable for any injury or damage suffered by any person, directly or indirectly, as a result of the use or repair of the **ALEX RS** in violation of your agreement with Wearable Robotics Srl. Wearable Robotics Srl assumes no responsibility for any damage caused to its products, directly or indirectly, as a result of use and/or repair by unauthorized personnel.

No modifications to the device may be made without the prior written authorization of Wearable Robotics Srl.

Additional components (tools, software, etc.) not supplied by Wearable Robotics Srl must be approved by Wearable Robotics Srl before being integrated with the device. The user is solely responsible for any damage these components may cause to the device, other material property, or persons. The safety information in this Manual cannot be used against Wearable Robotics Srl. Authorized technicians are responsible for ensuring that the device is installed and handled in accordance with the safety standards of the country in which it is installed.

Wearable Robotics Srl cannot be held responsible in any way for any accidents caused by incorrect or improper use of the device and/or following tampering with circuits, components, or software.

#### Environmental policy

Service personnel are advised that when replacing any part of **the ALEX RS**, care must be taken to dispose of such parts properly; where applicable, the parts must be recycled. WEEE should be disposed of or recycled in accordance with all applicable national, state/provincial, and local requirements. Batteries must be fully discharged before disposal and/or terminals must be capped or sealed to prevent short circuits. Do not incinerate. For more detailed information on recommended procedures, contact Wearable Robotics Srl.



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## Symbols and Acronyms used

This guide uses the following warning symbols and acronyms. Warnings are important for your safety and must be observed by everyone.

### Warning symbols:



This warning indicates that: **it is certain, or highly probable, that serious injury will occur if precautions are not taken.**



This warning indicates that: **serious injury could occur if precautions are not taken.**



This warning indicates that: **minor injuries could occur if precautions are not taken.**



This warning indicates that: **damage to the device may occur if precautions are not taken.**

## Acronyms:



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ACU	Acquisition and Comm. Unit - Acquisition and Communication Unit
ALEX	<i>Arm Light Exoskeleton</i> , integrated (both right and left) in <b>ALEX RS</b>
<b>ALEX RS</b>	Arm Light Exoskeleton Rehab Station
DCU	Device Control Unit - Device Control Unit
MD	Motor Driver - Motor Driver
OC	Operator Console - Operator Console
VRU	Virtual Reality Unit - Virtual Reality Unit
WR	Wearable Robotics Srl, manufacturer of <b>ALEX RS</b> .



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## **1 Introduction**

### **DANGER**

Improper use can result in potentially serious injury. Do not use **ALEX RS** if you are unable to ensure your own safety and that of any patient or other nearby persons. Wearable Robotics Srl is not responsible for any loss or damage arising from the use of **ALEX RS**.

**ALEX RS** can only be used under the direction of a professional (for example a physiotherapist or a doctor), who has been authorized by Wearable Robotics Srl to use **ALEX RS**.

### ***1.1 General overview of the device***

**ALEX RS** is a **medical device for the rehabilitation of the upper limbs**, equipped with two **wearable robotic exoskeletons** integrated with an **adjustable seat**, a **control console** and a **screen** for displaying interactive 3D scenarios.

Rehabilitation treatment with **ALEX RS** offers various options and possibilities, and the different modes can be set and customized as described later in this Manual.

The exoskeletons, which can be used simultaneously or individually, can passively follow the patient's movements or exert force to move the wearer's limb or relieve its weight. A **patient status assessment mode** and an **assistance mode** that can be activated during exercise are available. Furthermore, the device is equipped with a **database** to store each patient's data and monitor the progress of therapy. It is scientifically proven that the use of robotic devices in rehabilitation meets the need for high-intensity, repetitive, task-oriented, and interactive treatments: **ALEX RS** offers these capabilities and is a device

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objective and reliable way to monitor patient progress and provide comprehensive, customizable and effective treatment.

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*Figure 1. ALEX RS Seat and Operator Console*



*Figure 2. Rear view of ALEX RS, which also shows the screen for visualizing 3D rehabilitation scenarios*



*Figure 3. Side view of the ALEX RS seat and operator console*



## 1.2 Purpose of the Manual

This Manual provides information regarding **ALEX RS** and its use, its intended use, the personnel authorised to work with the device itself, the safety requirements and measures, installation, transport, maintenance procedures and requirements, the graphical user interface and the related parameters and modes that can be set.

## 1.3 Device dimensions

The dimensions of **ALEX RS** are shown in Figure 4 and Figure 5.

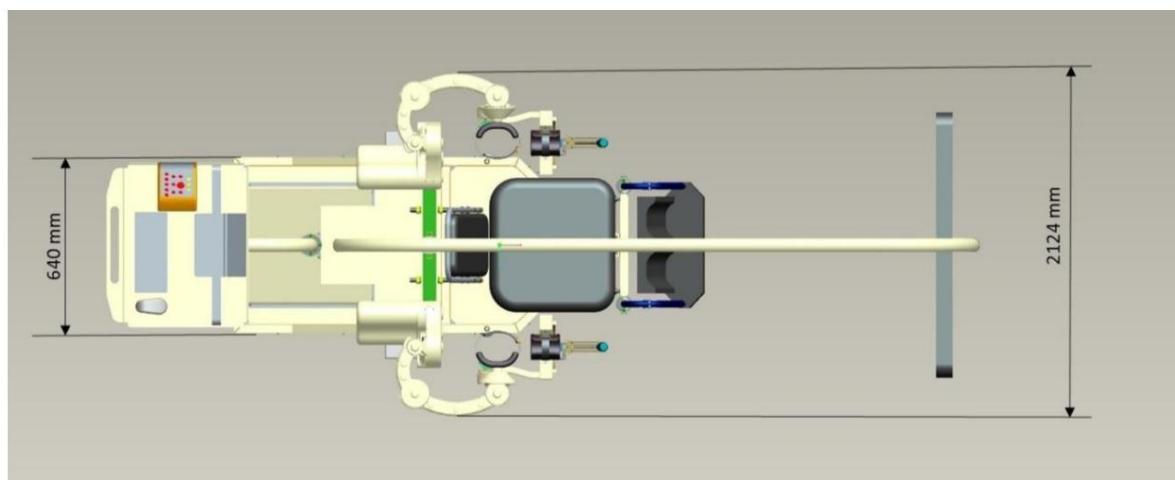


Figure 4. **ALEX RS** model and dimensions in mm (top view)

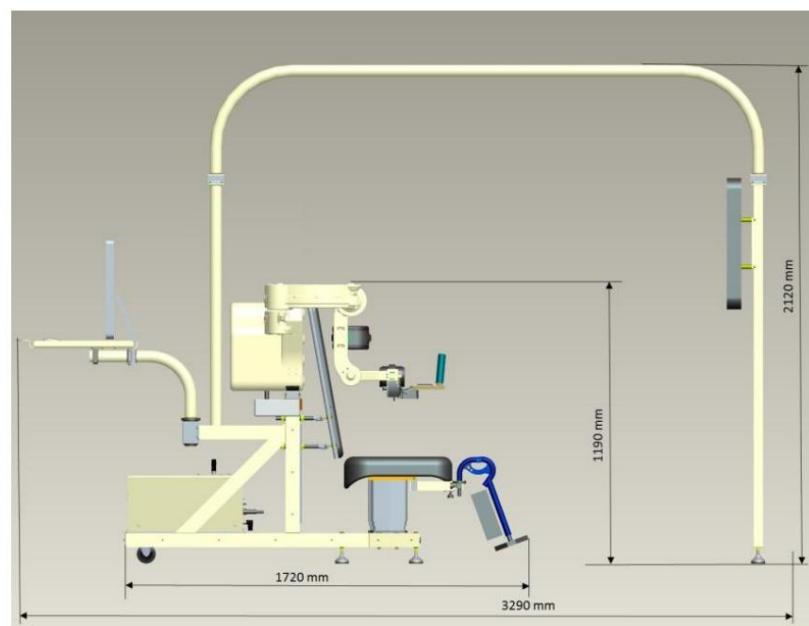


Figure 5. **ALEX RS** model and dimensions in mm (side view)



### 1.4 Symbols on the Device Label

The Device

Label contains the following symbols.

Symbol	Description
	Identification code, or Catalog number, of the device
	Serial Number
	Type B Applied Part
	Name and address of the device Manufacturer
	Manufacture Date
	CE mark followed by the code of the Notified Body
	Fragile device, handle with care
	Protect the device from heat and radioactive sources
	Keep the device dry, protect it from moisture
	Temperature lower and upper limits to which the device can be safely exposed
	The range of humidity to which the device can be safely exposed
	Caution. Consult the instructions for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself
	Do not use with patients who are pacemaker wearers
	Refer to instructions manual
	For disposal, refer to the Waste Electrical and Electronic Equipment (WEEE) Directive
	Type of fuses for protection against overheating



## **2 Safety information, warnings and general instructions**

### **2.1 General information**

**ALEX RS** is a mechatronic device capable of exerting significant mechanical energy on external entities that interact with it, such as human subjects (operators, patients, healthy people) or external objects.

Although various software and hardware measures have been implemented to ensure the safety of users and operations, improper use of the device by inadequately trained personnel may result in injury to humans and damage to materials and the device itself.

This chapter contains only general safety instructions.

Further specific requirements can be found in the sections relating to installation, transport and operational use of the device.



Each patient must be carefully evaluated, measured, and monitored to determine their suitability for use of the **ALEX RS**. Failure by a physician or physical therapist to adequately assess a patient's suitability for use of the **ALEX RS** may result in injury to the patient and/or damage to the **ALEX RS**.



Observe the general and specific safety instructions given in this User Manual.



Use the device only for its intended use as described in this guide. Any use or application other than the intended use is considered improper use and is not permitted. The manufacturer is not responsible for any damage resulting from such improper use. The risk lies entirely with the user.



Operators authorized to use the device must be adequately trained.



## 2.2 General safety requirements

- Read all **safety instructions** and **operating instructions**.  
before you start using the device.
- Read and keep the device's **User Manual** for future reference.
- Use the device only after it has been **correctly installed**.
- **ALEX RS** is a highly sophisticated mechanical system that requires **care** by operators and patients to avoid damage.
- Do not leave the device **turned on** when not in use.
- Do not leave the device **unattended** when it is turned on.
- Do not leave the device **turned on for more than 8 hours**: after 8 hours of continuous use,  
Turn off the device for at least **30 minutes**.
- Do not connect the device to the **Internet** or other devices with wireless protocols.  
compatible communications.
- Be careful not to insert your hands into the **trapping zones**  
of the exoskeleton (see 2.7) which may cause crushing or cutting of the fingers or  
upper limbs. Inform patients appropriately.
- If there are conditions to do so safely, **support** the *ALEX* exoskeleton  
before disabling the motors, in order to avoid the weight of the moving parts bearing on the patient's  
arm or, if the patient is not wearing the device, the **moving parts** of the exoskeleton from hitting the  
seat or its mechanical stops.
- **Constantly monitor** the patient's physical condition. **Stop** rehabilitation exercises if the patient shows signs  
of fatigue or other symptoms of discomfort.
- Perform **periodic backups** of your saved data.
- Ensure that the exoskeleton workspace is **free from obstructions**.
- Operators must ensure that their hair, necklaces, bracelets or clothing are not at risk  
of being **caught** in the moving parts of the exoskeleton.  
Pay the same attention to patients' hair and clothing.
- To prevent the spread of diseases transmitted by contact, **disinfect** the  
robotic arm.
- If you experience any improper device behavior, please contact WR **technical  
support**.
- In an emergency situation, press the **emergency button**, then turn off **the ALEX RS**  
and then follow the company or organization's internal procedures for an emergency  
situation.
- In case of **fire**, use CO<sub>2</sub> to extinguish it.
- Do not use **ALEX RS** if the device has **frayed or broken wires**.
- Do not use **ALEX RS** if the device is **not working properly**.



### **2.3 Intended use**

**ALEX RS** was specifically designed for upper limb rehabilitation in public or private healthcare facilities. Motor rehabilitation performed with **ALEX RS** is primarily intended for patients who have survived neurological trauma, such as stroke. At the physician's discretion, **ALEX RS** therapy can also be administered to orthopedic patients or those requiring rehabilitation.

of the upper limbs following surgery. Furthermore, at the therapist's discretion and depending on the patient's condition and needs, motor rehabilitation exercises with **ALEX RS** can be performed:

- with one arm or with both;
- actively or passively ;
- with or without the visual feedback and activities proposed by the Virtual Reality Unit.

### **2.4 Improper use**

Any use or application other than the *Intended Use* (see above) is considered *Improper Use* and is not authorized. This includes, for example:

- entertainment (e.g. video games);
- muscle strengthening;
- "physically based" simulation;
- use as a master device for teleoperation;
- use in hazardous environments (e.g. explosives);
- use in life support systems;
- use in residential installations;
- use where the device is subject to excessive heat/humidity conditions;
- operations outside the permitted operational parameters.

Unintended use of **ALEX RS** may:

- cause harm to the patient and/or operators or other persons in the vicinity;
- damage the device itself or other devices;
- reduce the reliability and performance of the device.

**NOTICE**

For any questions regarding a different use, please contact WR.

**NOTICE**

Use in combination with other devices or products is permitted only with the prior approval of WR.

**NOTICE**

Any modification (whether internal, external, hardware or software) to the device may be harmful and is not permitted: such use is considered improper and leads to the loss of warranty and WR's liability.

**NOTICE**

Deviation from the operating conditions specified in official WR documents or the use of special functions or applications may lead to premature wear of the device.



## 2.5 Authorized Users

Users authorized to use the device are:

- **Qualified operators trained in the use of the device**
- **Patients**
- **Qualified technicians**
- **Informed service staff**

**Qualified operators trained in the use of the device:** Doctors, Physiotherapists, other

Professionals in the Rehabilitation sector or any other person who has proven competence in motor rehabilitation practices and who has received appropriate training from WR staff or other personnel authorised by WR.

They are responsible for the correct functioning of the device in all its operational phases, including its storage during periods of inactivity.

Operators must also have the following requirements:

- proven medical knowledge, particularly in the field of rehabilitation  
motor skills
- experience and familiarity with the most important standards, so as to be able to evaluate the work to be done and detect any hazards
- have successfully attended a training course and have read and understood the documentation relating to the device

**Patients:** are authorized to use the system only under the responsibility and continuous supervision of the Operators (see above).

The device can only be used with patients with the following characteristics:

- age over 18 years
- height range 1.50 m/1.90 m
- weight not exceeding 130 kg
- healthy bone density and skeleton that does not suffer from unhealed fractures

**NOTE:** Always give patients clear information and instructions on how to use **ALEX RS**.

**Qualified technicians:** These are WR professionals, or third parties authorized by WR, and are the only ones who can work on the device to:

- install it
- provide maintenance
- fix it

**Informed service personnel:** these are the personnel who clean and sterilize the device and must be adequately informed by the Operators about the procedures and requirements that must be followed.



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**DANGER**

Any person not specified in this paragraph is not authorized to use the device. Operators must protect the device from unauthorized use. Operators must restrict access to the device using any appropriate means.

**DANGER**
**CONTRAINDICATIONS**

People with the following conditions should not use the device (except under the sole discretion of a doctor):

- Serious concomitant pathologies: infections, circulatory, cardiac or lungs, bedsores.
- Severe spasticity (Ashworth 4).
- Spinal instability or unhealed limb fractures.
- Heterotopic ossification.
- Significant muscle contractures.
- Psychiatric or cognitive complications that may interfere with proper functioning device operation.
- Impulsive behavior that can lead to unsafe movements.
- Cognitive impairments that lead to the inability to follow the doctor's instructions during therapy. If the patient has cognitive or psychiatric impairments that may lead to the inability to follow instructions, **ALEX RS** should not be used.
- Pregnancy.
- Poor skin integrity in areas in contact with the device.
- Excessive asymmetry in the length of the arms.
- Uncontrolled autonomic dysreflexia.
- Upper limb prostheses.
- Unsafe changes in blood pressure or heart rate. If these conditions are detected, the session must be stopped immediately.
- Discomfort or pain experienced while using the device, or unusual spasticity. Discontinue use if the patient experiences any such condition.
- Bony prominences or other bony projections on which the device exerts pressure.
- Excessive joint limitations that make it difficult or painful to use the device.



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## 2.6 Electromagnetic compatibility

### NOTICE

This equipment is intended for use by healthcare professionals only.

This equipment may cause radio interference or disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as relocating the **ALEX RS** or shielding the location where it is installed.

### CAUTION

This medical electrical equipment requires special precautions regarding EMC and must be installed and put into service according to the EMC information provided in this manual (see Appendix B).

### CAUTION

Portable and mobile RF communications equipment can affect medical electrical equipment. See Table 12 for recommended separation distances between portable and mobile RF communications equipment and this medical electrical equipment.

### CAUTION

The use of accessories, transducers, and cables other than those intended, with the exception of accessories, transducers, and cables sold by the manufacturer of this equipment, as replacement parts for internal and external components, may result in increased emissions or decreased immunity of the equipment.

### CAUTION

**ALEX RS** should not be used adjacent to or in combination with other equipment. If **ALEX RS** is used while placed adjacent to other equipment, it should be observed to verify normal operation in the configuration in which it will be used.



## 2.7 Trap zones

Each of the *ALEX* exoskeletons integrated with the seat (see below for more details) has **3** entrapment zones that can cause crushing, breaking or severing of the patient's or operator's fingers or upper limbs.

Observe Figure 6 and pay attention to the warning stickers.



Check that warning signs are present and visible.



Do not wear necklaces or bracelets while using **ALEX RS**.

Keep your hair tied up.

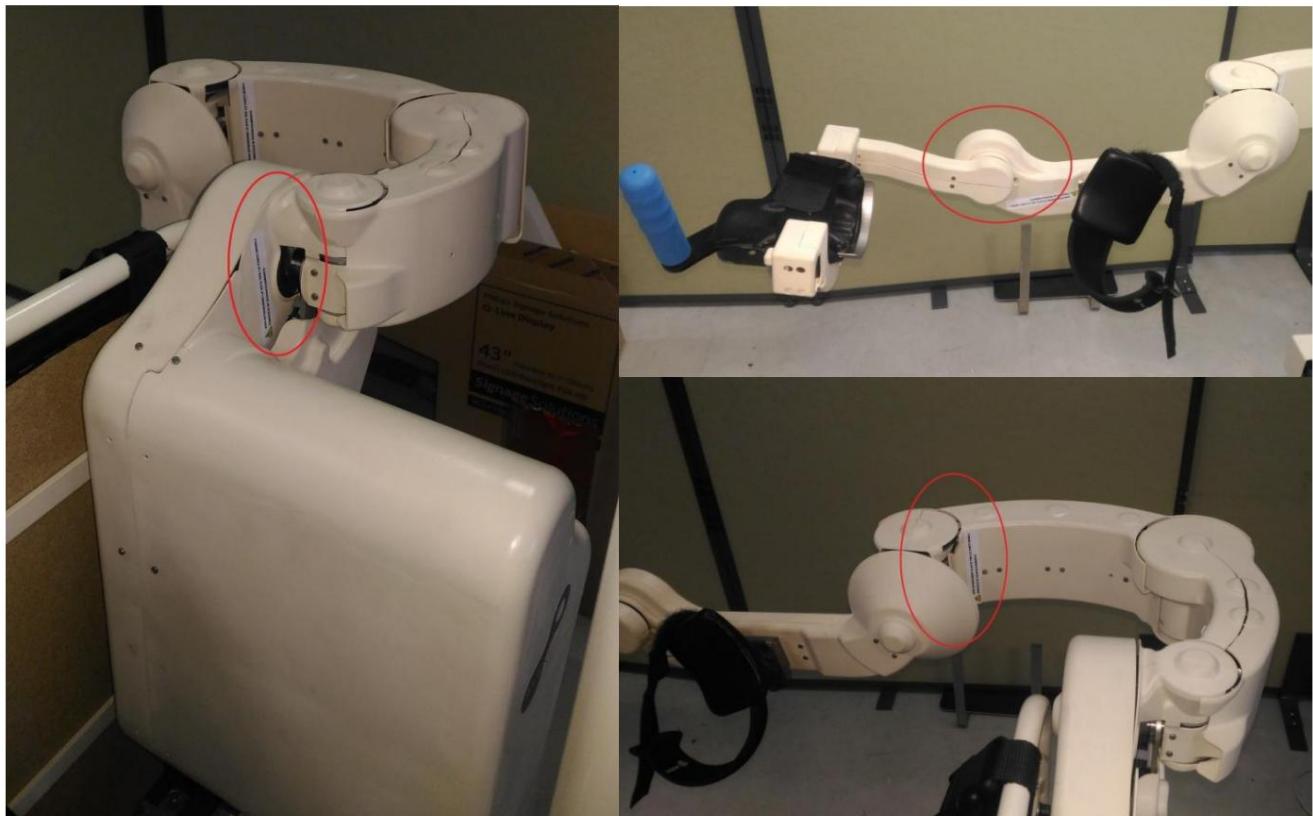


Figure 6. *ALEX* exoskeleton entrapment zones



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## 2.8 Adverse events

Any adverse reactions observed by an Operator or patient during or after use of **ALEX RS** must be **carefully documented and reported** immediately to Wearable Robotics Srl. Examples of adverse reactions include:

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- Skin integrity problems
- Bruises
- Pain
- Dizziness, headache
- Nausea or changes in skin color, such as turning pale or red
- Unusual swelling

Any undesirable mechanical behavior of **the ALEX RS** must be noted and reported to Wearable Robotics Srl before continuing use. Examples of undesirable behavior include:

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- Irregular movements related to software rather than performance patient
- Unusual oscillation of any joint of the exoskeleton
- Unusual sounds not present during treatment or regular operation of **ALEX RS.**



### **3 Installing the device**

This chapter is intended for technicians who install **ALEX RS**.

Installation must be carried out according to the instructions given in this chapter.

**NOTE:** See section 7.1.1 for instructions on moving the device.

#### ***3.1 Connection to the main power grid***



The device requires a supply voltage of 100-230 VAC at 50/60 Hz with maximum surge voltage category 2 (IEC 60664-1), with a nominal power of 1000 VA.



Make sure the circuit breaker on the main line is sized correctly for the required current draws.



Ensure that a residual current device (RCD) is installed and that the earth connections comply with standard regulations.



To avoid inadvertent power interruptions, install an uninterruptible power supply (UPS) appropriately sized for the absorption, which can power the device for at least 10 minutes.

#### ***3.2 Installation room***



Install the device on a flat, horizontal surface.

Installation and commissioning of **ALEX RS** is permitted only within a dedicated area of adequate size to accommodate the entire device and its working area.



The installation area of the equipment must be free of materials that may impede or limit visibility.



Leave adequate space for patient and operator access to the device.



The total weight of the device is approximately 150 kg. Ensure that the floor can safely support the weight of the device, patient, and operators.

#### ***3.3 Environmental conditions***



The device must be installed at a maximum altitude of 2000m above sea level.



For optimal use, the room temperature should not exceed 30°C or fall below 5°C. The heat produced by the device is limited, however, the room should not be too small or thermally insulated to prevent the temperature from exceeding the indicated limits during use.



Make sure that the magnetic field in the area of the robotic arm does not exceed 10 Gauss, to avoid interference with the position sensors.



### **3.4 Installation procedure**

Considering what is reported in the previous paragraphs, the main steps are indicated here

of the installation procedure of the **ALEX RS medical device**.

Upon delivery to the Customer, the device is supplied partially assembled.

- Place the device, with all its components, in the installation room.
- Place the exoskeletons on their guides and secure them with the appropriate screws.  
Then connect the power cable of each exoskeleton and secure it with the appropriate mechanism.
- Place the Control Unit on the **ALEX RS** Base and secure it with the appropriate screws, if any.  
case.
- Fit the footrests into the appropriate slots.
- Connect the cables to the appropriate sockets located in the CU.
- Connect the patient monitor to the bracket, using the screws and spacers provided.  
equipment.
- After mounting the monitor on the bracket, connect the connecting tube to the monitor support and to  
the **ALEX RS** Base using the appropriate screws, then connect the monitor cables, previously passed  
inside the connecting tube, to the monitor and to the CU.

Contact Wearable Robotics Srl for more details.

**See section 7.1.1 for instructions on how to correctly lock the device, without which it cannot be used.**

After completing these steps correctly, the device can be turned on and used.



## 4 The **ALEX RS** medical device : description and instructions for use

### 4.1 Description

**ALEX RS - Arm Light Exoskeleton Rehab Station** is a medical-grade upper limb rehabilitation station,  
suitable for therapeutic treatments and objective assessment of patient motor skills. The **ALEX RS** device  
integrates robotic and virtual reality technologies into a single system and was specifically designed to  
administer exercises and therapies for motor rehabilitation, including:

- engaging
- high intensity
- repetitive or repeatable
- task-oriented, i.e. aimed at very specific tasks
- interactive
- configurable and customizable

The **ALEX RS** seat is height-adjustable while the robotic arms are width-adjustable, allowing the device to accommodate patients of different body sizes.

The **ALEX RS** robotic arms (exoskeletons) can be used simultaneously or one at a time, depending on the need.

Thanks to its integrated sensor system, **ALEX RS** is able to:

- monitor, record and display on the screen the movements performed
- monitor changes in grip strength (grip training)
- detect the Range of Motion for each joint of the robot.

**ALEX RS** exoskeletons are able to cover a range of motion that corresponds to **92% of the working space** of the upper limbs of a healthy person.

Furthermore, thanks to the metal cable movement transmission system (and therefore the absence of motors integrated into the joints), the robot's movements are fluid and transparent and faithfully follow those of the user.

After assessing the patient's clinical situation, the therapist can **select and configure a training program that offers a wide range of modalities and options.** Specifically (as described in more detail below), **various exercises** can be selected and configured , requiring the resolution of **different tasks** , all with **varying levels of difficulty**, depending on the patient's needs and abilities. Furthermore, specific sliders in the GUI (Graphic User Interface) allow the user to **limit the range of motion of each joint of the robot.** This is because the device allows for very wide movements, and the aim is to avoid those that, due to excessive extension, could cause discomfort or pain to the patient, depending on their clinical situation. For further and more in-depth details on the technical characteristics of the **ALEX RS** device, **please refer to Chapter 5.**

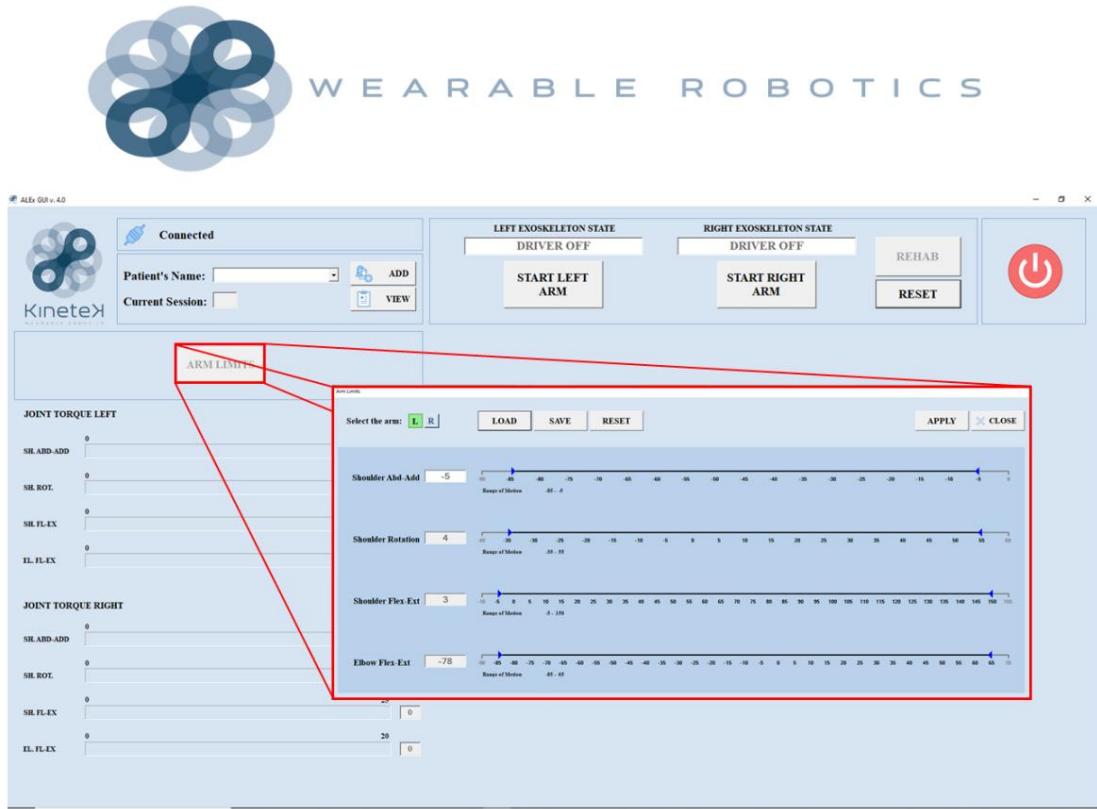


Figure 7. One of the ALEX RS GUI screens where you can see the sliders to set the joint limits

With **ALEX RS** it is also possible to evaluate the patient's motor skills thanks to:

- a specific Virtual Reality scenario that proposes the achievement of specific positions in space (**Evaluation Scenario**);
- a way in which certain movements can be recorded and replicated an arbitrary number of times, proposing a sort of "passive gymnastics" during which the patient's muscle stiffness is measured (**Record&Play**);
- a specific application that, with precise visual indications, prompts the patient to perform certain shoulder and elbow movements and measures the amplitude of those performed (**Angular Ranges**).

The data acquired with these tools are then explained in **specific reports** that can be easily consulted by the Operator (see 4.2.4).

Another feature of **ALEX RS** is that it can physically assist the wearer **by imposing movements or generating forces to relieve the weight of the arm**. Specifically, the patient's **arm relief** can be set and adjusted using a specific slider in the graphical interface and allows for the generation of a **constant vertical force**. The primary purpose of this feature is to provide the patient with **relief from the weight** of their arm, resulting in:

- **significant increase in the range of active movements** that the patient can perform during treatment
- **reduction of pain** during the execution of movements
- **more effective treatment** than those performed with traditional therapy
- **reduced rehabilitation times**, as now also demonstrated by the literature scientific.



The ability to impose movements on the patient's upper limbs, however, also allows for **assistance and guidance during treatment** or to **simulate the weight of an object** (when using Virtual Reality Applications), depending on the exercise you want to propose.

An **adjustable automatic assistance system** can be used where the patient has reduced mobility and is unable to complete a motor task independently (**"Assist-as-Needed"**). This is a system that can be activated **either automatically**

(in a timed manner) **either manually** and, depending on the case, provides constant or increasing/decreasing assistance based on the performance detected.

## 4.2 How to use

**NOTE:** To learn how to set up the **ALEX RS** device and use it correctly, read Chapter 6. The information provided there must be combined with that contained in this paragraph, which illustrates the different modes of use that can be activated via the device's graphical interface.

Once you turn on the device, **the Graphical User Interface (GUI)** will automatically appear (see Figure 8).

**INTRODURRE**  
A special label indicates whether the GUI is properly connected to the device's control electronics: if "Connected" is displayed, the connection is successful and you can proceed; if "Disconnected" is displayed, a connection problem has occurred. Try restarting the device and, if the problem persists, contact Wearable Robotics Support.

**The Graphical User Interface (GUI)** of the **ALEX RS** device is mainly divided into two "macro-areas":

1. The **Assessment Area** which includes all the activities that allow the patient's conditions to be estimated
2. The **Treatment Area - Treatment** relating to the various exercises and activities proposed by the Therapist during treatment with the **ALEX RS** device

Through the screen displayed when the device is turned on, you can press the appropriate virtual buttons to activate one or both robotic arms (see Figure 8).

**NOTICE**

**WARNING:** Once you press the button to activate an arm

**ALEX robotics, wait until it has completed the power-on procedure before**

**move it and wear it. The left and right ALEX robotic arms can be**

**turn on even at the same time.**

Once this is done, the device will be in the **WEARING operating state.**

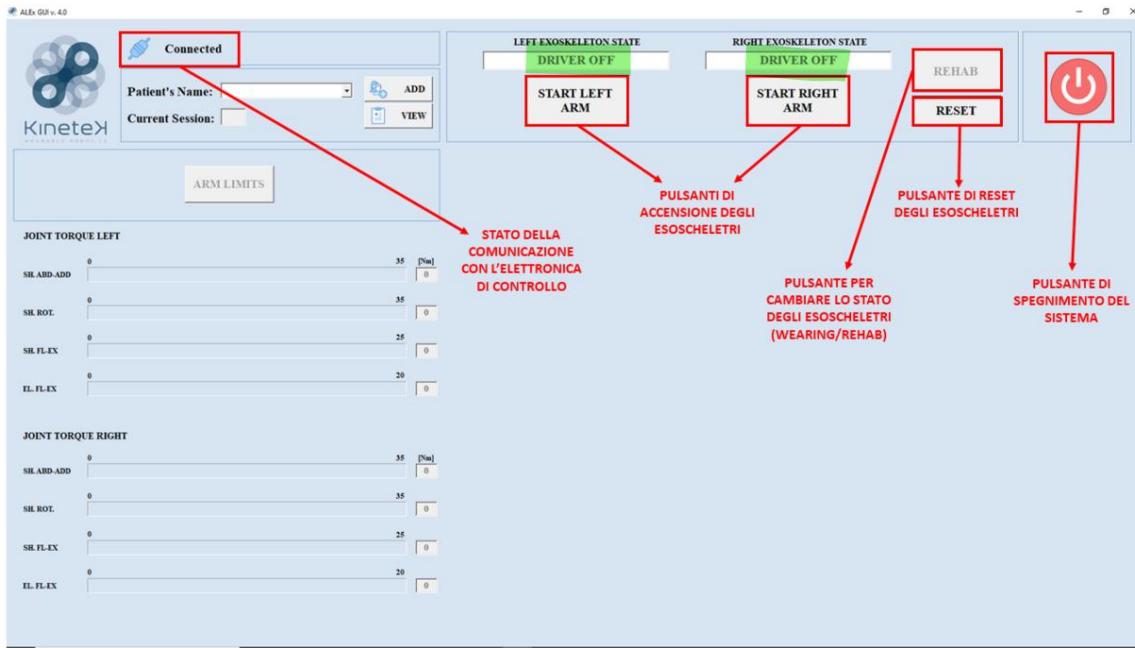


Figure 8. ALEX RS GUI screen shown when the device is powered on

Once the patient is properly wearing the exoskeleton(s), press the appropriate button on the GUI to enter the **REHAB-REHABILITATION Operating State**. This is the Operating State from which you can initiate and manage all the activities you want to offer the patient during rehabilitation treatment.

introdurre

By pressing the appropriate button (**ARM LIMITS**) you can also set the limits for the robot's joints, each of which is identified by the movement it allows (Shoulder Abduction-Adduction, Shoulder Rotation, Shoulder Flexion-Extension, Elbow Flexion-Extension) which can then be **LOADED**, **SAVED**, **RESET** or **APPLIED** using the appropriate buttons (see Figure 9).

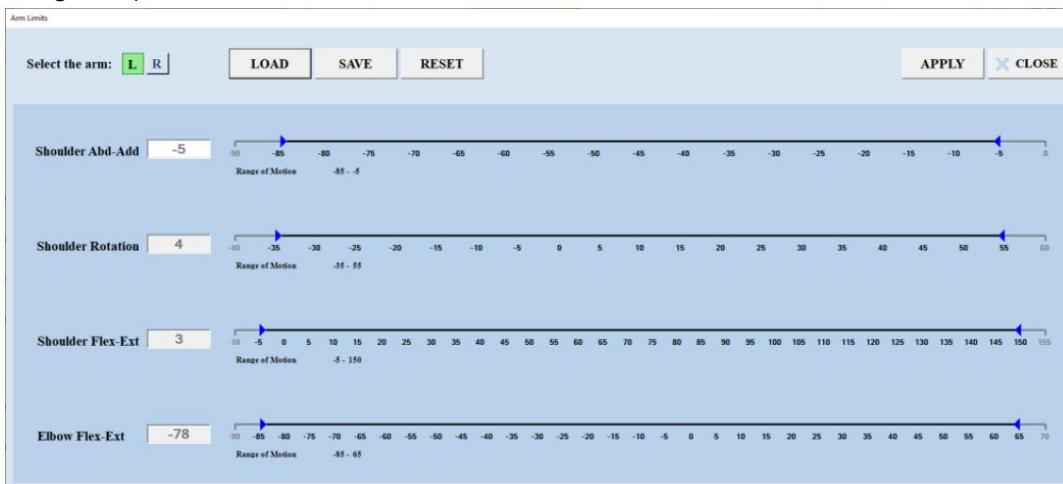


Figure 9. Screen for setting the limits of the robotic arms' joints



If set, **the joint limits of the ALEX robotic exoskeleton must be compatible with the motor capabilities of the patient** who is about to begin the rehabilitation session.

To define the limits of a specific joint, simply slide the relevant sliders to the desired values.

Using the virtual buttons you can perform the following operations on the limits:

- **LOAD:** One method for defining movement limits is to load them into the device's memory via an external file. This is useful when the same patient participates in multiple rehabilitation sessions, spread over a more or less prolonged period: the joint limits detected and saved previously can be recalled by the device by loading the file relating to the specific movement.

Patient. Once the joint limits are loaded, you can modify them simply by sliding the slider.

- **SAVE:** to save the joint movement limits set for a specific patient, click **SAVE**. The saved values can later be uploaded to the device using the corresponding button.
- **RESET:** Exoskeleton joint limits can be reset to their defaults. factory settings simply by clicking the virtual **RESET button**.
- **APPLY:** Once you have defined the joint movement limits using the sliders, click **APPLY** to make them effective.

At this point you can continue with the other activities: once at least one of the two exoskeletons is turned on, you can select one of the two active buttons that indicate the *Macro-Areas* of use of the device:

ASSESSMENT (includes activities to evaluate the patient's capabilities )

- **TREATMENT** (includes specific rehabilitation activities)

The Assessment Area includes the following Usage Modes: **Record&Play, Evaluation Game, Angular Ranges**.

The Treatment Area includes the following modes of use: **Record & Play, Mirror, Coffee Table, Circles Wall, Library, Tray Game, Labyrinth, Trajectory**.

The above modes are described in detail below.

**NOTE:** It is possible to view the strings present in the software in both Italian and English, depending on the Customer's decision and request.



#### **4.2.1 RECORD&PLAY MODE:**

This mode, which can be used with one **ALEX** exoskeleton at a time, allows the robotic arm to be moved while recording, thanks to integrated sensors, the movement or sequence of movements performed. The recorded sequence can then be faithfully replicated: the therapist chooses the **time** or **number of times** the movement is repeated. This mode is essentially a passive exercise program, with the following features:



- highly **precise** and **reliable** treatment
- **intense** and long-lasting exercise , **adjustable** based on repetitions or time
- completely **effortless** for the therapist

When used as an *Assessment*, this Mode allows the patient's muscle stiffness to be detected. This occurs because, in the case of muscle stiffness, the patient will (albeit involuntarily) oppose a certain resistance to the movements imposed by the exoskeleton: the mechanical torques relating to this resistance are then detected and displayed as a percentage of the maximum values detectable by the device.

**To activate this mode:** once the device is turned on and the patient is correctly positioned, simply select the **RECORD & RUN** option

(**RECORD&PLAY**) from the Assessment Menu . Select/deselect the “*Assessment*” box to determine whether you want muscle stiffness data to be stored in the Database or not. See Figure 10.

**NOTE:** The first time you perform a treatment with a specific patient, you must **memorize** the movement sequence you want to use as an assessment during subsequent sessions. This sequence will then be used, during subsequent treatments, to compare the patient's stiffness compared to the first session.

---

**Make sure you store a sequence that is appropriate for the patient: once stored, the *Assessment* Record&Play sequence cannot be changed.**

---



Figure 10. RECORD&PLAY mode in the ASSESSMENT Area

Uncheck the **Assessment** box to use this modality as treatment.

By pressing the **Start** and Stop buttons, **you can record any movement or sequence of movements decided by the therapist**. The sequence can be deleted (**Clear**) or saved (**Save**) and reused in another session. The **Load** button allows you to load the sequence you want the robot to replicate, and then you can move on to the actual execution of the movement (**Start, Pause/Resume, Stop**). The robot repeats the previously recorded sequence, passively moving the wearer's arm.

Each time the sequence is repeated, it is **identical to the original**, as the movement has been precisely acquired by the patented sensors integrated into the machine's joints.

**Furthermore, the therapist can decide whether to set a specific number of repetitions for the robotic arm to perform or to perform it in a continuous cycle** (see the dedicated buttons below).

The treatment provided to the patient with this modality is therefore a very intense and potentially long-lasting **passive gymnastics treatment**, depending on how it is set up by the therapist, which therefore contributes significantly to the involvement and rehabilitation of the compromised brain areas by exploiting neural plasticity.

The modality proposed here can also be selected at the beginning of the treatment as a warm-up before the subsequent exercises.



#### **4.2.2 BILATERAL MODE (MIRROR)**

This mode is extremely interesting because it allows the patient to engage in a sort of "self-rehabilitation," naturally always under the therapist's supervision. Thanks to the wearable robot, the patient can autonomously move an impaired limb, controlling it with their healthy limb. In this operating mode, any movement imposed on one of the two robotic limbs (for example, the right) is instantly replicated on the opposite limb (in this example, the left). **The patient's arms therefore move simultaneously and in a mirrored fashion:** any movement produced by the user or the therapist on one robotic arm is detected by the machine's integrated sensors and reproduced **in real time** on the other. Therefore, thanks to this mode, **the patient is able, under the guidance and supervision of the therapist, to "pilot" the weakened limb with the healthy one.** This also allows for greater involvement of the brain areas responsible for movement and exploits a principle similar to that already widely used in medicine and known as *mirror therapy*. The patient moves his or her arm himself or herself, even in cases of hemiplegia, by using the movement of his or her healthy limb. This type of exercise can be suggested by the therapist, who, in front of the patient, would perform symmetrical movements following the principle of "*teaching by showing*." The patient would thus see themselves engaged in a voluntary activity, accomplished through imitation, thus engaging the neural areas of movement even more deeply and effectively.

**To activate this mode:** once the device is turned on and the patient is correctly positioned, simply select the appropriate button from the main screen under Treatment ( see Figure 11).

**DANGER** **WARNING: Before pressing the button, make sure the patient remains still and is wearing both exoskeletal arms. Once**

**Once the button is pressed, wait until the two arms are in a symmetrical position.**

Since the weight force of the patient's affected limb is also imposed on the other arm, if it is too difficult to move the arms, **use the slider to set a relief force** (adjustable as a percentage).

Two dedicated buttons allow you to separately select which limb, and at what percentage, **to apply the weight-relief force. Adjust these settings** and then proceed to the actual exercise. The relief forces can be changed at any time. Remember to always move the relief force slider gradually.

**There are no contraindications to using this mode with only one robotic arm worn: the important thing is that the other robotic arm is at a safe distance from the patient so as not to hit him or her during symmetrical movements.**



#### **4.2.3 VIRTUAL REALITY MODE**

This mode allows you to offer and propose to the patient a series of different and customizable exercises and activities, using the monitor to provide both real-time visual feedback on the progress of the treatment and the simulation of a pleasant or stimulating environment in which to carry out the tasks.

There is an entire library of applications built in **Virtual Reality environments**, specifically created for:

- a **varied** and **complete** treatment
- **motivating** and **engaging** exercises
- real-time **feedback on the progress** of the therapy and monitoring of performance

The exercises are **varied** and also aim to stimulate the patient's **concentration**, thus helping them undergo **cognitive** as well as **motor rehabilitation**. In each exercise, the patient must solve tasks by interacting with the virtual environment via the exoskeleton. Thanks to sensors integrated into the machine, the screen displays visual feedback on the patient's arm or hand movements: the scenario therefore evolves based on their actions.

Exercises have been created for:

- reaching
- moving objects
- coordination
- speed of reflexes
- association
- concentration and attention
- tracking and trajectory tracking

The environments were created using the **Unreal Engine 4** graphics engine developed by *Epic Games*.

During each exercise, the system is able to automatically generate movement assistance forces, to the extent strictly necessary for the specific patient, as already described in 4.1.

To activate scenarios in Virtual Reality: depending on the selected mode (*Treatment* or *Assessment*) , you can start the desired scenario after clicking on its name.

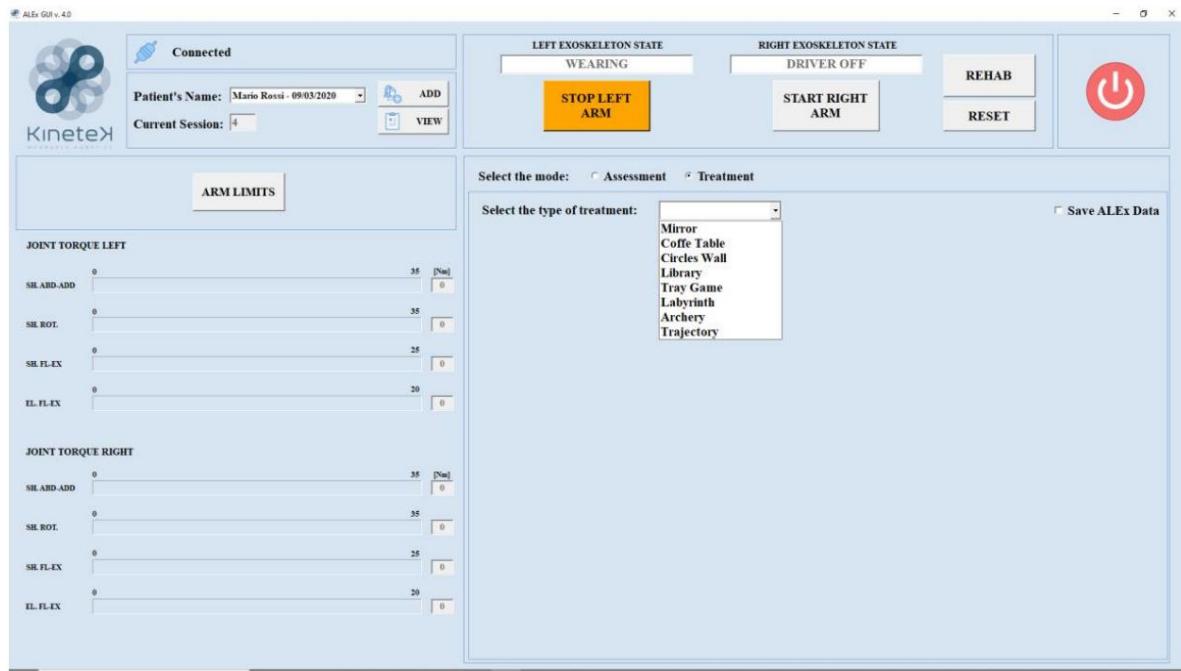


Figure 11. VR options and applications selectable from the TREATMENT Area

Once you've selected the app, simply set its parameters, such as *time* or *number of repetitions*. When you want to start the exercise, press **START**. This will activate the virtual scenario: press **PLAY** to start the specific exercise. If you want to reset the parameters, simply press **RESET**.

To exit the selected application, press **STOP**.



Figure 12. The configurable parameters relating to the Application you intend to launch



Using the sliders shown on the interface you can set other parameters including:

- **arm weight compensation** (selectable whether right or left);
- **amplification of the patient's movements** replicated in the virtual environment;
- **grip threshold** that must be exceeded to interact with objects (if the *Autograsp* box is selected, objects are grabbed automatically);
- **parameters of the interaction strength** with the virtual environment, i.e.: weight of the grabbed objects (settable with the slider);
- **Movement Assistance parameters**, adjustable in terms of maximum force and speed. This type of Assistance is called "**Position Control**," meaning it causes the device to apply a constant force to reach a specific point in space.

In some Applications (such as *Library*, *Circles Wall* or *Trajectories*) another type of Assistance is provided:

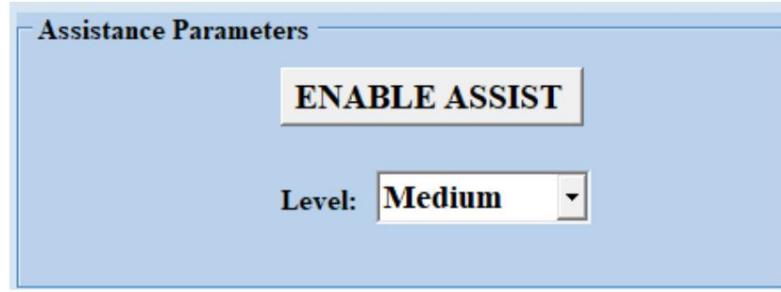


Figure 13. Detail of the assistance level setting

As shown in the figure, three levels of assistance can be set (minimum, medium, maximum) based on predefined values for *maximum force*, *maximum time to reach the latter*, and *reaction time*, i.e., the time after which the assistance should automatically kick in. This type of assistance is called "**Force Control**" and causes the device to apply a variable force (also in relation to the patient's autonomous movement) over a certain time, towards the desired target.

The next paragraph describes the **Virtual Reality Applications in more detail, including the Evaluation Scenario.**



#### 4.2.3.1 Virtual Reality Applications of ALEX RS

### Coffee Table



*Figure 14. The Coffee Table Application*

During this exercise, a table with objects on it appears on the screen.

(cups, books, bowls, and vases). The robotic arm's end effector (see below) is represented by a small ball that naturally follows all the user's movements.

ÿ Aim of the exercise: grab the objects one by one, lifting them and moving them to arrange them as indicated by the targets, which activate by flashing depending on the position to be reached.

The exercise offers **2 levels** of difficulty (in which the number of objects on the table changes).

There are also several other ways to customize the exercise: for example, **the grip threshold can be adjusted** to the patient's abilities, so that the object remains grasped only if this threshold is exceeded. The hand grip strength bar is visible on the top of the screen.

left during exercise.

You can also increase the **number of objects** to move.

For each round, the **execution time** is measured .

**The interaction forces** (the physical simulation of the table and the weight of the lifted object) can be activated to make the experience even more immersive and, above all, to adjust the difficulty (in particular, the virtual weight of the objects can be varied greatly based on the patient's abilities or the therapist's opinion).



## Library



Figure 15. The Library Application

Unlike the *Coffee Table Application*, this exercise shows an empty bookshelf that extends in the vertical plane.

ÿ Purpose of the exercise: to lift the books from the floor and place them on the shelves of the bookcase, moving along the vertical plane.

There are no different levels, but you are required to set the duration of the exercise.

The maximum number of books that can be stored in the bookcase is 80, i.e. 5 books per shelf. (there are 16 shelves).

During the exercise, the time taken and the targets achieved (i.e. the books sorted) are measured.

During each round, once the object is grabbed (adjust the grab threshold as needed) the section of the bookcase where the book is to be placed begins to glow green.

In this exercise, too, it's possible to adjust the physical interaction force with objects, such as the weight of the books. Always use an appropriate weight based on the patient's abilities. In this scenario, a physical interaction force with the wall is always active.

**NOTE:** When using the Assistance, it is strongly recommended to use the "ARM WEIGHT COMPENSATION" option if you are treating a patient with reduced mobility that does not allow them to support the weight of their own arm.



## Circles Wall



Figure 16. The Circles Wall Application

A wall appears on the screen with green or red lights turning on in the

At this point, they must be touched, as if they were buttons. By moving one hand in space, you will see a red ball move across the screen, while with the other hand, you will observe the movement of a green ball.

ÿ The goal of the exercise is to "touch" a light button when it lights up, associating the corresponding color (and therefore using the correct arm). Once it's pressed by the corresponding colored ball, the light goes out and another light comes on in a different location.

This is essentially a *reaching* exercise where you have to move through space to touch targets. Unlike the two previously described exercises, it's a **two-handed application**, meaning it can be used with one arm or both.

This Application offers two modesof exercise:

1. Time Mode : The time you want the round to last is selected hard and **the number of targets hit is measured;**
2. Target Mode : The therapist sets a specific number of lights for the patient to hit, and at the end of the round, **the time taken to complete the task is measured.** The exercise works whether using just one arm (with only green or red lights) or both (both green and red lights).

Before starting the Application, however, you must select the menu item relating to the treatment technique you wish to propose: **STANDARD** or **MEMORY**.

This last option encourages patient involvement by stimulating their attention and memory.



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In **MEMORY mode**, the number of targets to hit must be selected before each round. Once the trigger is given, the lights will change color in a sequence corresponding to the number selected. The patient is asked to observe and memorize that sequence, then hit the lights in the same order.

---

**The number of attempts made** before completing the task correctly is then recorded . This obviously has cognitive implications, as this exercise further encourages the patient to remain alert and focused, allowing them to observe and memorize the sequence quickly and correctly.

Even in this case, a physical interaction with the wall is always active.

**NOTE:** When using the Assistance, it is strongly recommended to use the “ARM WEIGHT COMPENSATION” option if you are treating a patient with reduced mobility that does not allow them to support the weight of their own arm.



## Tray Game



Figure 17. The Tray Game Application

The exercise in question is a **two-handed** activity that particularly develops the **coordination**, endurance and **attention** of the patient.

ÿ Purpose of the exercise: grasp and lift a tray, on which there are various objects such as bottles or glasses, and then place it on a specific shelf (automatically reported). The exercise ends when all the trays have been placed on the correct shelves. The time taken to put all the trays away is counted.

For the exercise to be successful, it is essential that the tray is gripped with both hands and that it is lifted symmetrically.

Indeed, **it's important that movements are coordinated and controlled** so as not to drop the tray. Otherwise, if the tray were to fall, the score for that repetition would be considered null. Naturally, you also need to pay attention to the speed at which the tray moves, for the same reason.

To increase the difficulty of the exercise, you can decrease the **size of the interaction area** with the tray (i.e. the **green circles** within which you have to move the cursors to lift it).



## Archery

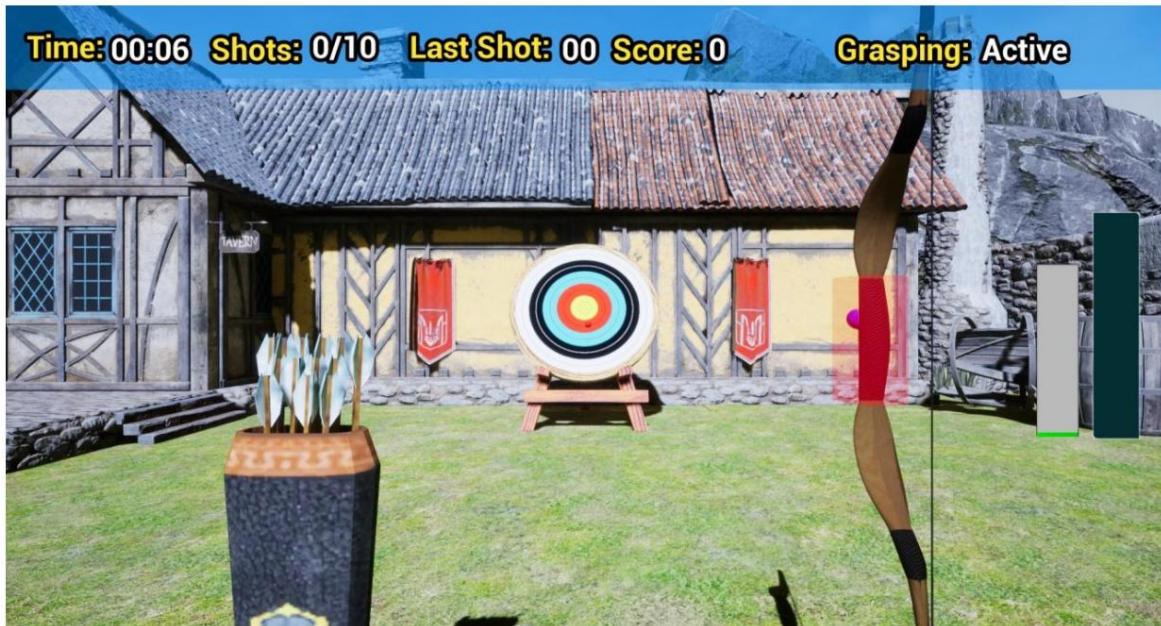


Figure 18. The Archery Application

This is also a bimanual application. Specifically, it simulates archery and therefore requires the patient to perform a task using both upper limbs asymmetrically .

---

By performing this exercise, **the** patient's **concentration**, precision and **endurance** are mainly stimulated .

ÿ Aim of the exercise: try to get the highest score possible by aiming at the center of the target, using a number of arrows set by the therapist.

Initially, you must grasp the bow (which can be set to the right or left of the screen) by moving your hand to the appropriate point. Once this is done, you must "grab" an arrow with your other hand, moving it toward the quiver, which will be on the opposite side of the screen from the bow. The arrow will be grasped by grasping (*if active*) by moving your hand to the corresponding point. The bow, however, is grasped automatically, without grasping . At this point, in order to "draw the bow" and subsequently "shoot the arrow," the bow must be kept at a certain distance (i.e., you must keep your arm extended), and then the hand holding the arrow must be brought closer to the bow; at that point, the crosshair will automatically appear. When the sight is visible, keeping the bow still, the other hand (holding the arrow) should be brought closer to the body by bending the elbow (mimicking the movement used to draw the bow) and, if activated, keeping the arrow "caught" with the grasping action .

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Once you have taken aim, simply release the grip of the hand holding the arrow to "shoot".



## Trajectories

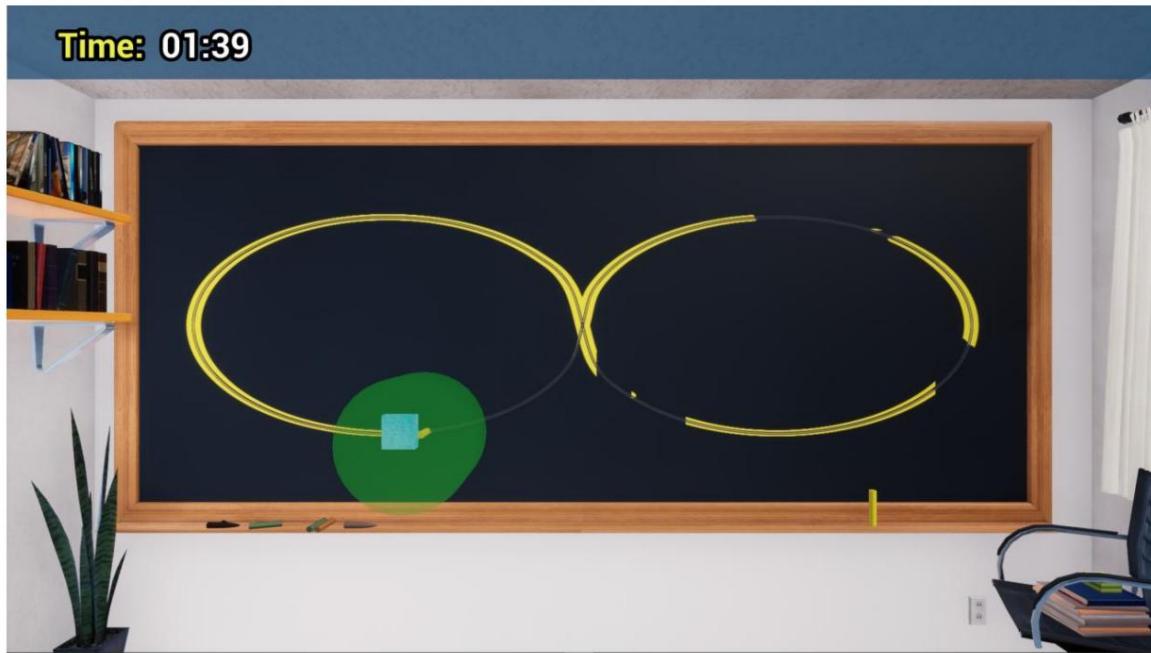


Figure 19. The Trajectories Application

This is a **one-handed activity**, meaning it can be done with just one arm.

By performing this exercise , the patient's **endurance**, coordination and **ability to perform a controlled and precise movement** are stimulated .

ÿ The goal of the exercise is to "follow" a trajectory shown on the screen, drawn by a moving object (a piece of chalk writing on a blackboard). Another mode requires you to trace a predefined trajectory shown on the screen (for example, a figure "8" drawn on the blackboard).

As mentioned, this exercise can be done in two ways. In the first, a piece of chalk will appear on the screen and move across the board, "drawing."

a predefined trajectory. The patient's movement corresponds to the movement of an eraser which, if held within a certain distance from the cast (defined and displayed on the screen), will "erase" the trajectory drawn by the latter.

If the second mode is used, the patient is asked to draw a trajectory with chalk (also predefined and displayed on the board) and then erase it with the eraser. Before each action, the patient is asked to "grab" the required object (in this case, first the chalk and then the eraser).



Figure 20. Trajectories Application Parameters and Modes

As shown in the image, in addition to choosing the mode, in this exercise it is possible to set various parameters: the geometry of the trajectory (rectangular, round, linear, figure 8, sinusoidal), its dimensions, the angle of inclination (in the case of a linear trajectory), the number of "turns" to be made, the speed of movement of the chalk, the direction of movement, the time within which to "draw" the trajectory.



## Labyrinth



Figure 21. The Labyrinth application in Standard mode

The Labyrinth application is placed in a wide corridor that is tilted to the right or left by flexing/extending both elbows. Specifically, the degrees of inclination are correlated to the "delta," calculated by the reciprocal difference between the joint angles of the elbows.

The screen displays a ball rolling forward on its own: the patient must "tilt" the horizontal plane so that the ball moves left or right (while continuing to roll forward). This tilt is achieved by flexing and extending the forearms (for example, starting from a "90° elbow position," slightly flexing the left forearm and slightly extending the right forearm will result in a rightward tilt, and the ball will then roll in that direction as it continues to roll forward).

By appropriately tilting the corridor plane, the patient will then be able to guide the sphere avoiding a series of obstacles that will appear in front of him.

*Aim of the exercise:* complete the course avoiding obstacles and coordinating the movement of the upper limbs in order to reach the end in the shortest time possible.

There are 2 different ways to use this game: **STANDARD** and **MEMORY**.

¶ In **STANDARD** mode, there are no parameters to choose. The path is always the same and consists of several levels. Some of them have obstacles or "holes" that the ball can fall into. Each time it encounters an obstacle, the ball slows down and takes longer to complete the path. Each time the ball falls into a hole, it will start rolling again from the beginning of that level.



Figure 22. The Labyrinth application in Memory mode

Fig. 22 refers to the Maze Memory mode, which, as can be seen, is set in a large corridor divided into three smaller paths with "obscured" and numbered entrances. As explained previously, by flexing/extending the elbows, the patient can guide the sphere toward the entrance they believe to be correct, containing a reward inside. However, since only one of the three corridors is "correct," after an initial "random" component, the patient must remember which entrance contains the reward and then identify the correct path.

After passing the first group of three corridors, we'll find three more groups of three corridors. All the groups are identified by the color of the entrance wall; this is because every time the patient finds a reward in the correct corridor, the associated number is written next to the corresponding color box, as you can see in the image at top left.

*ýPurpose of the exercise:* to memorize the incorrect corridors in order to be able to cross all the "correct" corridors in the shortest possible time.

Patient assistance can be achieved by enabling variable arm weight compensation. The physiotherapist knows the correct sequence from the start, as it is displayed on the graphical interface, and can therefore assist the patient if deemed appropriate and necessary. In addition to coordination, this exercise helps stimulate the patient's cognitive abilities, particularly in terms of attention and memory.



## Angular Ranges



Figure 23. The Angular Ranges application for assessing patient mobility

Although it is not found in the Treatment Area, the description of this Application has been included together with the others since it was developed using the same virtual environment.

After launching this application, the screen displays a person sitting on a seat similar to the one in **ALEX RS**; the person depicted on the screen performs a number of movements that can be performed with the device's individual joints (shoulder adduction and abduction, forearm flexion and extension, etc.). The movements performed by the person depicted on the screen do not follow those of the user: they only serve to demonstrate which movements to perform.

ÿ The purpose of the exercise is to replicate the movements performed by the virtual model as faithfully as possible, mimicking what is seen on the screen. The therapist moves from one proposed movement to the next (thereby changing the viewing angle and the movement performed by the character on the screen).

Thanks to the sensors in the machine, the Range of Motion for each individual joint is evaluated, thus providing an estimate of the range of movements that the patient is able to perform with the individual joints.



## Evaluation Application



Figure 24. The Evaluation Application

---

This application was specifically designed and developed to **evaluate the patient's motor skills**.

ÿ The goal of the exercise is to reach specific positions in space (identified by squirrels, which must be reached by moving an acorn, which is picked up with a virtual spoon placed in the center of the screen). Each time you reach a position, you must return to the center (to grab the new acorn) and then move again, following very precise and defined trajectories.

---

The therapist can set the position of the targets (horizontal or vertical, i.e. squirrels or rabbits).

**The device measures the time taken to reach each point.**

This application is intended to be used during each rehabilitation session, so as to monitor the patient's progress in terms of **trajectory accuracy, speed , and increase in range of motion**.



#### 4.2.4 REPORT

As mentioned above, **ALEX RS** collects and reports data acquired during the treatment in specific *reports* that can be easily consulted by the therapist to observe the progress of the therapy and intervene if necessary.

The **data reported**, which can be consulted in the *Reports*, are:

- exercises performed
- performance achieved during each session
- data acquired during the execution of the evaluation exercises

The personal data of each patient are stored in a database and displayed in the *report* together with all the information regarding the exercises performed during each session.

Figure 2 shows an example of a patient report. The top section of the figure contains the patient's personal data, which can be edited using the appropriate button. Below this section are **three comprehensive graphs** showing the progress of the therapy session by session:

- 
- **the first** represents a mapping of the exercises performed;
  - **the second** reports the resistance torques (in % of the maximum capacity of the device), an index of the patient's muscular stiffness, detected during the *Record&Play* mode
  
  - **the third** reports, always as a % of the maximum capabilities of the device, the angular ranges relating to the patient's movement capabilities and calculated during the execution of the *Angular Ranges Application*.

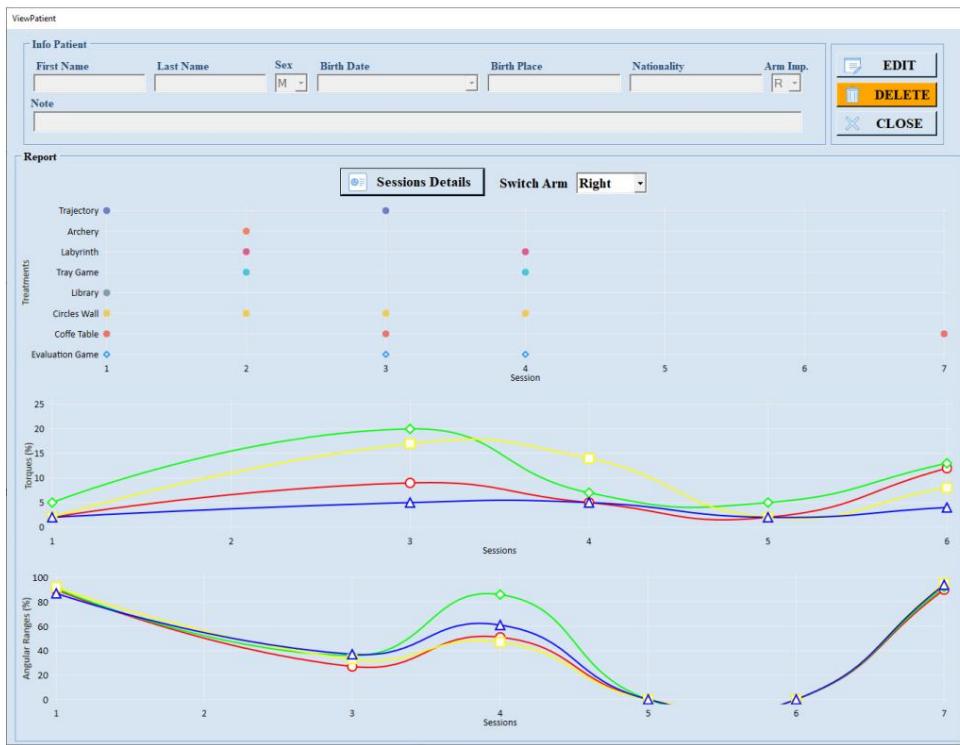


Figure 25. Example of Report Output from ALEX RS

By clicking on any of the points displayed in the graphs you can have direct access to the report relating to that specific session.

**In case the therapist would like to see more specific scores and parameters** related to each treatment exercise performed in a certain session, such as the interaction strength that was used in a certain exercise, the threshold level grasping (grip strength) or the arm weight compensation strength, it is possible to view a **more exhaustive table** containing all this information, illustrated in Figure:



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Session Report										SESSION n. 1 of 7 - 07/02/2020										CLOSE																																																															
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27	1	0	0	0	0	<input checked="" type="checkbox"/>	None	Right																																																																											

Figure 26. Table with specific data relating to a given session

Naturally, a specific *Report* is created relating to the results obtained during the Evaluation Applications.

**This report contains several pieces of information:**

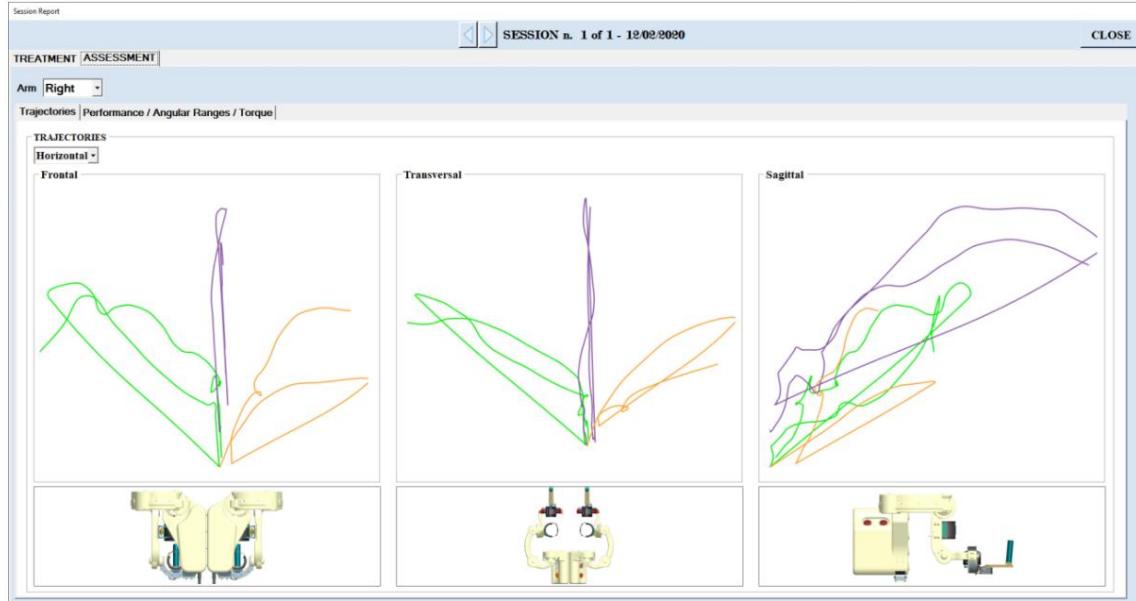


Figure 27. Trajectories



- **Trajectories followed** to perform the movements and represented with respect to the plane frontal, transverse and sagittal



Figure 28. Session Report

- **Fluidity of movement** calculated through the number of sudden speed changes detected: more speed "spikes" indicate discontinuous, uncoordinated, and less fluid movement. The average times to reach each target are also detected and displayed.
- **Angular excursion** detected and related to the 4 actuated joints of the robot, corresponding to elbow flexion-extension, shoulder adduction-abduction, shoulder intra-extra rotation, shoulder flexion-extension.
- **Muscle stiffness**, in terms of mechanical torques detected during a passive movement of the limb (Record&Play) and acquired by the machine.

Both the angular excursion and the muscular stiffness (mechanical torques detected) are expressed as a percentage of the machine, i.e. with respect to the maximum performance of the machine.

**PLEASE NOTE:** The *Report* function and all the consultable data obtained using the **ALEX RS device**, including the graphs and the performances detected, the total scores, the trajectories followed, the angular excursions related to physiological movements and the mechanical torques related to muscle stiffness are subject to the User's interpretation and must not be understood as a diagnostic tool or replace more specific devices designed to perform that function nor have an unconscious influence of any kind in the drafting of clinical reports. They are



These tools are offered to physicians and physical therapists as an additional tool for monitoring therapy based on the features offered by the machine, and for adapting it to the individual patient for more targeted and presumably more effective treatment. Proper use of the *Reporting* feature allows for daily monitoring of the patient's progress in using **ALEX RS** and for deciding how to structure the therapy session, comparing the data collected and stored by the machine day after day.



## 5 Technical Description of the **ALEX RS** Device

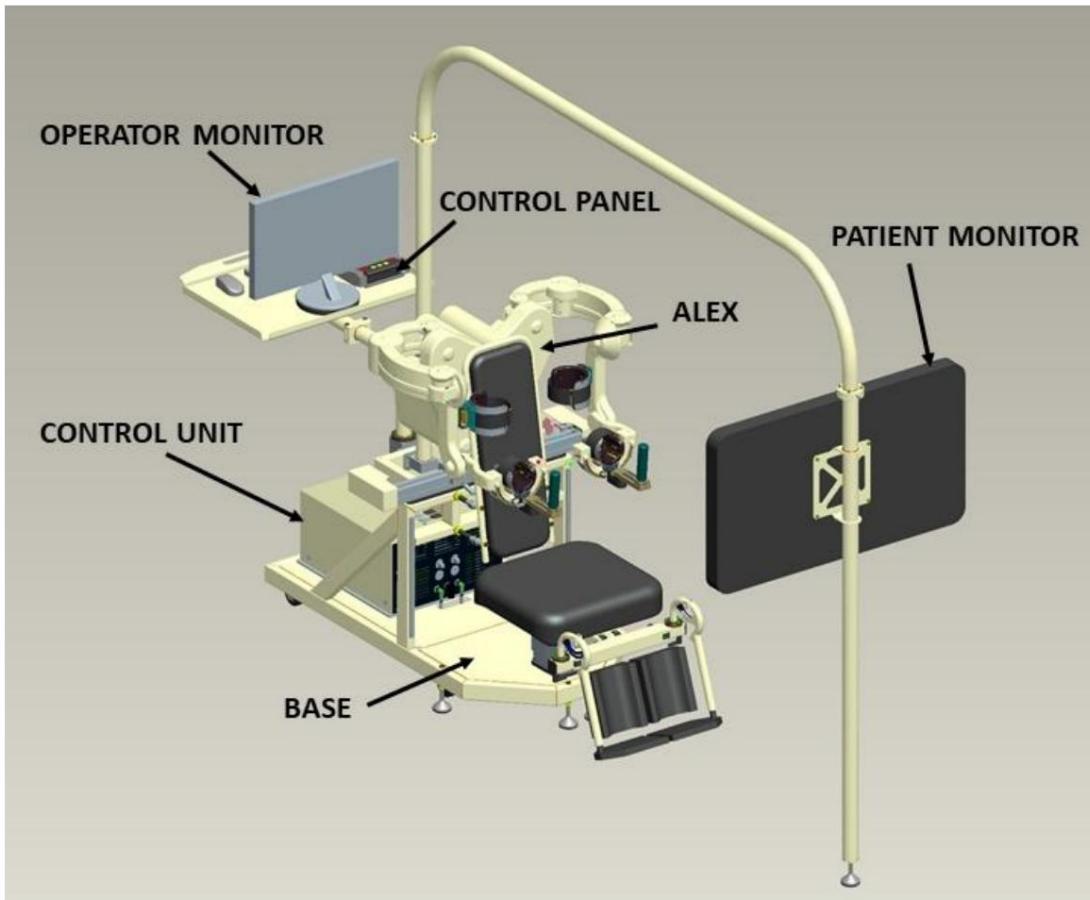


Figure 29. **ALEX RS** scheme and definition of the main macro-components

With reference to figure 25, the **ALEX RS** medical device is composed of:

- **ALEX - Arm Light Exoskeleton**, consisting of two independent and symmetrical exoskeletons, one for the right upper limb and the other for the left upper limb
- **Operator console**, mounted on a rotating support, from which the therapist can check the device and assist the patient
- **Motorized base**, which allows the correct positioning of the patient on the seat with respect to the ALEX exoskeletons and supports the Operator Console
- **Control and Power Unit**, which generates the exoskeleton's control signals and the Virtual Reality scenarios, as well as providing the electrical energy to power the ALEX's embedded electronics
- **Patient Monitor**, on which Virtual Reality scenarios are displayed

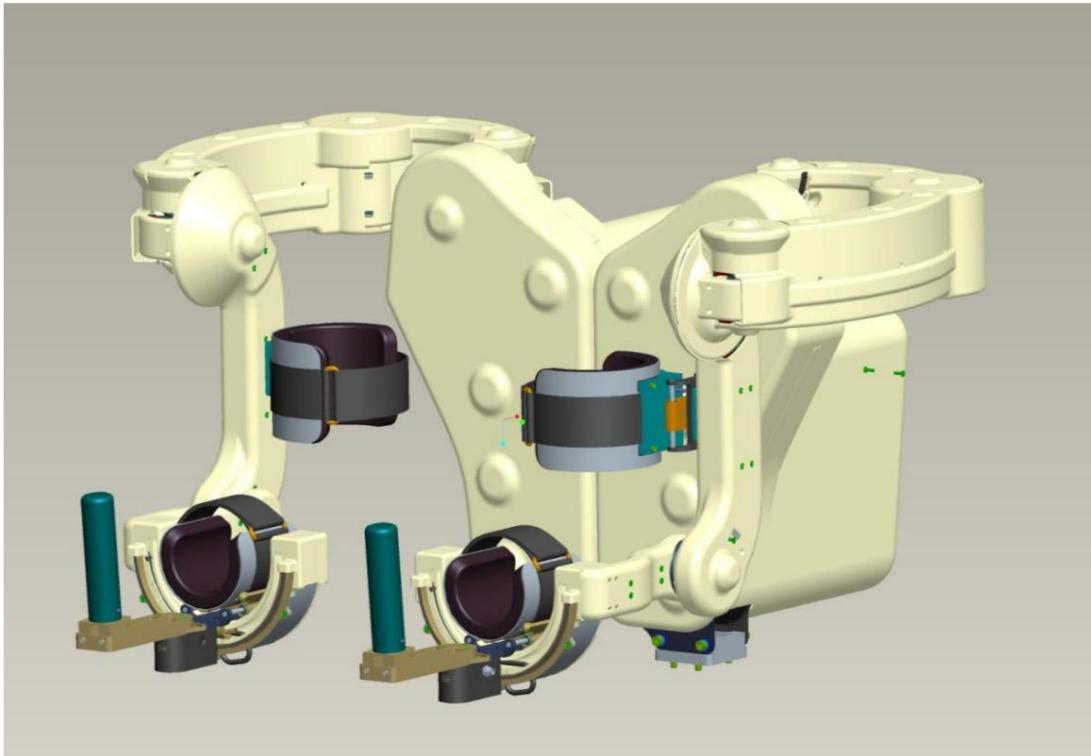
Further details are provided in the next paragraphs.



## 5.1 ALEX - Arm Light Exoskeleton

ALEX is an innovative wearable robotic device, specifically designed for the motor rehabilitation of patients who have suffered neurological or orthopedic trauma.

The device consists of two independent and symmetrical arm exoskeletons (see figure 26), whose relative position can be adjusted according to the patient's anthropometric dimensions (shoulder width).



*Figure 30. Image of the ALEX wearable robotic device*

Each exoskeleton is mainly made up of a fixed part and a certain number of moving parts articulated together to form a kinematic chain, with movement capabilities completely similar to that of the human arm.

ALEX exoskeletons can be used simultaneously (bimanual configuration) or individually (monomotor configuration), depending on the therapeutic treatment that is intended to be administered to the specific patient.

They allow you to:

- Generate a force to assist/resist the movement of the patient's upper limb. This force is applied at the forearm and can have an arbitrary direction in space;
- Generate independent joint pairs of assistance/resistance to the movements of the patient's shoulder and elbow joints (total 4 independent pairs, 3



for shoulder movements and 1 for elbow movement)

- Measure and acquire joint movements, forces and torques applied to the limb of the patient.

ALEEx exoskeletons are characterized by the following elements:

- **Kinematics isomorphic** to that of the human upper limb;
- **Slim and lightweight structure** of the moving parts in contact with the patient's limb;
- **Mobility ranges** close to those of the joints of the human upper limb with normal motor skills;
- **High degree of transparency**, i.e. negligible resistance to movements imposed by the patient (movement tracking);
- **Automatic adaptation to the different anthropometric dimensions** of patients, thus simplifying the dressing phase as much as possible;
- **Completely lateral dimensions** with respect to the arm, therefore free of elements wrapping around the arm that may interfere with the patient's trunk;
- **Mechanical flexibility of the joints**, such as to make them intrinsically secure the device

The fixed parts of the exoskeletons are mounted on motorized axes present in the support base, so as to allow the operator to easily set their lateral position using the specific control panel installed on the *Operator Console*.

Each exoskeleton is also equipped with **cushions** and **straps** to secure the patient's arm and forearm to the corresponding moving parts of the device (see figure 30).



### 5.1.1 Kinematics of ALEX exoskeletons



Figure 31. Photo of the **ALEX** seat and exoskeletons

The kinematics of each **ALEX** exoskeleton is characterized by having 6 degrees of freedom (GdL) serially connected rotational, of which 4 are sensorized and actuated and 2 only sensorized.

The kinematics of the **ALEX** exoskeleton is innovative, as *it is free of singularities* in the range of mobility of the joints of interest for the application in question.

More specifically, this kinematics has allowed to reach the **mobility fields** reported in the following table.

GdL	Movement	Lower Limit	Upper Limit
1	Shoulder Adduction/Abduction	0°	+110°
2	External/Internal Rotation of the Shoulder	-60°	+40°
3	Shoulder Flexion/Extension	-10°	+155°
4	Elbow Flexion/Extension	-90°	+70°
5	Pronation-supination Forearm	-80°	+80°
6	Wrist Flexion/Extension	-50°	+50°

Table 1. GDL mobility fields of **ALEX** exoskeletons

The Figure reports the **kinematic lengths** of the **ALEX** exoskeletons and the rotation axes of the GdL (J1, J2, J3, J4, J5, J6), related to the movements reported in Table 1.

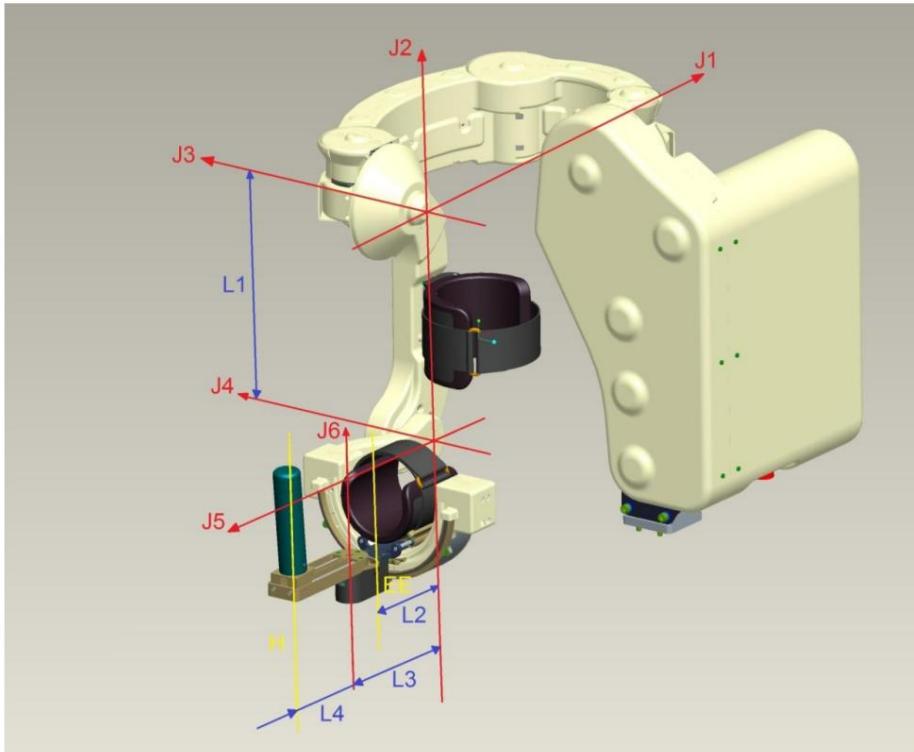


Figure 32. Kinematic lengths and rotation axes of the DOFs of the ALEX exoskeletons

The lengths indicated in the figure are as follows:

$$L1 = 278.0 \text{ mm}$$

$$L2 = 157.0 \text{ mm}$$

$$L3 = 256.0 \text{ mm}$$

$$L4 = 107.0 \text{ mm}$$

The ranges of motion described in Table 1 are such as to cover approximately **92% of the working space** of the human arm of a person with normal motor skills.

### 5.1.2 Features of ALEX exoskeletons

A technical solution that more than others characterizes ALEX exoskeletons, compared to other types of exoskeletons, is the placement of all the motors that actuate its joints in the fixed part of the device (remote placement of the actuators).

Compared to the traditional solution of placing the actuators at the joints, this solution has made it possible to obtain peculiar characteristics that make ALEX exoskeletons unique in their kind, such as an **extremely slim and light structure of the moving parts** and **very high ranges of joint mobility**.

The remote location of the engines has also allowed us to obtain further important advantages, such as:

- the presence of **mechanical flexibility** in the transmission of movement and forces between the actuators and the joints, to the benefit of the **safety** of the device



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- a **drastic simplification of the electrical wiring**, as it is all contained in the fixed part of the device and therefore not subject to bending and torsional stresses, thus improving its **reliability**.

Another notable feature of the *ALEX* exoskeletons is the presence of **connections**

with the patient's arm that allow **dynamic compensation** of any misalignments between the kinematics of the device and that of the patient's arm.

One of the main advantages of this type of connection is **the automatic adaptation** to the different anthropometric dimensions of the patients, which makes it **unnecessary to adjust the kinematic lengths** of the device before starting a rehabilitation session.

Dynamic compensation was achieved by providing the links with appropriate passive (non-actuated) degrees of freedom, which allow relative sliding between the patient's limb and the corresponding exoskeleton structure.

These connections, illustrated in Figure 29, are located at the patient's upper arm, forearm, and hand. They allow for adaptation to the anthropometric dimensions of patients with a height range of **150 cm to 190 cm**.

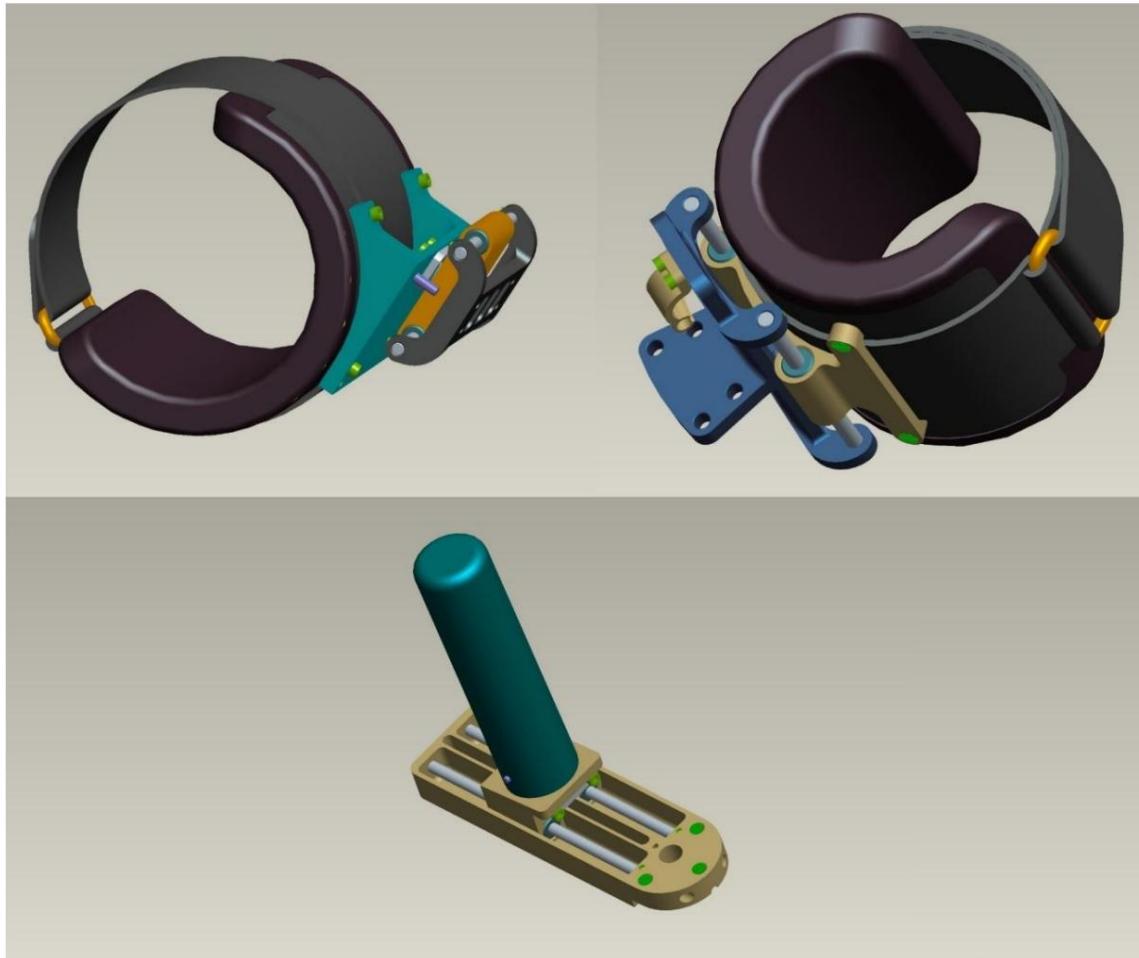


Figure 33. Axonometric views of the connections to the user's arm, forearm, and hand.

To acquire the absolute sensors of the angular position of the joints and to control the phase currents of the motors, application-optimized boards have been developed, housed in the fixed part of the device.

### 5.1.3 Functionality and mechanical performance of ALEX exoskeletons

Each of ALEX's two exoskeletons can be controlled in 4 distinct modes:

1. **Force control at the EE:** generation at the End Effector (center of the forearm cradle) of 3 independent and time-varying force components;
2. **EE-compliant position control:** generation at the End Effector (center of the forearm cradle) of 3 independent, time-varying positions with associated compliance (3 independent components);
3. **Joint torque control:** generation of 4 independent and time-varying torques at the actuated joints;
4. **Compliant joint position control:** Generation at the actuated joints of 4 independent and time-varying angular positions with associated compliances (4 independent compliances).

come seleziono la modalità ?



Table 2 reports the **mechanical performance** of the ALEX exoskeletons .

Characteristic	Unit Value	
Total number of degrees of freedom	6	-
Actuated and sensorized degrees of freedom	4	-
Sensorized degrees of freedom only	2	-
Maximum continuous force EE (for each direction with arm extended) 50		N
Maximum peak force EE (for each direction with arm extended)	70	N
Maximum continuous single torque at the joint:		
• Shoulder Adduction/Abduction (J1)	35	Nm
• Shoulder Rotation (J2)	35	Nm
• Shoulder Flexion-Extension (J3)	25	Nm
• Elbow Flexion-Extension (J4)	20	Nm
Maximum peak single torque at the joint:		
• Shoulder Adduction/Abduction (J1)	45	Nm
• Shoulder Rotation (J2)	45	Nm
• Shoulder Flexion-Extension (J3)	35	Nm
• Elbow Flexion-Extension (J4)	30	Nm
Maximum joint speed (single movements, zero torque):		
• Shoulder Adduction/Abduction (J1)	200	°/s
• External/Internal Rotation of the Shoulder (J2)	200	°/s
• Shoulder Flexion-Extension (J3)	200	°/s
• Elbow Flexion-Extension (J4)	200	°/s
Weight of ALEX moving parts	5.60	Kg

*Table 2. Mechanical performance of ALEX exoskeletons*

The performances associated with force/torque control and position control are shown in the table below.

PERFORMANCE	CONDITIONS	UNIT VALUE
<b>BANDWIDTH</b>	Harsh environment and small signals	12 Hz
<b>LATENCY</b>	All modes	3.5 ms
<b>MAX REFRESH RATE</b>	All modes	2500 Hz

#### 5.1.4 Measurement and performance features

ALEX RS allows you to estimate and store mechanical variables associated with the execution

of the therapeutic treatment, which can serve to support the operator in the objective evaluation of the evolution of the patient's motor recovery.



More specifically, ALEX RS is able to estimate the following variables:

- Absolute position of the center of the forearm cradle (EE position);
- Angular positions of the exoskeleton joints (joint positions);
- Force exerted at the center of the forearm cradle (force EE)
- Torque exerted at the joints of the exoskeleton (joint torques)

The accuracy and resolution of these estimates are reported in the table below.

PERFORMANCE	CONDITIONS	UNIT	VALUE
EE position accuracy	EE within the reference space *	mm	20
EE position resolution	For all reachable postures	mm	0.05
Joint position accuracy Within the specified angular range		°	2
Joint position resolution In the specified angular range		°	0.005
Force accuracy at EE	All joints move and EE within the reference space *	N	8
Resolution of the force at the EE	Distance of force at EE from all axes > 0.3 m 0.2	N	

\* The reference space for EE is a sphere, 50 mm in radius, centered at the point reached by the EE when all the joints of the exoskeleton are centrally positioned with respect to their limits.

Table 3: Accuracy and resolution of mechanical variable measurements provided by ALEX RS

### 5.1.5 Belts and straps

ALEX RS. is equipped with padded parts at the points of contact with the body, in order to guarantee the maximum possible comfort for the patient.

Some of these parts, such as the backrest and the arm and forearm attachments, are equipped with belts and straps to secure the patient to the device (see figure 30).



Figure 34. Safety belts to secure the patient's arm to the device



## 5.2 Operator Console (OC)

The Operator Console allows the therapist to access all the features of **ALEX RS**.

The following devices make up the OC:

- operator monitor and related mouse and keyboard
- control panel with buttons, diagnostic LEDs and emergency button

These components are installed and secured on a **mobile tray** which in turn is located on a **rotating arm**: this allows the operator to reach and monitor the patient from the desired side while using the device.

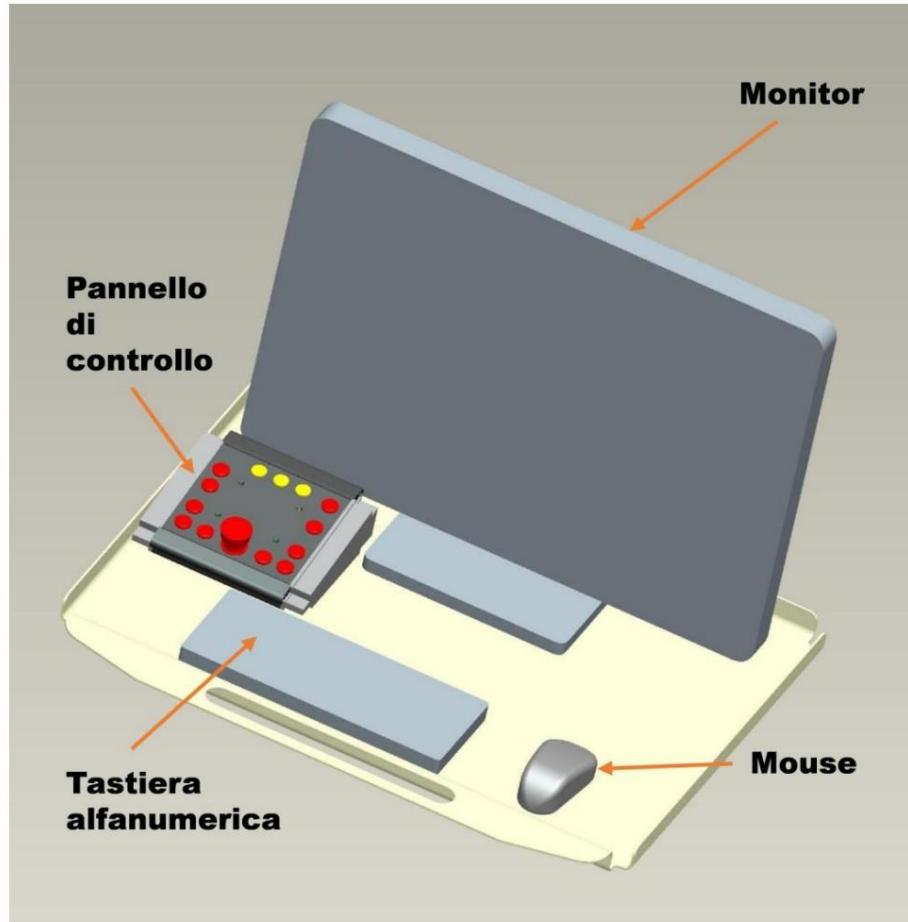


Figure 35 CAD Model of the Operator Console

### 5.2.1 Operator Monitor and Related Mouse and Keyboard

When the device is turned on, the OC monitor displays the **ALEX RS User Interface**, already described previously in this Manual. The following are particularly noteworthy:



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- the **WEARING Operating State**, which is related to the dressing phase of the exoskeleton on the patient

- the **REHAB Operating State**, or **REHABILITATION**, which is related to the setting and to the management of various rehabilitation activities.

The controls and settings are chosen by the therapist using the appropriate mouse and keyboard.

### 5.2.2 Control Panel

The control panel is equipped with a specific keypad, three diagnostic LEDs (green, yellow and red) and an emergency button.



Figure 36 The **ALEX RS** control panel

#### 5.2.2.1 Keypad

As you can see in the figure, the function of each button is clearly indicated on the panel itself:

---

The **POWER ON** button is the power button on the **ALEX RS**. This is the button you press to start the device's power-on procedure.



- The **STOP/CLEAR** button turns off the robotic arms that are currently turned on. (only one or both). In case of *FAULT*, this button resets any previously detected errors to avoid data overwriting.
  - The **START** buttons in the *RIGHT ARM* and *LEFT ARM* sections start the right and left ALEx respectively.
- 
- In the same sections, the buttons with the **horizontal arrows** are used to adjust the width of the two robotic arms by sliding them on the appropriate motorized guides.
  - In the *SEAT* section , the buttons with the **vertical arrows** are used to adjust the seat height by moving it up or down according to the patient's height.

### 5.2.2.2 Diagnostic LEDs

Three diagnostic LEDs of different colors (**green, yellow, red**) indicate the device's status to the operator. Table 3 shows the coding of the different states.

LED			DESCRIPTION
GREEN	YELLOW	RED	
ON	OFF	OFF	The device is <b>fully operational</b> . In particular the ALEX engines are enabled and the operator can access the WEARING Operating State or the REHAB - REHABILITATION.
OFF	ON	OFF (Yellow LED flashing)	The device is completing the <b>shutdown procedure</b> . The Operator must wait until the device has completed the procedure.
OFF	ON	OFF	The device is completing the <b>power-on procedure</b> . The operator must wait until the device has completed the procedure.
OFF	OFF	ON	The device is in <b>error state</b> . The ALEX motors have been automatically disabled by the software. To reactivate the device, press the <b>STOP/CLEAR</b> button and then resume operations from the beginning.

Table 3. Diagnostic LED states and their coding

### 5.2.2.3 Emergency button

The Operator Console emergency button, installed in the keypad, is electrically connected to the power supply section of the Motor Driver (MD).

If the button is pressed, the motor phases are immediately disconnected and, therefore, **the torques generated by the motors are immediately zeroed**.



As a hardware security measure, **activating the emergency button is the safest action to take in case of danger.**

---

The reduction of the torque generated by the motors means that the ALEEx exoskeleton is no longer balanced against the action of gravity:

- if the exoskeleton **is not worn**, this produces a free movement of its moving parts until the mechanical limit causes them to stop abruptly
- if the exoskeleton **is worn**, the weight of the moving parts is held by the arm of the patient.

Due to the very small masses of the moving parts of ALEEx, in both cases the practical consequences for the device or the patient are completely negligible.

---



**If a fault is automatically detected by the device's control software, or if the device is not functioning properly, the operator must press the emergency button as soon as possible to disable the motors.**

---

### 5.3 Motorized base

The motorized base, illustrated in the figure, is made up of:

- the welded steel support structure, equipped with wheels and adjustable feet
- the mobile support arm of the Operator Console
- the patient seat, equipped with adjustable footrests
- the patient backrest with adjustable inclination
- the two motorized axes (in horizontal direction), which allow the lateral positioning of the two ALEEx exoskeletons
- the motorized column that allows the vertical positioning of the patient seat according to his height



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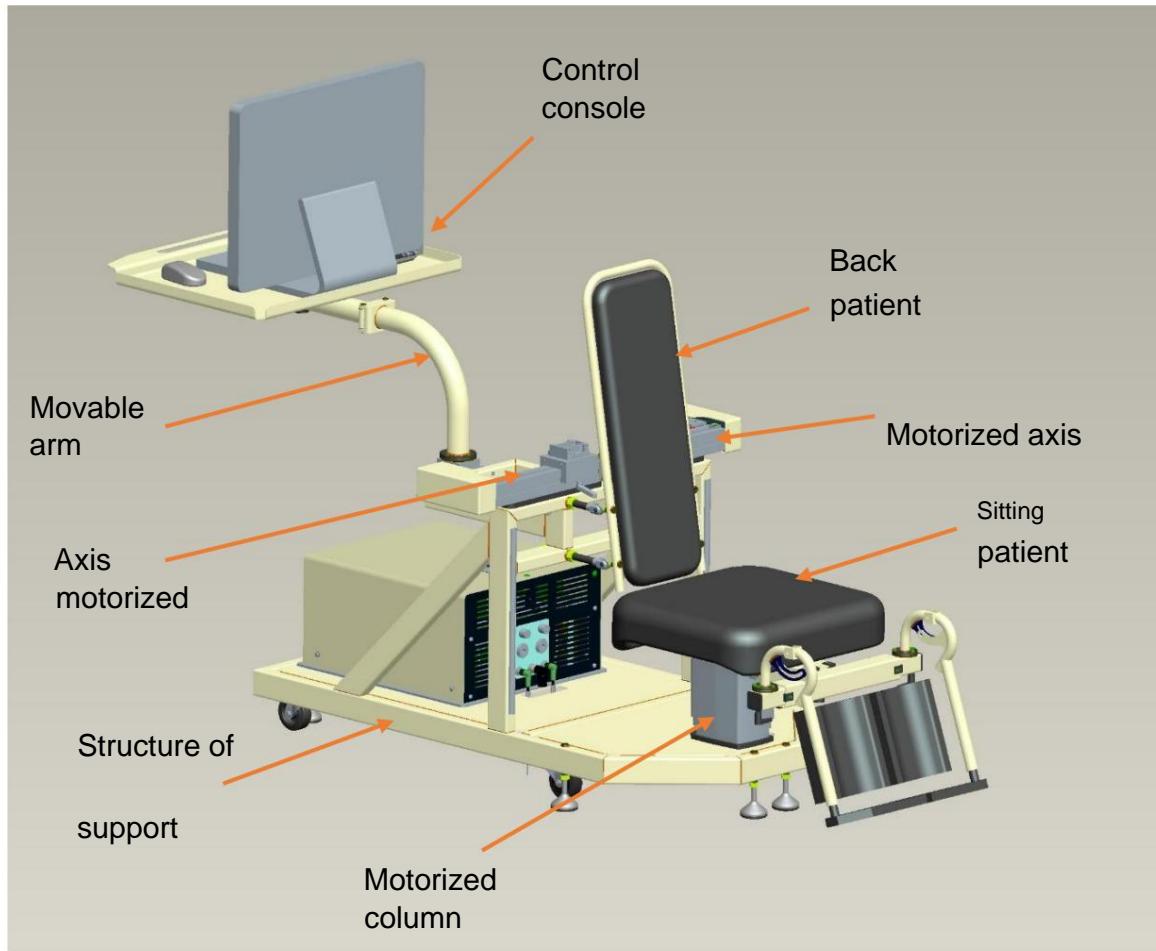


Figure 37. CAD model of the motorized base



## 5.4 Control and Power Unit (CSU)

The main components of the **ALEX RS** Control and Power Unit are housed in a rack box rigidly attached to the main chassis. Generally, the Control and Power Unit controls and supplies the electrical power required by the **ALEX RS's integrated electronics**.

The **ALEX RS** CSU is composed of:

- a **Power Supply Unit** (PSU) relating to all the electrical components and electronics and actuators of both the motorized axes and the motorized column.
- two **Control Units** based on commercial PCs:
  - or the first (**Device Control Unit**, DCU) dedicated to the control of low level of **ALEX RS**
  - or the second (**Virtual Reality Unit**, VRU) dedicated to the generation of the Virtual Reality and Graphical User Interface scenarios.

The **ALEX RS** control electronics also consists of a section integrated into the backrest of each **ALEX exoskeleton**.

## 5.5 Patient Monitor (PM)

This component is defined indiscriminately both as the actual Monitor and as the macro-section of **ALEX RS** which in turn consists of:

- a large LED technology screen (43 inches).
- a welded steel support structure, rigidly connected to the base motorized

**The screen displays the scenarios generated by the device's VRU**, which can be in 3D or 2D. **The screen's position relative to the motorized base is predefined** and optimized to ensure maximum patient comfort.

The screen **signal cables** are housed **inside the support structure** in order to reduce the emission of electromagnetic radiation.

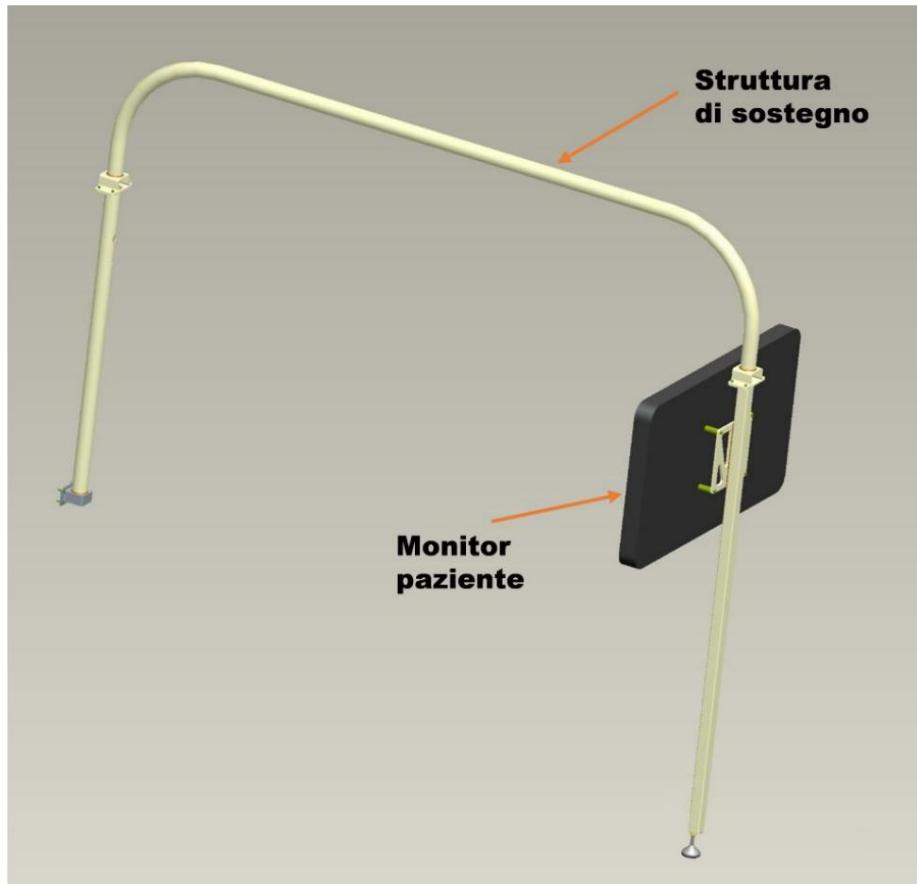


Figure 38. Patient monitor and support structure



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## 6 Rehabilitation with the **ALEX RS** device

### 6.1 General information on the operational use of **ALEX RS**

The operational use of **ALEX RS** is defined in different “states.” Correct operational use requires the user to follow well-defined procedures and perform well-defined actions, according to which the device transitions **from one current state to the next.**

The **ALEX RS** control software automatically performs several checks, but **it is** **It is the operator's sole responsibility to verify that, between entering one status and the next, both the device and the patient are in conditions compliant with the safety requirements.**



The device must be used by personnel with a thorough understanding of its operation, its various operating states and transitions, and the checks required. Use of the device by an inadequately trained operator can cause serious injury and damage to the device itself or other devices.



## 6.2 Device operating states

In general, **6 different operating states** are identified, described in Table 6. For each state, the configurations of the 3 LEDs on the Operator Console are shown.

Table 6. **ALEX RS** operating states and corresponding OC LED configurations

<u>NAME</u>	<u>DESCRIPTION</u>	<u>OC LED Status</u>
<b>OFF</b>	All electronic units of the device are disconnected from the main power line.	<b>LEDs off</b>
<b>STAND BY</b>	The device is connected to the power line. From this state, you can disconnect the power or turn the device on.	<b>Red LED off</b> <b>Yellow LED off</b> <b>Green LED</b> <i>flashing</i>
<b>READY</b>	The device has completed the power-on procedure, at the end of which it shows automatically the Home Screen on the PC Operator. From there you can activate the <b>WEARING</b> Operating State by turning on one or both <b>ALEXs</b> .	<b>Red LED off</b> <b>Yellow LED off</b> <b>Green LED on</b>
<b>WEARING (WEARING)</b>	The device can be worn as long as at least one arm is turned on and compensates for its weight. The <b>WEARING</b> Operating State is active.	<b>Red LED off</b> <b>Yellow LED on</b> <b>Green LED on</b>
<b>REHAB (REHABILITATION)</b>	In the <b>REHAB Operating State it is possible</b> select the type of activity from those proposed ( <b>RECORD&amp;PLAY, VIRTUAL REALITY, MIRROR</b> ). In particular, if <b>VR is selected</b> , ALEX is controlled by the VRU to simulate <b>the interaction</b> physics with virtual objects and <b>physical assistance</b> to the patient's movement.	<b>Red LED off</b> <b>Yellow LED</b> <i>flashing</i> <b>Green LED on</b>
<b>FAULT</b>	All electronics and software are fully functional. The ALEX motors are disabled by software.	<b>Red LED on</b> <b>Yellow LED off</b> <b>Green LED off</b>

A separate section is needed to describe the **FAULT state**: if the device detects an anomaly, an error code will be displayed under "Device Status" in the GUI. Press the CLEAR FAULT button on the control panel or power cycle the device, then proceed with the tasks again. If the problem persists, and after multiple power cycles the error code is still present, contact Wearable Robotics Technical Support and quote that code.

**NOTE:** Contact Wearable Robotics Srl Technical Support for further details regarding any faults or errors detected by the device.



### 6.3 Treatment with ALEX RS

The first thing to do during treatment is to turn on the **ALEX RS device** correctly; **before positioning the patient on the seat**, the start-up procedure must be completed and successful.

---

Therefore, make sure that the patient is far enough away from the device at this stage.

---

#### CONNECT ALEX RS TO THE POWER LINE

Press the main switch of the device, which is located on the CSU (see Figure).

All LEDs on the OC control panel will light up. Wait a few seconds until all three are off.

#### TURN ON THE ALEX RS DEVICE

Once all three LEDs are off, press the *POWER ON* button located at the top right of the control panel (see Figure). Wait for the device to complete the power-on process before performing any other actions.



Figure 39. The main switch of the device is located on the CSU

At the end of the power-on procedure, the Graphical User Interface will automatically appear on the Operator Monitor:

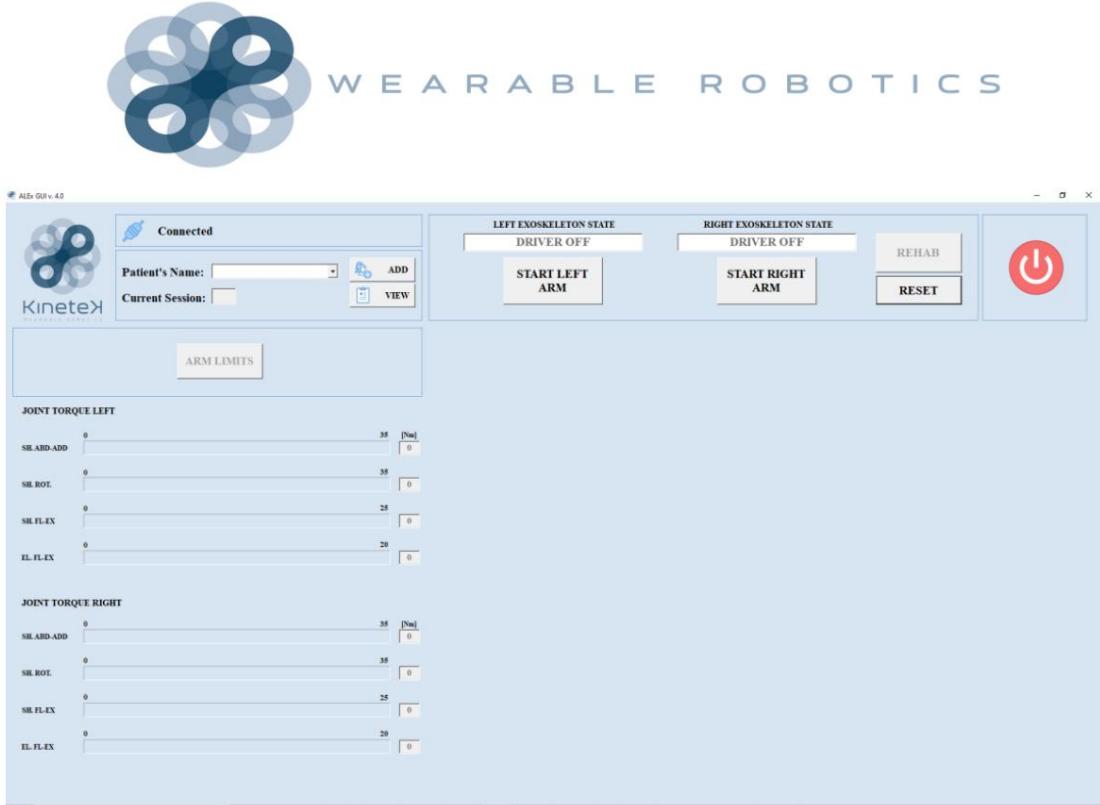


Figure 40. The screen that appears once the start-up procedure is complete

From this screen you can launch the exoskeletons, either simultaneously or one at a time.

**NOTE:** At this point, you can adjust the seat height or horizontal position of one or both **ALEEx exoskeletons using the appropriate buttons on the control panel**. It is recommended to adjust the **ALEEx exoskeletons to a width sufficient** to allow the patient to sit comfortably in the seat.

---

**NOTE:** If this is your first time treating a particular patient, you may want to save their data to monitor their progress. Click ADD and fill in the fields. See Figure.

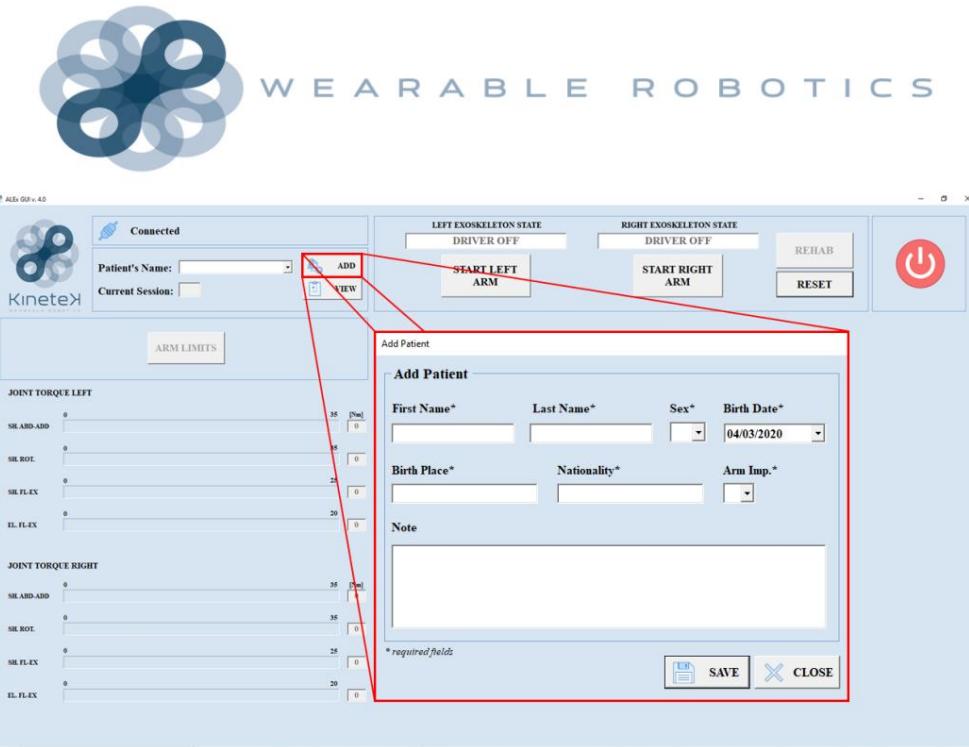


Figure 41. Detail of the screen relating to saving data for a new patient

#### ACTIVATE THE ALEX EXOSKELETONS

By pressing the start buttons on the screen, you can turn on the **ALEX exoskeletons**.

Depending on how you plan to set up the treatment, **you can begin with one or both ALEX exoskeletons turned on**. If you plan to use only one exoskeleton, we recommend moving the other to the maximum distance from the patient (when the patient is positioned in the seat) using the control panel on the Operator Console.

#### NOTICE

The ALEX exoskeleton's power-on process takes a few seconds, as does the power-off process. Before moving the exoskeleton, wait until the virtual power button on the GUI turns orange and the exoskeleton comes to a standstill. During the power-on process, the exoskeleton performs some **initialization movements**: please exercise due caution.

The same virtual power button also turns off the exoskeleton. During the shutdown process, wait until this button is grayed out and the exoskeleton is completely inactive before performing any other actions.



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**PLACE THE PATIENT ON THE SEAT AND ADJUST THE DEVICE**

It is now possible to help the patient sit on the **ALEX RS** seat and put on the exoskeletons.

**DANGER** During each use of **the ALEX RS**, the therapist must take care to help the patient position themselves correctly on the seat in the **safest** and most **comfortable** manner possible. Help the patient sit down after the device has been set up for this purpose (see below). If the patient requires special assistance, for example, because they are paraplegic and use a wheelchair, use appropriate procedures to help them move safely and position themselves on the seat. If necessary, use a lift.

---

First, adjust **the footrest opening** according to the patient's needs, using the appropriate **stops** to allow **greater comfort** and **facilitate** the patient's positioning on the seat; for the same reason, adjust the seat height via the **control panel**.

Sit the patient on the **ALEX RS** seat and make sure he or she is as comfortable as possible.

If necessary, the footrests can be easily removed and reattached to the seat once the treatment is complete.



Figure 42 Adjustable footrests of the **ALEX RS** seat

Once the patient is comfortably seated, use the **control panel** on the Operator Console to adjust the seat height and the distance of the exoskeletons.

---



Figure 43. Adjusting the seat via the control panel

#### **HOW TO CORRECTLY ADJUST THE DEVICE:**

For optimal use, it is important that the distances are adjusted as precisely as possible, based on the patient's anthropometric dimensions (**particularly height and shoulder width**).

Paragraph 5.1.1 describes the parameters to be respected for correct adjustment of the device, based on the kinematics of *ALEX exoskeletons*: further useful information is provided below.

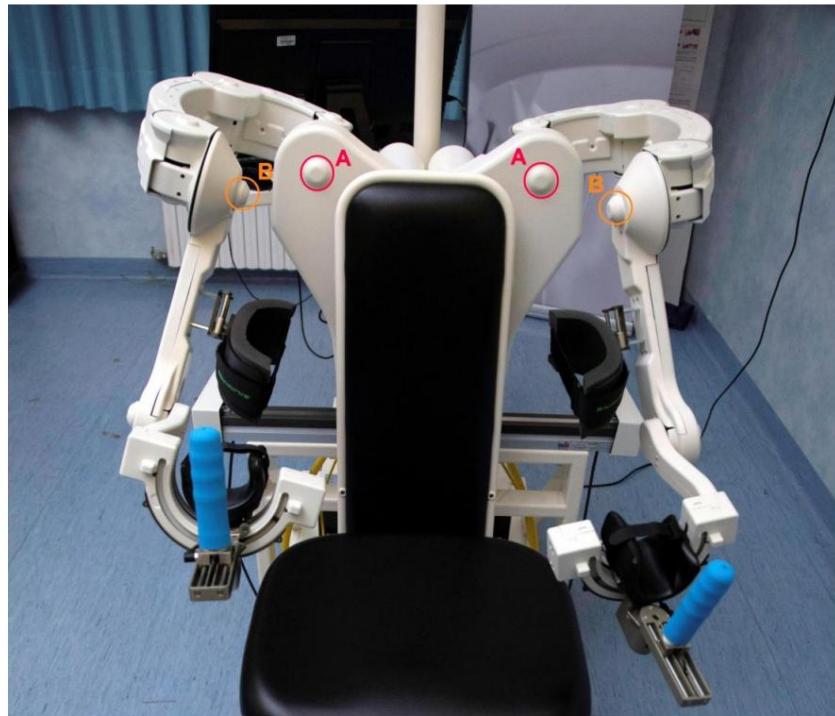


Figure 44. References for correct seat and width settings of *ALEX exoskeletons*

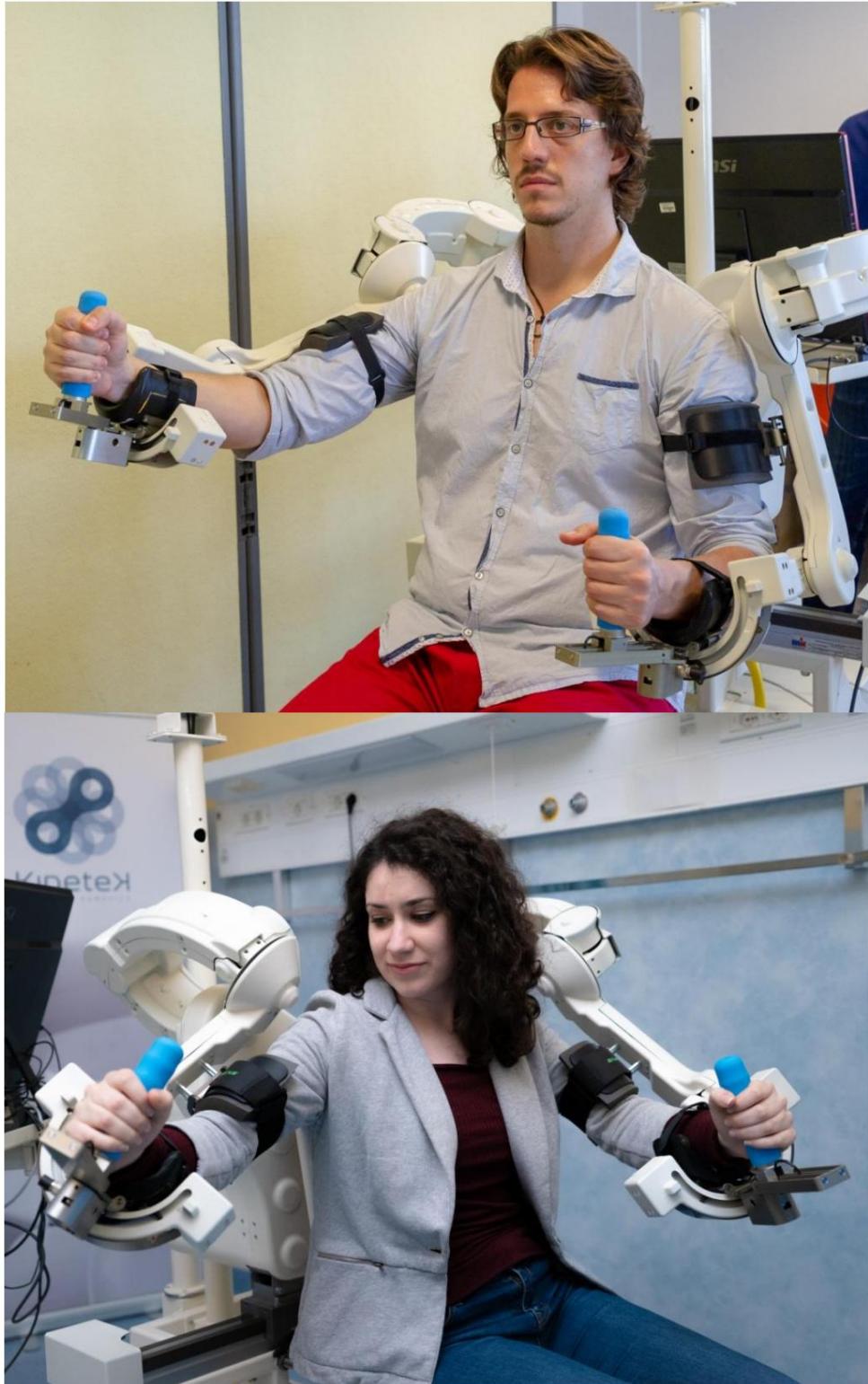


- First, adjust the seat height until **point A** in Figure approximately coincides with the *posterior prominence* of the patient's scapular acromion.
- Once done, move the *ALEX* exoskeleton closer or further away (or both, when you want to propose an exercise for both upper limbs) until **point B** it is approximately 1 - 3 cm from the area between the *greater tubercle of the humerus* and *the patient's acromion*.

**NOTE:**

The instructions above are indicative and vary from patient to patient. Always adjust the position of the exoskeleton so that the patient's arm has the **greatest possible freedom of movement** and remains **attached** to the device (i.e., neither too close nor too far away). Set distances so that the device **adheres to the patient's upper limb**, as if it were a garment or an extension of the limb itself, in all its degrees of freedom. Press the seat height or right/left arm distance adjustment buttons individually: the motorized guides do not work if activated simultaneously, but must be activated one at a time.

---



*Figure 45. Examples of situations where the device is worn correctly*



## SECURE ALEX TO THE PATIENT AND START TREATMENT

Once the optimal position for the patient has been found, it is possible to have him put on the *ALEX* exoskeletons (which must be in the *WEARING Operating State*) and proceed with the desired Treatment Mode.

To properly secure the device to the patient's arm, simply use the arm and forearm straps (and, if applicable, the belt):



Figure 46. Armband of an ALEX exoskeleton



Figure 47. Forearm strap of an ALEX exoskeleton



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**⚠ CAUTION**

Avoid overtightening the elastic arm and forearm straps. Always ensure the patient is in a comfortable position and feels no discomfort while wearing the *ALEEx exoskeleton*.

Once the elastic bands are fastened, make sure that the patient's hand grasps the **sensorized knob** at the end of the robotic arm.



Figure 48. *ALEEx RS* device knobs

Check which movements the patient can perform without pain, especially if it's the first time they've undergone treatment. If necessary, set the exoskeletons' joint limits via the graphical interface.



Figure 49. Checking patient mobility while wearing the device (proceed with caution)



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**NOTE:** The sensorized knobs, in addition to sliding on special guides to better adapt to the patient's anthropometric dimensions, allow the wrist to be flexed and extended.

---

If necessary, however, **it is possible to lock this degree of freedom** to ensure that the user's wrist remains in a fixed position.

To do this, simply hold the knob in the desired position and, using a flathead screwdriver, tighten the screw highlighted in the figure until the mechanism is locked. A light tightening is sufficient; do not use excessive force to avoid damaging the screw or the mechanism.

To unlock the mechanism, simply loosen the screw until it slides properly.



Figure 50. Knob of an ALEX exoskeleton and screw to lock/unlock the flexion-extension movement of the wrist.



At this point, you can begin the rehabilitation treatment by starting the desired Mode. **See section 4.2 for more information on the various Modes of use of the device.**

---

## **CONCLUDE THE TREATMENT AND TURN OFF THE DEVICE**

Once the treatment is complete, the exoskeletons must be removed from the patient's limbs and the patient must be removed from the device seat. Follow this procedure:

- First make sure you have exited the last Mode you started, then press the virtual WEARING button to enter the relevant Operating State. Once this is done, set the **arm weight compensation to 0%** using the appropriate slider.
- At this point you can **remove the bands** from the arm and forearm of the patient. Be sure to perform this action gently.
- The patient can now **be removed from the seat**. If necessary, adjust the seat height using the control panel, change the position of the footrests, and help the patient safely remove themselves from the device.
- Once the patient is no longer on the **ALEX RS** device seat , turn off the **ALEX exoskeletons** using the dedicated virtual buttons. Wait until the exoskeletons have been turned off and the virtual buttons are gray.
- Close the ALEX RS device GUI . To do this, simply close the interface by pressing the X key with the mouse.
- Turn off the Operator PC like a normal PC.
- Wait for the **shutdown procedure** to complete and for the PC and device fans to turn off. At this point, the green LED on the control panel will start flashing and the device will be in **STANDBY mode**.
- Disconnect the **ALEX RS** device from the power line by pressing the **main device switch** on the CSU.

**NOTE:** If you want to turn the device back on, wait at least 120 seconds before pressing the main switch on the CSU again.

---



## **7 Transport, storage and maintenance of ALEX RS**

### **7.1 Transport and storage**

**ALEX RS** must be transported and stored in a temperature-controlled environment, within the range **[ -20°C, +55°C ]**.

The recommended humidity range for proper storage is **[ 5%, 90% ]**, non-condensing.

**ALEX RS** should be shipped and stored in the supplied packaging, which is designed to prevent damage from shock and vibration. Also, protect the packaging from excessive shock and vibration.

To transport the packaged equipment, use a **forklift**, **pallet jack**, or similar means. The device must always be stored and transported properly, in a clean, dry, condensation-free area, and kept out of direct sunlight.

---

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**NOTICE**

Do not lay the speaker on its side or in any other inappropriate position: this may damage the equipment.



*Figure 51 Packaging boxes of the two ALEX robotic exoskeletons (right and left)*



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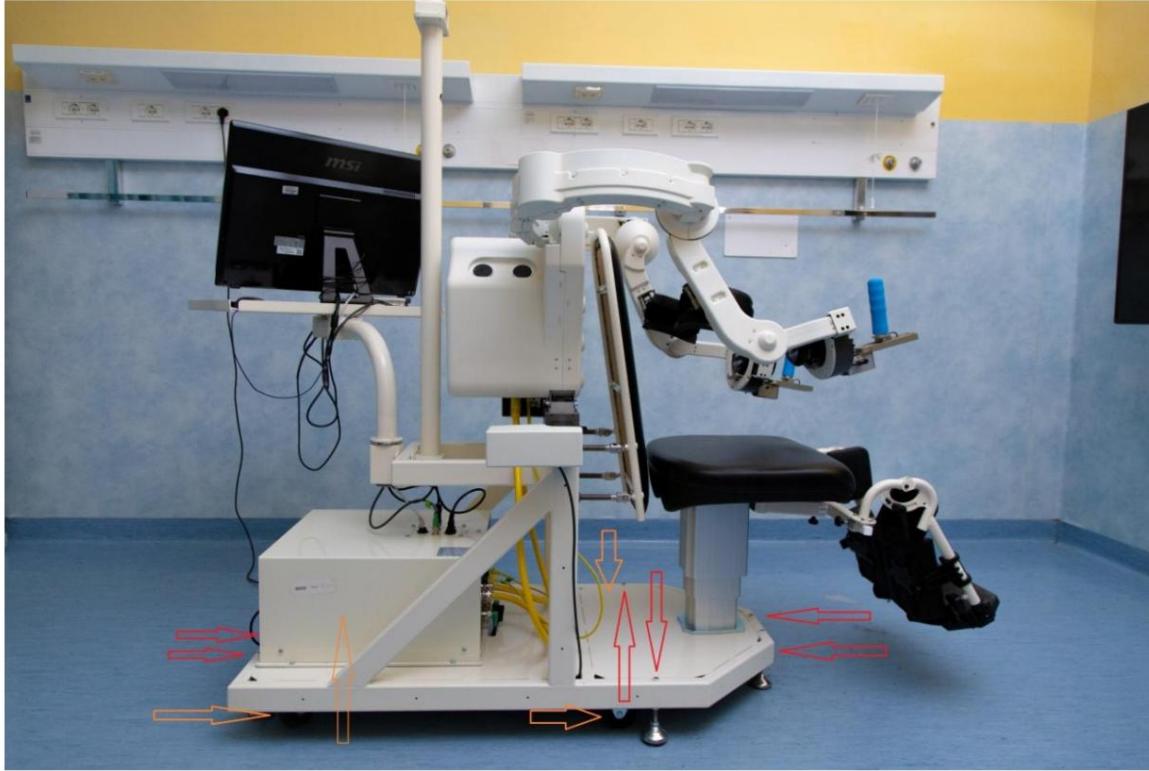


*Figure 52 Packaging of the device Base and Seat (right) and the boxes containing the two ALEX exoskeletons (left)*



### 7.1.1 Moving ALEX RS

It may happen that the **ALEX RS** device , once installed, needs to be moved from the room where it is located to another: for this purpose, **ALEX RS is equipped with 4 wheels (2 swiveling at the front and 2 fixed at the back) and 6 height-adjustable feet.**



*Figure 53. Positioning feet (at the red arrows) and wheels (at the orange arrows) located under the ALEX RS support structure*

**⚠️ WARNING**

Once the device has been placed in the room where it will be used, whether after **installation** or after being **moved**, always make sure that the feet have been returned to the correct locking position for the device.

**⚠️ DANGER**

Do not perform treatment unless the feet have been moved to the locked position and the device is stabilized in a fixed position in the room where it will be used. Always follow the procedure described in this manual.

**NOTICE**



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**HOW TO USE THE STABILIZING FEET AND WHEELS OF THE ALEX RS DEVICE**

Make sure **ALEX RS** is turned off and disconnected from the mains. If necessary, unplug the power cords from the electrical outlets.



*Figure 54. One of the adjustable feet and a wheel on the **ALEX RS**. You can see the groove on the screw that houses the foot and the nut used to lock it at the desired height.*

Make sure the **ALEX RS** device is in the desired position, then unlock the feet by loosening the retaining nut. To unlock the nut, use a size 19 **open-end wrench**.



*Figure 55. Locking/unlocking the adjustable foot fixing nut*

Once the nut is unlocked, the foot can be raised or lowered. Focus first on the 4 feet on the side of the Operator Console. Rotate each foot by hand to the desired height: when necessary, use a size 10 **open-end wrench** in the appropriate slot to achieve the best position (see figure).



Figure 56. Using a wrench to raise the foot to the desired height

**Raise the four feet until the transport wheels no longer touch the ground.** Once this is done, make sure the device is level using a spirit level in the two directions shown in the figure.



Figure 57. Using a level along the two directions shown to verify that the device is level

At this point, fix the feet with the appropriate bolts (lock with a wrench as shown in Figure ) and finally bring the two feet on the side of the patient's seat to the same height.

---

If you want **to move the device**, the procedure is essentially similar: loosen the nuts and raise each foot to a height where the wheels touch the ground, transport the device to the new location and repeat the procedure for locking the feet.

**NOTICE**

During transport, at least one person must lift and hold the Patient Monitor stand, which does not have wheels.



## 7.2 Cleaning and disinfection

Use a mild detergent to wash the covers and visible mechanical parts of the ALEX exoskeletons.

Apply the cleaner to the areas to be cleaned, preferably with a spray bottle, then wipe and remove any remaining cleaner. Use a soft cloth. Leave no residue.

If necessary, disinfect the device after use to prevent the spread of bacteria or viruses. Pay particular attention to the parts that come into contact with the patient, such as: **handles, forearm attachment and elastic strap, arm attachment and elastic strap, seat, backrest, and footrest.**

---

If contact with bodily fluids occurs, wipe all contaminated surfaces with a disposable disinfectant wipe to clean and remove bacterial load, disinfect cleaned surfaces with a fresh towel, and allow all cleaned surfaces to dry before using **the ALEX RS** on another patient.

### NOTICE

Be careful not to leave residue on the device after cleaning, especially not to allow detergent or disinfectant to enter inaccessible internal parts of the device. Pay particular attention to electrical or electronic components. Do not spill water on the device or its components.

### NOTICE

Do not use aggressive sprays or detergents on the device or those that could damage the device itself or its components.

### DANGER

#### **Contamination by third parties:**

If the user or patient has an infectious disease or is a potential carrier of a pathogen on their hands, even greater caution is required. Before and after each use, all contactable parts of the device must be disinfected using a special spray, particularly the footrest, backrest, arm and forearm cushions, handgrips, and exoskeleton covers. Using suitable tools to disinfect electronic components, also disinfect the control panel, mouse, and operator keyboard. Use an alcohol-based hand sanitizer before and after each use and, if necessary, wear a protective mask. If necessary, wear sterile gloves during all use.



## 7.3 Maintenance

### 7.3.1 Safety requirements to be adopted for correct maintenance

**⚠ WARNING** To avoid causing damage to the equipment or to persons, always turn off the main switch before performing any maintenance, cleaning, repair or upgrade activities.

**⚠ WARNING** Use appropriate warning signs by placing them on the device and on the Operator Console, to indicate that the maintenance process is in progress. Remove the signals after the maintenance process is complete.

**NOTICE** **ALEX RS** is a highly sophisticated device that must be handled with care during all maintenance operations; in otherwise it may be damaged.

### 7.3.2 Maintenance by the manufacturer

Every 6/8 months of operation, a check of the device must be carried out with:

- test for correct functionality
- visual inspections

in order to evaluate the **state of wear** of critical components and then proceed, if necessary, to replace them.

In particular, the following checks must be performed:

- verification of position sensors (calibration, integrity)
- cooling fan control
- Checking the ground connections
- verification of internal mechanical components

**⚠ WARNING** The Customer must contact Wearable Robotics Srl to request an appointment to carry out maintenance at least **20 days before** the scheduled or desired date for the intervention.

**NOTE:** The Customer is required to contact Wearable Robotics Srl via email to arrange a call with a specialized Operator to schedule a remote inspection of the device. The Operator will guide the Customer through the device analysis, after which the need for further in-person intervention will be assessed. In-person maintenance is the Customer's responsibility.

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### 7.3.3 User maintenance

Piston rings are subject to wear and should be regularly inspected and replaced if necessary.

In the event of failures or problems, the device's components can be replaced by qualified Wearable Robotics Srl personnel or by authorized personnel; however, it should be noted that the **ALEX RS device has a useful life of 8 years**.



## **8 Troubleshooting**

As soon as the device control system detects a malfunction, the relevant fault code is immediately displayed on the GUI and the red LED on the Control Panel lights up.

All possible fault codes reported by the device and referring to malfunctions of the exoskeletons are listed in Table 8 (different codes for the right and left arm), while Table 9 lists the fault codes due to malfunctions of other components of the device. For each code, a description is provided.

A brief description of the problem encountered and the possible causes that may have generated it. The last column of Tables 8 and 9 lists the possible actions to take to attempt to resolve the problem.

**⚠ WARNING** To try to resolve each reported fault, the following steps must be taken: only the proposed solutions: no other type of intervention on the device is permitted, nor any modification to the methods of use provided for in the this manual.

The actions are coded and the codes are listed in Table 7.

**NOTICE** The corrective actions proposed for each error should be performed in the order listed, moving on to the next one only if the previous one has not resolved the problem.

*Table 7. Possible solutions in case of failure*

Code Description	Description
SC	Clear the error by pressing the “CLEAR” button on the Control Panel, verify that the error does not persist after clearing, resume normal use
SR	Turn off the device, wait for all fans to stop completely, restart the device, resume normal use
SM	Remove any equipment with high voltage from the vicinity of the device. high electromagnetic emissions
SL	Check that the ends of the communication cables between the exoskeleton and the Control Box are correctly inserted into their respective connectors
SO	Make sure the robotic arm is completely free to move (no obstacles in its workspace)
SV	Check if: <ul style="list-style-type: none"> <li>- the type of error reported is consistent with the speed or forces applied by the arm at the time of the report;</li> <li>- the behavior of the arm at the time of the fault appeared consistent with as required by the current financial year</li> </ul> If at least one of the two conditions above is not met, contact support.
SA	Verify that the environmental conditions and usage cycles of the device comply with the provisions of this user manual. If so, contact support.
IF	Make sure the emergency button on the Control Panel is not pressed.
SX	Contact support



Table 8. Exoskeleton faults reported by the GUI

<b>Fault Code Description</b>		<b>Possible causes</b>	<b>Code solutions</b>
<b>DX</b>	<b>SX</b>		
110M 120M	DCU detected an error reported by the motor position sensor acquisition electronics <M>	Excessive electromagnetic interference may have decalibrated the position sensor.	SM, SR
111D 121D	DCU has detected too low a refresh rate for data received from the embedded electronics identified by the letter <D> of the code: 1 -> ACQ card 2 -> first MD card 3 -> second MD card	The cable for data communication between the DCU and the integrated electronics on the affected arm may not be making good contact.	SL, SC SR SX
112J	122J DCU detected an inconsistency between the value of the joint position <J> estimated from the motor positions and the same value estimated at starting from the measurement of the absolute sensor at the joint	The error could have been presented in the face of a forceful interaction between the patient's arm and the robotic arm.	SC SR SX
113M 123M	During the engine activation phase, DCU detected that the positive direction of rotation of the engine position sensor <M> is discordant with the positive direction of rotation for phase switching.		SX
114M 124M	During the engine activation phase <M>, DCU did not detect the position sensor index signal		SX
115M 125M	During the activation phase of the <M> motor, DCU detected incorrect phase angle	During the initialization phase the robotic arm could be hindered in movement.	SO SC SX
116J	126J DCU detected an error during the zeroing phase of the absolute position sensor mounted on the joint <J>	During the initialization phase the robotic arm could be hindered in movement.	SO SC SX
1190 1290	DCU detected incorrect acquisition of analog signals from arm sensors	The acquisition electronics may not have initialized correctly.	SR SX



1191	1291	DCU encountered an error while loading arm position sensor calibration parameters from file	The storage media where the data is saved may have been corrupted. damaged.	SX
1192	1292	DCU encountered an error while loading the arm friction compensation calibration parameters from file	The storage media where the data is saved may have been corrupted. damaged.	SX
210M	220M	MD detected disabled state of the power module dedicated to driving the <M> motor		SX
211M	221M	While monitoring the current sensing signal, MD detected an excessive value of the current supplied to the motor <M>	The error may occur due to a forceful interaction between the patient's arm and the robotic arm during the execution of a rehabilitation exercise.	SV, SC SX
212M	222M	MD detected activation of the signal produced by the electronics dedicated to the detection of a overcurrent delivered to the motor <M>	The error may occur due to forceful interaction between the patient's arm and the robotic arm while performing a rehabilitation exercise.	SV, SC SX
213M	223M	MD detected a speed of excessive engine rotation <M>	The error may occur when one or more joints of the robotic arm reach a high speed.	SV, SC SX
214M	224M	MD has detected a malfunction in the motor current control system <M>	The error may occur due to a forceful interaction between the patient's arm and the robotic arm during the execution of a rehabilitation exercise.	SV, SC SX
215M	225M	MD has detected the fault status reported by the power module dedicated to driving the motor <M>		SX
216M	226M	MD has detected an excessive temperature reached by the power module dedicated to driving the <M> motor	The device may have been used intensively (high forces applied almost continuously to the patient) and in a particularly hot environment.	SA, SC SX



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218D	228D	MD has detected a voltage of Power supply too low for power modules; the letter <D> in the code identifies the MD board that detected the error	The emergency button may have been left pressed. The driver power supply may be faulty.	SE, SC SX
219D	229D	MD detected a data refresh rate received from DCU too low; the letter <D> in the code identifies the MD board that detected the error		SL, SC SR SX



Table 9. General faults reported by the GUI

Code broken down	Description	Possible causes	Code solutions
100	VRU detected a data update rate received from DCU too low	If the error occurs immediately after the device has booted, the DCU may have taken longer than expected to boot.  If the error occurs during machine operation, performing some VRU functionality (such as viewing test reports) may have required excessive resources at the expense of communication with the DCU.	SC SR SX
1000	DCU detected an error related to the real-time execution of the control algorithm	The values of some control parameters may not have been loaded correctly during the DCU startup phase	SR SX
1001	DCU detected a data update rate received from VRU too low	Software applications running from the VRU may not have started correctly.  Performing some VRU functionality (e.g. viewing test reports) may have consumed excessive resources at the expense of communication with the DCU.	SC SR SX
3001	VRU detected that the refresh rate of data received from the Power card is too low	The communication driver may have initialized Not correctly.	SR SX
301V	VRU has detected too low a rotation speed of the Control Box fan <V>; the letter <V> in the code identifies the fan to which the error refers (<V> = 1..4)	A fan might have failed.	SX
3021	VRU detected an excessive value of the temperature measured by the first sensor integrated on the Power board	The device may have been used intensively (high forces applied almost continuously to the patient) and in a particularly hot environment.	SA, SC SX



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3022	VRU detected an excessive value of the temperature measured by the second sensor integrated on the Power board	The device may have been used intensively (high forces applied almost continuously to the patient) and in a particularly hot environment.	SA, SC SX
3023	VRU detected fault status reported by integrated stepper driver on Power board	<p>The emergency button may have been left pressed.</p> <p>The stepper driver power supply may be faulty.</p> <p>The stepper driver could be broken down.</p>	SE, SC SX



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## A. Appendix - Essential Performance

The Essential Performances of **ALEX-RS** are defined as follows:

- The exoskeleton must be able to generate controlled movements of its moving parts, ensuring that the lower and upper limits of motion of its joints are within those typical of the corresponding joints of the human arm and that the maximum angular velocities of its joints are below specified limits, to contain the mechanical energy of possible collisions with the operator or patient.
- The exoskeleton must be able to generate controlled torques on its joints motorized, ensuring that their maximum values are below the specified limits.

For the quantitative definition of the limits and ranges to which the essential performances refer, see the ALEX technical specifications (chapter 5).



## B. Appendix - Immunity and electromagnetic emissions

*Table 10. Electromagnetic Emissions - Manufacturer's Declaration*

Electromagnetic Emissions - Manufacturer's Declaration		
ALEx RS is intended for use in the electromagnetic environment specified below. The customer or user of the ALEx RS should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guide
RF emissions CISPR 11	Group 1	ALEx RS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference in nearby electronic devices.
RF emissions CISPR 11	Class A	ALEx RS is suitable for use in all establishments, except domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Compliant	
Fluctuation emissions voltage/flicker IEC 61000-3-3	Compliant	



Table 11. Electromagnetic Immunity - Manufacturer's Declaration

Electromagnetic Immunity - Manufacturer's Declaration				
Immunity Test Level of Test	Level Of compliance	Electromagnetic environment - guide		
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	Compliant Floors must be wood, concrete or ceramic.  If the floors are covered with synthetic material, the relative humidity should be at least 30%.		
Transients / rapid pulse Of sequence electric IEC 61000-4-4	+/- 2 kV for power supply lines	Compliant Mains voltage quality should be that of a typical domestic or hospital environment.		
Overvoltages IEC 61000-4-5	+/- 1 kV line to line +/- 2 kV line to ground	Compliant Mains voltage quality should be that of a typical domestic or hospital environment.		
Power sags, short interruptions and variations Of voltage on the power Of supply input lines IEC 61000-4-11	>95% Ut hole for 0.5 cycles 30% hole in Ut for 25 cycles >95% Ut hole for 5 cycles	Compliant Mains voltage quality should be that of a typical domestic or hospital environment.		
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	Compliant Power frequency magnetic fields should have levels characteristic of a location typical in an environment home or hospital.		
Radiated RF IEC 61000-4-3	Field (V/m)	Frequency	Modulation	In accordance with the Portable and mobile RF communications equipment should be used no closer to any part of the ALEX RS, including cables, than the recommended separation distance calculated from the equation applicable of the transmitter. to the frequency
	3	80MHz-2700MHz	1kHz AM 80%	
	27	380MHz-390MHz	18Hz PM 50%	
	28	430MHz-470MHz	18Hz PM 50%	
	9	704MHz-787MHz	217Hz PM 50%	
	28	800MHz-960MHz	18Hz PM 50%	
	28	1700MHz-1990MHz	217Hz PM 50%	
	28	2400MHz-2570MHz	217Hz PM 50%	
	9	5100MHz-5800MHz	217Hz PM 50%	



Table 12. Recommended separation distances

<b>Recommended separation distances between portable and mobile radio communication equipment furniture and ALEX RS</b>			
Rated power of maximum transmitter output (W)	Separation distance at the transmitter frequency		
	from 150 kHz to 80 MHz d= 1.2 √P	from 80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.5 GHz d= 1.2 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d, in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.



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## **NOTE**