MARSI BIONICS

ATLAS 2020 EXOSKELETON TECHNICAL MANUAL

Coding	MB-A20-MU
Version	2
Date	23/02/2017
Reference	161021
Prepared By	D. Sanz
Revised By	M. Prieto
Authorized by	M. Prieto

Marsi Bionics SL
Avenida Punto ES, 10
28805 Alcalá de Henares – Madrid, Spain
Tel: +34 911 898 293
www.marsibionics.com

Table Of Contents

1 INTRODUCTION

1.1 FOREWORD

This document describes the research manual for clinical trials with the ATLAS2020 exoskeleton. It has been created as a walking assistance device for children with neuromuscular diseases such as Spinal Muscular Atrophy. The instructions outlined here should be sufficient for the preparation, use and maintenance of the orthosis. The ATLAS 2020 exoskeleton is a 10 degree of freedom robotic orthosis. It focuses on improving user motor level, expecting not only to increase life expectancy but also to reduce or to delay complications.

1.2 MANUFACTURER

The device has been manufactured by Marsi Bionics with the scientific and technical advice of the Spanish National Council for Scientific Research (CSIC). Several research prototypes have been produced, which are apt for clinical trials in hospitals and universities under professional supervision.

The ATLAS2020 exoskeleton is currently in development as a motoric aid for pediatric patients. It is not approved for sale in any country. The information presented herein is provided for information purposes solely.

1.3 INTENDED USE

A physical therapist or medical advisor should assist the patient in selecting the proper functions to be generated by the orthosis. The active ATLAS 2020 orthosis will be used under the supervision of qualified technical staff from Marsi Bionics.

1.3.1 The clinical and rational problem for the design and specific use

The device is designed specifically for walk training of children with non-itinerant Type 2 Spinal Muscular Atrophy (SMA). Current disease patterns show the onset of complications derived from the loss of walking ability. It is believed by doctors and physical therapists that active practicing with exoskeletons can provide improvements in the quality of life of patients.

1.3.2 Alternative solutions

For SMA Type 2 patients, who do not have the ability to walk, the only suitable help are the passive orthosis of lower limbs allowing patients to stand. Unfortunately, there is in the present no procedure that allows these children to walk. Since those patients have a significant force deficit not only on the lower limbs but also in upper torso and the trunk, the use conventional orthoses produces a significant fatigue on them. Therefore, there is a real need to have a device that allows to these children to walk without effort and delay the usual complications.

1.3.3 Expected outcomes

Pilot and pre-clinical trials allow health professionals to explore and perform research on the effects of using prototype exoskeletons on affected children. Safety, alignment and correctness of operation is evaluated during trials. Usually it is arranged as follows. In several weekly sessions a number of volunteer children with SMA Type 2 practice walking with the help of the ATLAS2020 exoskeleton. During that time, several clinical variables and scales are measured. The usual 6 meter walk is done.

The exoskeleton is a non-implantable device, with external use and do not represent any risk to the child. This studies provide data that will be useful to the clinicians who treats these patients and, therefore, improve its handling of the disease.

With regard to future therapies with the exoskeleton, a significant delay in the onset of complications associated with the loss of the walking ability is expected and therefore an improvement in the health of the children.

1.4 GENERAL WARNINGS

- Before a user operates Marsi Bionics' orthoses without technical supervision, he must be sufficiently trained.
- Always follow the recommendations given in this manual.
- Do not use the exoskeleton outside the purpose for which it was designed.
- Never open the orthosis or make modifications or adjustments other than those described in this manual.
- Never use the orthosis in high-impact applications.
- Keep your fingers away from the moving areas of the orthosis to avoid crushing.
- A visual inspection is recommended prior to each use.
- Do not use in case of alarm indication.
- Do not expose to rain, nine or water impact.
- Keep in a clean and dry place.
- The operating temperature of the brace is -5 ° C to + 40 ° C.

1.5 INDICATIONS AND CONTRAINDICATIONS FOR USE

As it is mentioned before, the ATLAS 2020 exoskeleton is designed for children with neuromuscular disease from three to twelve years old.

This product is contraindicated in the following cases:

- Trochanter knee length smaller than 22 cm and bigger than 38 cm.
- Knee ankle length smaller than 21 cm bigger than 37 cm.
- Hip width (from trochanter to trochanter) smaller than 24 cm bigger than 40 cm.

- The weight of the user bigger than 40 kg.

- The flexo in the hip bigger than 18º.
- The flexo in the knee bigger than 18º.

- The level of spasticity in the joints bigger than 2 in the Ashworth scale.
- Bone factures or osteoporosis.
- Excessive fragility or superficial skin lesions in the areas of the grips.

1.6 REGULATORY CLASSIFICATION

In the classification of medical devices, it corresponds with a medical device of class IIa, for standing and gait training in children affected by Spinal Muscular Atrophy.

2 SYSTEM OVERVIEW

The ATLAS 2020 exoskeleton is a THKAFO active orthopedic device (Trunk-Hip-Knee-Ankle-Foot Orthosis). It is defined as a pediatric class IIa sanitary device for gait training in children affected by spinal muscular atrophy, spinal cord injury or other neuromuscular diseases.

It is characterized by:

- It attaches to the human body in a non-invasive way through a physical interface based mainly on Straps and clamps.
- Its chassis is adjustable in length and width for children from 95 cm up to 140 cm in height.
- Performs human walking with active mobility in three-dimensional space, providing controlled motion in the sagittal and frontal plane.
- In addition to walking, it reproduces the actions of getting up and sitting down.

The structure of the exoskeleton is distributed on two legs and a chest union.

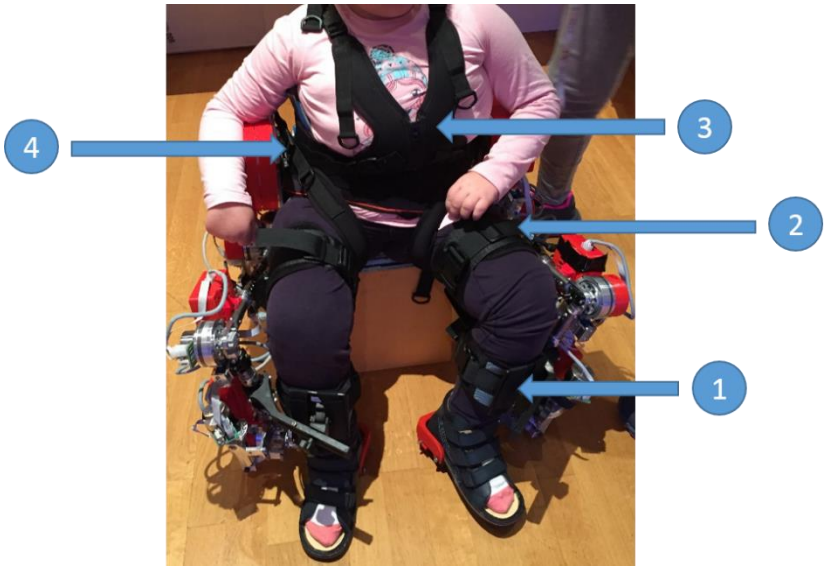
Each leg is composed by three links: femur (upper) that links the joints of hip and knee, and tibia (bottom) that links the joints of knee and ankle. Both links have telescopic capability to adapt for child size and growth. This provision allows for adjustment of each link to the measures of each user. A third leg link joins the ankle to the shoe of the user.

Each leg includes 5 degrees of mobility. These degrees of mobility are the following:

- Flexion and extension of the hip by rotating on the sagittal plane;
- Adduction of the hip by rotating on the lateral plane;
- Flexion and extension of the knee by rotating on the sagittal plane;
- Flexion and extension of the ankle by rotating on the sagittal plane;
- Adduction and eversion of the ankle by rotating on the lateral plane;

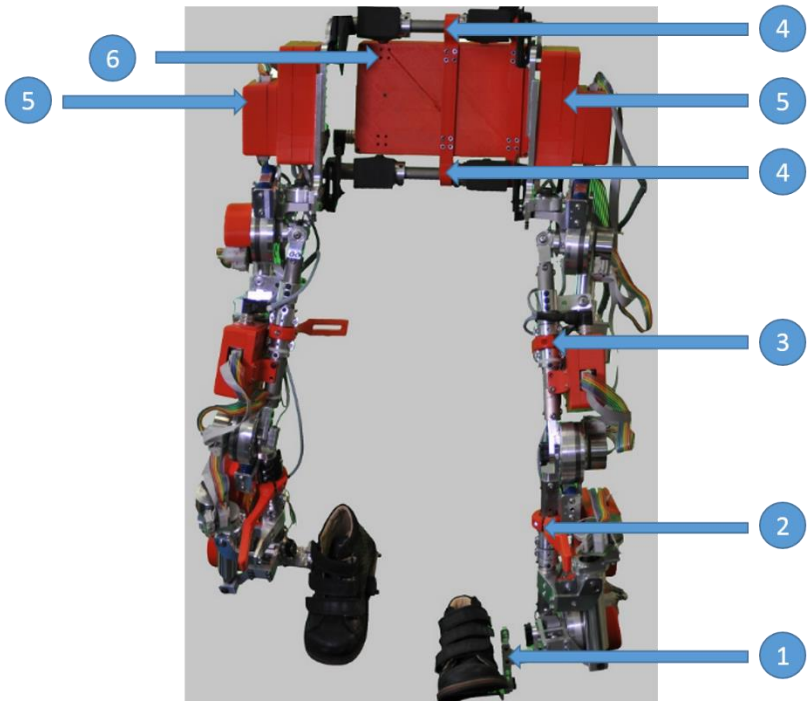
2.1 ELEMENTS OF THE ORTHOSIS AND NOMENCLATURE

The orthosis is composed of the following elements show in the next figures, throughout this manual each of the mentioned parts will be referred to by that name.



1. **Shank brace**
2. **Thigh brace**
3. **Thoracic brace**
4. **Pelvis brace**

Figure 1 - Main points of support



1. **Foot height adjustment.**
2. **Adjustment for size changes in the shank.**
3. **Adjustment for size changes in the thigh.**
4. **Adjustment for size changes in the torso.**
5. **Container box of batteries in the legs.**
6. **Container box of batteries in back.**

Figure 2 - Main points of adjustment and battery containers.

2.2 CUSTOMISATION AND SIZE REGULATION

The Atlas2020 exoskeleton is highly adjustable to meet the user characteristics.

2.2.1 Changing the shoes

Shoes can be easily changed according to the size of the patient's feet. In order to change the shoe, two screws at the base of the ankle to foot link have to be taken out. The foot support element is now free and the new shoe can be attached at the same place. The height of the foot to ankle joint can be adjusted by selecting the proper holes in the support element in steps of 10 mm.

2.2.2 Adjusting the length of the legs

The size adjustment system allows you to adjust the length of extremities to align the axes of the joints of the exoskeleton with the corresponding ones of the users. The system presents the feature of an intermediate tube inside the link allowing the modification of the distance between motion axes. This range can be increased or decreased by changing the intermediate tube to achieve larger or smaller size, thus modifying the range of lengths without requiring significant changes in the exoskeleton. When using the proper tube, small adjustments in steps of 10 mm can be made. The regulation of the measure of each segment is made in telescopic form by simply loosening and tightening a clamp.

2.2.3 Torso width and depth adjustment

Torso width can be changed using a very similar system as the ones used in the legs. Regulation details follow:

- Hip width: 18-34 cm by 2 sizes of tubes and 20 points of regulation.
- Depth of hip: Of 4.1 to 8.3 cm with 8 points of regulation. (Measured from the axis of rotation of the hip).

The minimum measures correspond to a child of 4 years and the maximum to a girl of 11 years in the 90th percentile.

2.3 TECHNICAL ESPECIFICATIONS

ORTHOSIS	
Type of user	Neuromuscular AME type II, máx 35 kg
Dimensions	250x700x300 mm (Min. size)
Weight	12 Kg
Operating conditions	0ºC to +40ºC, 10 to 90 % RH non-condensing
Autonomy	4 hours depending on the level of activity

POWER SUPPLY	
Dimensions	220 x 95 x 46 mm
Weight	1.25 kg
Input	85 → 264 V ac
Output	24 V dc
Manufacturing	Mean Well
Model	GST280A24-C6P

BATTERY CELLS	
Dimensions	18.40Ø 65 mm
Weight	48 g
Charge time	3 hours
Product	Lithium-ion Battery
Manufacturing	Samsung
Model	INR18650
Nominal Voltage	3.65 V
Configuration in legs (12 V)	3S 1P
Configuration in back (24 V)	6S 1P

BATTERY CHARGER LEGS	
Dimensions	100 x 51 x 63 mm
Weight	250 g
Input	190 -264 VAC
Output	13,7 V 2,7 A
Manufacturing	Mascot
Model	9641

BATTERY CHARGER BACK	
Dimensions	90 × 45 × 32 mm
Weight	150 g
Input	90-264 VAC
Output	27,4 V
Manufacturing	Mascot
Model	2241

3 PREPARATION FOR USE

3.1 GATHERING OF PATIENT DATA

Before the actual session, the following measures must be taken on the child who will use the exoskeleton so that the device can be prepared for the corresponding sizes:

- Trochanter knee length.
- Knee ankle length.
- Hip width (from trochanter to trochanter).
- Hip depth.
- Shoe size

In addition to the major size adjustments mentioned, the design of the exoskeleton allows to perform some minor adjustments:

- The height of the corset with respect to the exoskeleton.
- The height of the breastplate connection.
- The height of the shoe relative to ankle

3.2 START UP

The ergonomics of the exoskeleton are designed to be placed in a seated position. From this sitting position will be transferred to the user who will sit on the orthosis with all the fastenings open. Shin guards fasteners will be opened to allow the user to wear the shoes comfortably.
The leg supports are fixed to a suitable height before seating the user.
The shins attachments are placed just below the knee bone so that the attachment does not disturb the wearer. Once adjusted, it will be tightened with its handle to prevent unwanted movement.

3.3 OPERATION

3.3.1 Size adjustment

The exoskeleton ATLAS 2020 allows the adjustment of sizes, in the length of its segments in children from 4 to 12 years old.

After measurements of each limb of the patient, these measures must be adjusted in shank, thigh and torso.

3.3.2 Software installation

Marsi Bionics provides an application for portable devices such as smart phones and tablets to operate the exoskeleton. This app is suitable for control by the therapeutic specialist. In order to use the application, the following steps are followed:

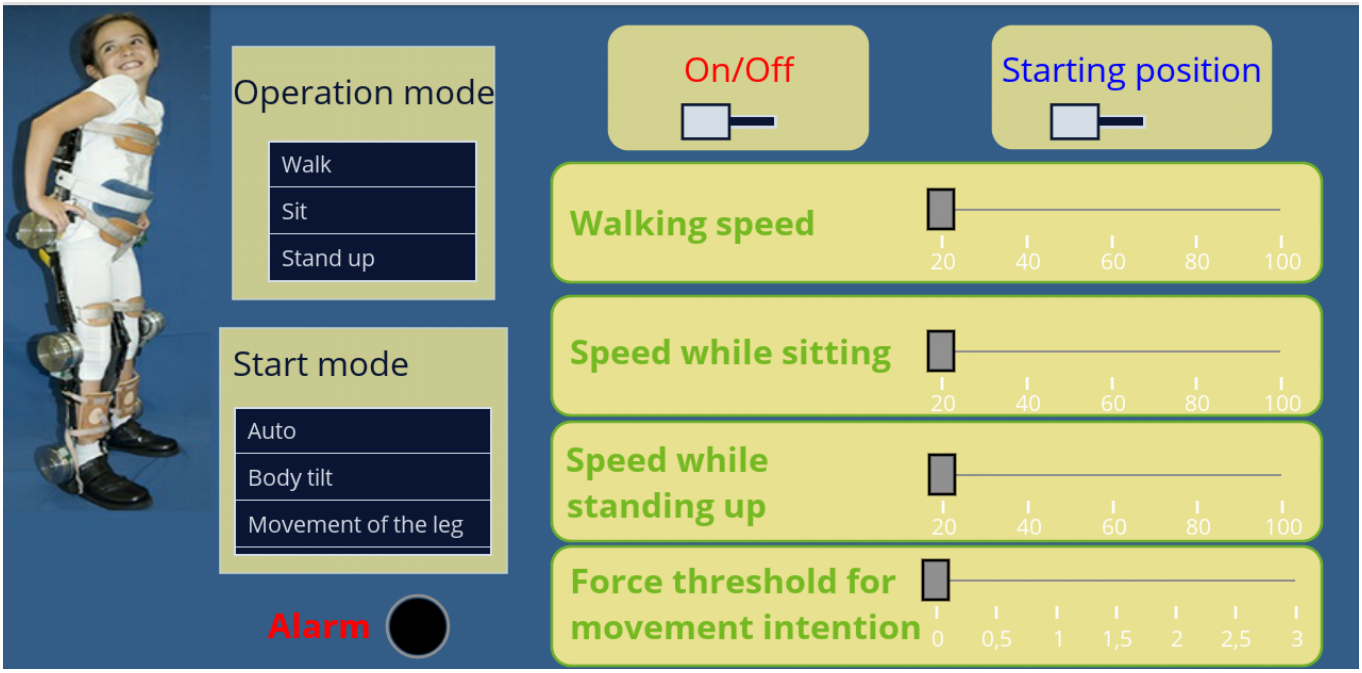
- Install the National Instruments "Data Dashboard" application from the "Play Store"

- Double click on the file "Marsi_app.lvdd" provided by Marsi Bionics to open the application that allows a very complete configuration of the operation as well as monitoring of the exoskeleton function.

3.3.3 Software use

IMPORTANT: Changes to these parameters should be made by personnel with the appropriate preparation and training.

The **main screen** shows the basic commands for the use of the exoskeleton.



As the user moves from the seated position, the “Stand up” button will be pressed in the "Operation mode" box. To start standing up, press the "On/Off" button. The exoskeleton will rise at the speed indicated in "Speed while standing up". Once the "On/Off" button has completely risen, it will automatically go out.

The start of the gait can be configured according to the desired event:

- If the "Auto" command is marked in the "Start mode" box, the exoskeleton will start walking with activation of the "On/Off" command.
- If the "Body tilt" command is marked in the "Start mode" box, the exoskeleton will start walking when the user tilts the body making enough force to exceed that indicated in the field "Force threshold for movement intention".
- If the "Movement of the leg" command is marked in the "Start mode" box, the exoskeleton will start walking when the user moves the leg forward making enough force to exceed that indicated in the field "Force threshold for movement intention".

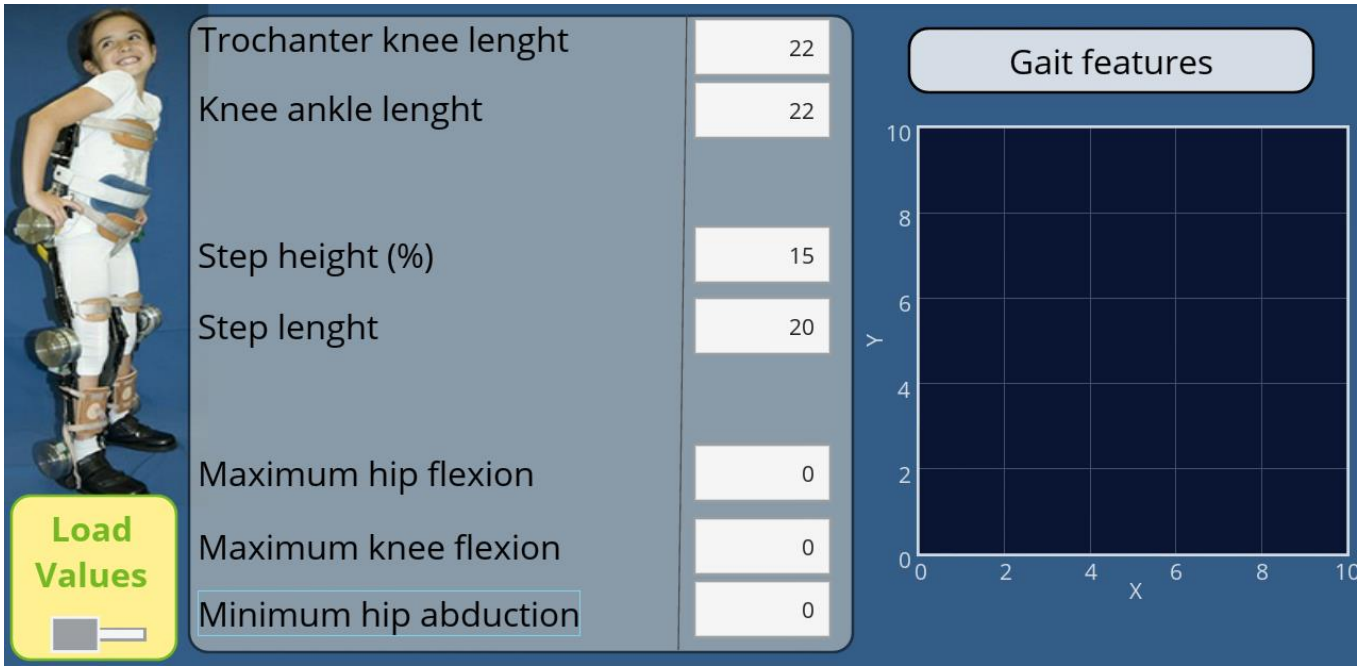
When the run command is received, the exoskeleton will walk at the speed indicated in the "Walking speed" field.

In the case of "Body tilt" or "Movement of the leg" starting command, the exoskeleton only will take one step. To take another step the user have to make the enough force again.

In the case of “Auto” starting command, the exoskeleton will stop when the button will be pressed again.

In any position of the gait, with the exoskeleton stopped, the exoskeleton will return to its standing position, stretched, when pressing the button "Starting position".

If the "Alarm" light were on any critical alarm would have occurred on the device. It will be necessary to send the exoskeleton to the Marsi Bionics service for review.
In the **"Gait features"** screen are introduced the main physiological characteristics of the user, as well as the most important parameters of gait.



In the "Trochanter knee length" and the "Knee ankle length" fields, you specify the user measurements that have been set. The exoskeleton control use this parameters in the kinematics to calculate the ankles of the joints in order to follow an stablished trajectory.

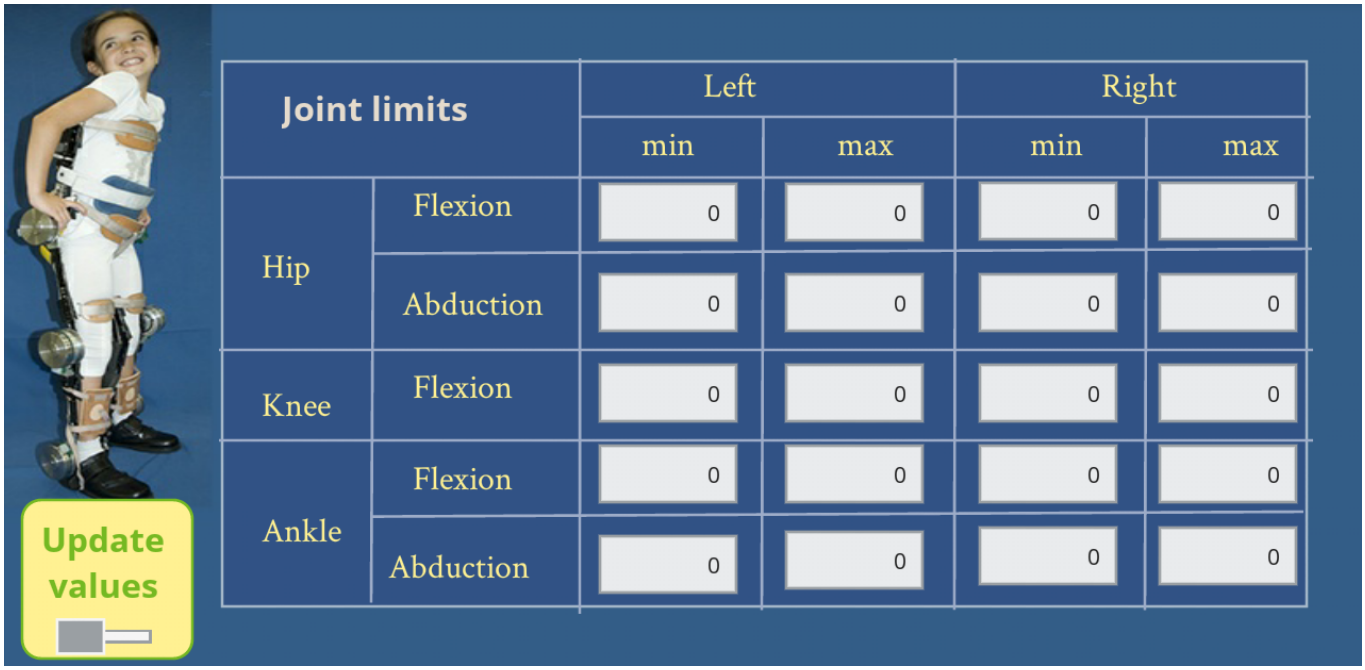
Most of the users have problems with the complete hip and knee flexion. To avoid damage in that cases the fields "Maximum hip flexion" and "Maximum knee flexion" are defined. The kinetics of the gait will be change to avoid exceeding these limit values.

In addition, a minimum of hip abduction is established, for users who may have hip dislocation problems. This value is set in the "Minimum hip abduction" field.

The height and the length of the gait can be changed if it were necessary.

The values introduced in all of these fields will be load when the button "Load values" is pushed.

In the **"Joint limits"** screen appear the maximum and minimum values that are reached when walking with the restrictions established previously. These values should be taken into account in case the user has significant kinematic restrictions. These values will be update when the button "Update values" is pushed.



3.4 CHARGING THE BATERIES OF ATLAS 2020

The ATLAS 2020 exoskeleton has three batteries, two on each leg and one on the back. It has three chargers. The leg loader connectors are distinguished from the one in the rear. The batteries are fully charged after four hours of charging process. The two chargers that charge the batteries of the leg are equal, and the one that charge the back battery is the smaller one. Plugs cannot be interchanged since they only plug into the proper connector.

4 MAINTENANCE

4.1 DAILY MAINTENANCE

Make sure that the orthosis remains in good conditions. Never clean up the surface of the orthosis with water, only wipe with a dry damp cloth.

4.2 SCHEDULED SERVICING

ATLAS active orthosis should by revised by the technical staff of Marsi Bionics in intervals (once every 12 months).

5 STORAGE AND TANSPORT CONDITIONS

The Exoskeleton includes a tailored suit case provided by Marsi Bionics to transport and store in the best conditions.
The orthosis should be stored and transported at temperatures between -5°C and +45°C at a humidity level of 10% to 90% RH, non-condensing, and atmospheric pressure of 700 hPa to 1060 hPa.
To extend battery life, avoid storing batteries at full charge for extended periods of time.
Handle with care.
Do not transport in harsh or marine environments.