UNIVERSITY CEU - SAN PABLO

POLYTECHNIC SCHOOL

BIOMEDICAL ENGINEERING DEGREE

BACHELOR THESIS

Methodology for assembly, setup, and use of the POWERUP exoskeleton.

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July 2023

UNIVERSIDAD SAN PABLO-CEU
ESCUELA POLITÉCNICA SUPERIOR
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Datos del alumno

NOMBRE:

Datos del Trabajo

TÍTULO DEL PROYECTO:

Tribunal calificador

PRESIDENTE:	FDO.:
SECRETARIO:	FDO.:
VOCAL:	FDO.:

Reunido este tribunal el _______/_______/_______, acuerda otorgar al Trabajo Fin de Grado presentado por Don____________________________________la calificación de ____________________.

ACKNOWLEDGMENTS

Finalizar este Trabajo de Fin de Grado no puede sino hacerme reflexionar en todo lo vivido y aprendido durante estos años, significa cerrar una etapa muy especial en la que he crecido en más sentidos de los que jamás creí posible. Es por ello, que quiero agradecer a todas las personas que me han acompañado a lo largo de este camino su apoyo, consejo y cariño.

En primer lugar a mi familia, a mis padres, mi hermano y mi abuela, por guiarme siempre. A Alicia y a mi tía María Teresa, por haber hecho de Madrid un poco más casa.

En segundo lugar, quería agradecer todos los momentos y experiencias vividas con las amistades que me han regalado estos años, así como lo que la experiencia ERASMUS ha aportado a mi vida, y todo lo que me ha enseñado el amor.

Por último, gracias Rafael Raya y Eloy por darme siempre la confianza en este proyecto, por guiarme y ayudarme en este último trabajo.

Gracias.

ABSTRACT

In Spain, currently, approximately 2.8 out of every 1000 inhabitants suffer from cerebral palsy (CP). Cerebral palsy is a group of disorders that affect posture, balance, and movement, and it is attributed to non-progressive impairments that occur due to inadequate development or injuries to the immature brain. These impairments cause limitations in the activity of affected individuals. In recent years, various exoskeletons have been developed with the aim of promoting and correcting motor control in these patients, in order to improve their therapy.

In this project, a series of assembly and usage manuals have been created for a 3D-printed passive upper limb exoskeleton. The purpose is to share these manuals on an open-source platform, so that any hospital or rehabilitation center can assemble and use the exoskeleton autonomously.

RESUMEN

En España, actualmente, aproximadamente 2.8 de cada 1000 habitantes sufren parálisis cerebral (PC). La parálisis cerebral es un conjunto de trastornos que afectan la postura, el equilibrio y el movimiento, y se atribuye a alteraciones no progresivas que ocurren debido al desarrollo inadecuado o a lesiones en el cerebro inmaduro. Estas alteraciones causan limitaciones en la actividad de las personas afectadas. En los últimos años, se han desarrollado diversos exoesqueletos con el objetivo de promover y corregir el control motor en estos pacientes, con el fin de mejorar su terapia.

En este proyecto, se han creado una serie de manuales de montaje y uso para un exoesqueleto pasivo de miembro superior fabricado mediante impresión 3D. El propósito es compartir estos manuales en una plataforma de código abierto, de manera que cualquier hospital o centro de rehabilitación pueda montar y utilizar el exoesqueleto de forma autónoma.

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1 INTRODUCTION

1.1 Cerebral palsy overview

1.1.1 Definition and classification

Cerebral palsy (CP) is a neurological disorder that affects mobility, posture, balance, and limits activity, it is caused by brain injury or malformation, the injury typically occurs before brain development is complete, during gestation, childbirth, or the first three years of a child's life when the central nervous system is maturing [1-2], leading to motor disabilities, as well as cognitive, communication, and sensory impairments. These disabilities may also cause behavioral disturbances, seizure disorders, or a combination of features. [3-5].

The most common cause of childhood motor paralysis is Infantile CP (ICP), which refers to the loss of sensory or motor function in children [6]. Prevalence is determined by population surveys and indicates the number of children with CP in a specific population during a given period. Incidence is calculated by dividing the number of children who develop CP in a defined region by the number of neonatal survivors in that region [7]. In Spain, the current prevalence rate is 2.8 per 1000 inhabitants, and the frequency increases to 40/1000 live births in premature infants. About 120,000 people in Spain are affected by CP, and around 10,000 newborns in the European Union are diagnosed with it every year [8].

ICP is a syndrome that originates in the Central Nervous System (CNS) first neuron or upper motor neuron. It encompasses all non-progressive neurological injuries occurring during the prenatal, perinatal, and postnatal stages, resulting in motor dysfunction due to encephalic damage [2,3,6,9]. Many pathologies with different causes are included because they all produce a clinical picture with common features, such as delayed motor development, delay in the development of postural balance mechanisms or postural reflexes, and persistence of primitive reflexes that have already integrated or disappeared as neurological maturation progresses.

In many cases, the cause of CP is unknown. Many factors can contribute to problems with brain development [10]. Some examples include:

- Gene mutations that cause genetic disorders or differences in brain development.
- Maternal infections that affect the developing fetus.
- Fetal stroke, disruption in blood supply to the developing brain.
- Bleeding into the brain while in the womb or as a newborn.
- Infections in infants that cause inflammation in or around the brain.
- Traumatic head injury to an infant, such as from a car accident, a fall, or physical abuse.
- Lack of oxygen to the brain as a consequence of difficult labor or delivery.

CP can be classified in different ways [1], taking into account factors such as postural tone and topography. The classification that holds the most significance is described below.

Categorizing CP based on motor type involves considering the primary motor problem and the level of impairment. This classification is crucial for determining the appropriate treatment approach and predicting the outlook for the individual. The classification provided (See Table 1) aligns with this motor type and postural tone categorization.

Table 1 Classification of CP by Motor Type and Postural Tone.

Spastic cerebral palsy (60-70%)	Patients have difficulty controlling some or all their muscles, which can become stiff and weak. This is typically caused by dysfunction of the nerve cells in the outer layer of the brain
Dyskinetic or athetoid cerebral palsy	Characterized by slow, involuntary movements that worsen with fatigue and emotions, and uncoordinated movements that hinder voluntary activity. Those with athetoid CP often have muscles that change quickly from loose to tight, and they may struggle to control their arms, legs, tongue, breathing, and vocal cords due to central brain

	dysfunction.
Ataxic cerebral palsy	Difficulty controlling their balance due to a lesion in the cerebellum. They may still be able to walk, but in an unstable way.
Mixed cerebral palsy	Brain has lesions in multiple structures, resulting in a combination of characteristics from different types.

In addition to motor type, CP can also be classified the part of the body that is affected, thus having a topographical classification (See Table 2), CP can be divided into five groups based on the location and severity of the damage inflicted.

Table 2 Classification of CP by Topography.

Hemiplegia	Disability is only present on one side of the body, either left or right.
Paraplegia	Affects mostly the lower limbs.
Quadriplegia/Tetraplegia	Both arms and legs are affected.
Diplegia	Affects both legs, with little or no involvement of the arms.
Monoplegia	Only one limb is affected.

Finally, cerebral palsy can also be classified according to its severity (See Table 3), this refers to the degree of motor impairment and functional limitations experienced by the individual. The severity can range from mild to severe and helps determine the level of assistance and support required. This classification provides valuable information for treatment planning and prognosis.

Table 3 Classification of CP by Severity.

Mild	Patient is not limited in daily activities but may have some physical impairments.
Moderate	The individual has difficulties in performing daily activities and requires assistance or support.
Severe	The person needs assistance for all activities.

1.1.2 Diagnosis and treatments

Early signs of cerebral palsy (CP) play a crucial role in facilitating an early diagnosis. Some of these signs include [10]:

- Abnormalities of muscle tone: These can manifest as hypertonia, characterized by hyperextension of the head and trunk, extensor activity of the arms, and intermittent extensor spasms. Alternatively, hypotonia may be observed, presenting as low postural tone, reduced activity, and joint hypermobility.
- Thumb enclosed in palm.
- Persistence of archaic reflexes.
- Hyperextension of both lower extremities when suspended in the axillae.
- Absence of straightening reactions.

All people with CP have movement and posture issues. Other functions such as attention, perception, memory, language, and reasoning may also be affected by the injury. Some people have intellectual disabilities, whereas others do not. Therefore, cerebral palsy is referred to as a multi-disability condition.

It is critical to understand that CP is a permanent disorder, this implies that the neurological lesion that has occurred is irreversible and persists throughout life. The lesion does not change, it is immutable. The neurological damage does not increase or decrease although the consequences and the symptoms that manifest themselves may change, improve, or worsen.

Once a diagnosis of CP has been established, it becomes crucial to comprehend the available rehabilitative, medical, and therapeutic interventions. In this regard, a compilation of treatments proven to enhance the health and independence of patients with CP has been assembled.

Rehabilitation of body functions encompasses a variety of methods and approaches aimed at improving function and quality of life for those affected by the condition. These methods focus on addressing the physical, cognitive, and communication limitations. There are various treatments options available [11]:

- Physiotherapy: Aims to improve muscle strength, coordination, balance, and mobility. This is achieved through specific exercises and techniques tailored to the individual needs of the patient.
- Occupational therapy: Points to develop fine motor skills, improve hand-eye coordination, and promote independence in daily activities such as dressing, eating, and writing. Customized techniques and adaptations are used to address functional difficulties.
- Speech-Language Therapy: Focuses on improving oral communication, speech articulation, fluency, and understanding of language. It may also include alternative communication strategies, such as the use of assistive communication devices.
- Behavioral and Educational Therapy: Used to develop cognitive, social, and emotional skills. This may include personalized teaching programs, behavior modification techniques, and psychological support.
- Use of Aids and Adaptations: Environmental aids and adaptations, such as wheelchairs, orthopedic devices, assistive devices, and assistive technology, can facilitate mobility, communication, and participation in daily activities.
- Medical and Surgical Interventions: In specific cases, medical and surgical interventions may be used, such as the administration of drugs to reduce spasticity, the application of botulinum toxin, orthopedic surgery, or deep brain stimulation.

The overarching goal is to reduce muscle tone, increase range of motion, enhance functionality, and promote independence in daily activities. It's important to note that CP rehabilitation is a multidisciplinary approach involving a team of healthcare professionals, such as physiotherapists, occupational therapists, speech therapists, psychologists, doctors, and specialists, who collaborate to create personalized treatment plans and provide comprehensive support for individuals with CP.

1.2 Rehabilitation robotics

An exoskeleton is an external technology that helps people with motor disabilities or impairments to enhance, retain, or improve their functional abilities. They come in different forms such as upper limb exoskeletons, lower limb exoskeletons or full body exoskeletons, and can be made of hard or soft materials. They are powered by various energy sources, such as electric, hydraulic, or fully mechanical systems, which are passive exoskeletons [12].

1.2.1 Lower limb exoskeletons

Lower limb exoskeletons are a rapidly evolving technology and there is a lot of research being done in this field. A review of the literature shows that powered lower-limb exoskeletons are emerging as a suitable robot-aided therapy for human-impaired locomotion [13]. Medical and rehabilitation exoskeletons are being increasingly considered by therapists when choosing a treatment for individuals affected by lower limb impairments [14] (See Figure 1).

- Lokomat [15]: robotic gait training system that assists individuals with walking impairments. It provides highly repetitive and intensive gait therapy in a controlled and safe environment.
- ReWalk [16]: Powered exoskeleton system that enables individuals with spinal cord injuries to stand upright and walk. The system uses a controller on the wrist to control the movement of the exoskeleton. It is designed to be used in rehabilitation centers and at home.
- Ekso Indego [17]: Powered exoskeleton developed by Ekso Bionics, that enables individuals with spinal cord injuries to stand upright and walk. The system uses a controller on the wrist to control the movement of the exoskeleton. The Indego exoskeleton is designed for use in rehabilitation centers and at home.

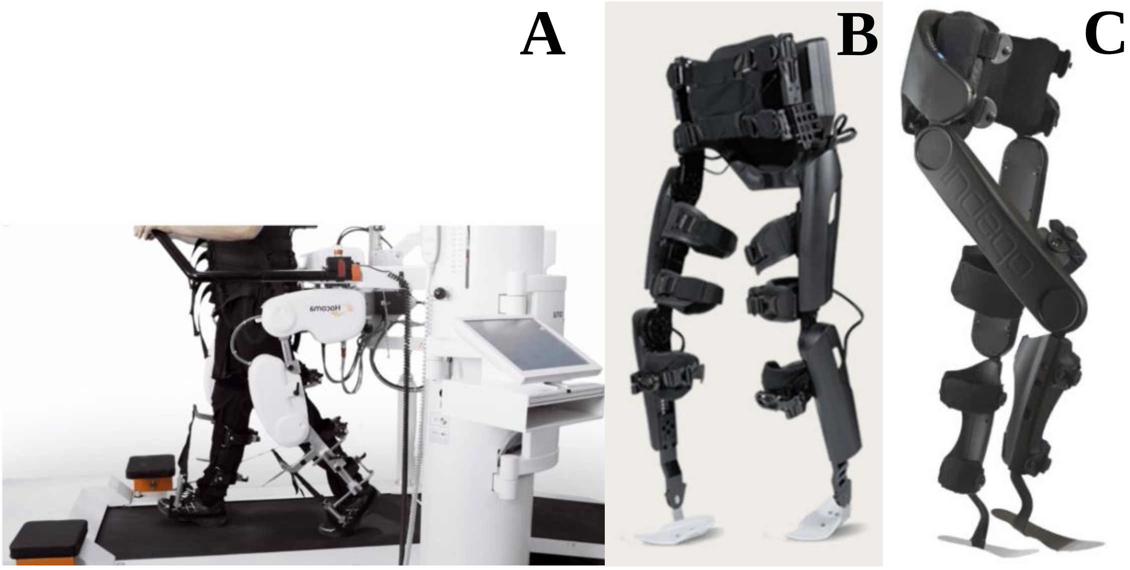


Figure 1 A. Lokomat [15] - B. ReWalk [16] - C. Indego[17].

1.2.2 Upper limb exoskeletons

Over the past decade, there has been a significant advancement in robotic systems for the rehabilitation of sensorimotor deficits [18-19], which allows standardizing training protocols, adapting support, and regulating the intensity and duration of therapy while reducing the effort of clinical staff. Also, they enable the creation of particular movement sequences and objectives by collecting sensory information. Robotic applications in CP have demonstrated positive results recently [20-22].

There are various upper limb exoskeletons available in the market, such as the WREX [23], T-WREX [24], and Armeo Spring [25] systems standing out (See Figure 2), which have been used as the basis for designing the POWERUP exoskeleton.

- WREX exoskeleton [26-27]: uses elastic bands to counteract the effects of gravity, it generates a feeling of being weightless for the patient to ease the movement of their upper limbs, allowing people with neuromuscular weakness to move their arms in three dimensions. It has 4 degrees of freedom (DoF), which correspond to shoulder flexion-extension and abduction-adduction, elbow flexion-extension, and humeral internal-external rotation. and is designed to be adaptable to a child's anatomy using 3D printing technology.

- T-WREX exoskeleton [28]: is an evolution of the WREX system, incorporating position and pressure sensors to record joint angles and grip moment, respectively. It is used in conjunction with a graphical interface that simulates functional activities to improve upper limb skills.
- The Armeo Spring exoskeleton [29-30]: is a 5 DoF orthosis that includes 7 angular sensors and a pressure sensor in the handle, along with a spring system with configurable intensity. It also has a graphical interface for functional exercises that records movement data, and studies show it to be effective for people with cerebral palsy.

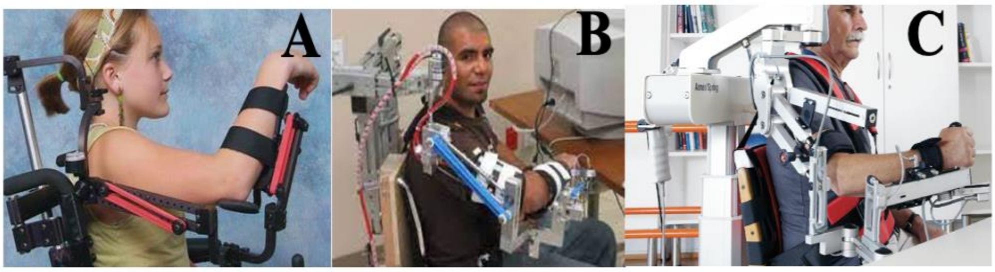


Figure 2 A. WREX [26] exoskeleton - B. T-WREX [28] - C. Armeo Spring [29].

Robotic therapy has the potential to enhance functional strength and enhance isolated movements. By ensuring consistent assistance, adjusting intensity and complexity based on the patient's progress, and incorporating virtual reality interfaces, it can contribute to improve patient motivation and facilitate the performance of daily activities [4].

1.2.3 Upper-limb 3D-printed exoskeletons

The exoskeleton used in this project is fabricated using 3D printing technology. To provide a better understanding of current 3D prototypes, a brief explanation of a research prototype based on 3D printing for medical rehabilitation will be presented [31].

The exoskeleton used in this project is manufactured using 3D printing technology, an innovative approach to medical rehabilitation. One example of a research 3D prototype is the EAsoft [32] module for neurorehabilitation (EAsoftM), which employs a combination of soft materials and active exoskeleton components. By integrating 3D-printed structures with passive and active joints, the lightweight system assists with planar reaching motion and utilizes visual feedback. The use of soft materials and pneumatic actuation provides flexibility and support during reaching movements. Another application of 3D printing in rehabilitation is a hand exoskeleton designed for post-stroke therapy [33]. Clinical testings have shown that this low-cost robotic gear, powered by an embedded controller and servomotors, increases finger range of motion and hand dexterity for simple activities.

1.3 POWERUP exoskeleton

POWERUP is a 3D-printed orthosis for upper limb rehabilitation. The system was developed by the Bioengineering lab of CEU university between 2019 and 2022. This project aims at making this technology accessible for all type of care centers worldwide, following a “do-it-yourself” approach. Any care center could download all the required resources to manufacture the exoskeleton and use it. However, this is not an immediate task. Previous to publish all the drawing of the exoskeleton, it is necessary to study the affordability and accessibility of the exoskeleton to guarantee the success. In this context, this work has the objective of defining the guidelines of assembly, setup and use of the exoskeleton POWERUP. The next stage of the project involves developing an instruction manual and uploading it onto a public repository to enable hospitals and rehabilitation centers to print, assemble and use the exoskeleton independently [34].

The primary objective of this exoskeleton is to reduce the physical disability experienced by children with CP in their everyday life, allowing them to improve their physical abilities and carry out essential daily activities after rehabilitation. It is essential to note that although the device aims to enhance patients' lives, it is created as an assistive tool to be utilized during therapy and rehabilitation sessions.

Furthermore, the exoskeleton is created using 3D printers, which provide the device's structure with sufficient flexibility and rigidity to function correctly. The most commonly used thermoplastic filament materials in 3D printers are ABS and PLA, which melt out of the extruder during printing and harden as they cool. Another significant advantage of this exoskeleton is its low manufacturing cost compared to other exoskeleton production processes.

The exoskeleton has 5 degrees of freedom, which correspond to the next movements:

- Shoulder pieces, which allow:
  - Shoulder extension and flexion
  - Internal and external shoulder rotation
- Elbow pieces perform:
  - Elbow extension and flexion
  - Internal and external elbow rotation
- Wrist pieces, that support:
  - Pronation and supination movements

The components comprising the exoskeleton prototype, including assembly, setup, usage, and validation processes are illustrated in Figure 3.

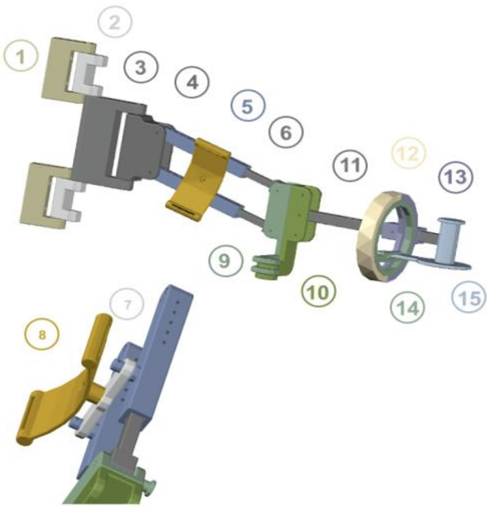


Figure 3 Exoskeleton and number of pieces.

The POWERUP exoskeleton is anchored to an external metal rolling frame (see Figure 4) This structure is easily moveable and can be adjusted to the user's shoulder height. The wheels are locked once in a convenient position to prevent unintentional displacement during training sessions.

Figure 4 General view of POWERUP exoskeleton.

POWERUP has a dual function mechanism for elbow flexion and extension movement: assistance and resistance. The assistance mode provides anti-gravity weight support, assisting patient in lifting and maintaining the weight of their arm, thereby improving flexion movement. As a resistive movement, the resistance mode opposes flexion, so patient must exert extra effort to perform any activity that involves bringing the arm closer to the trunk. The goal of this mode is to provide a pro-gravity effect that promotes muscle tone gain or maintenance. A physiotherapist is responsible for and supervises the therapeutic prescription of the use of these modes.

This assistance-resistance method is implemented in the exoskeleton through lugs and elastic rubbers. The assistance or resistance mode is selected depending on which lugs the band is placed on.

The exoskeleton can carry elastic rubbers to assist or resist shoulder flexion and extension, as well as to assist or resist elbow flexion and extension. Elastic bands can also be used to prevent the elbow internal flexion that occurs naturally in many people with upper-limb motor disabilities.

Assistance mechanism is shown in blue and resistance mechanism in red (see Figure 5), what translates into shoulder flexion and extension.

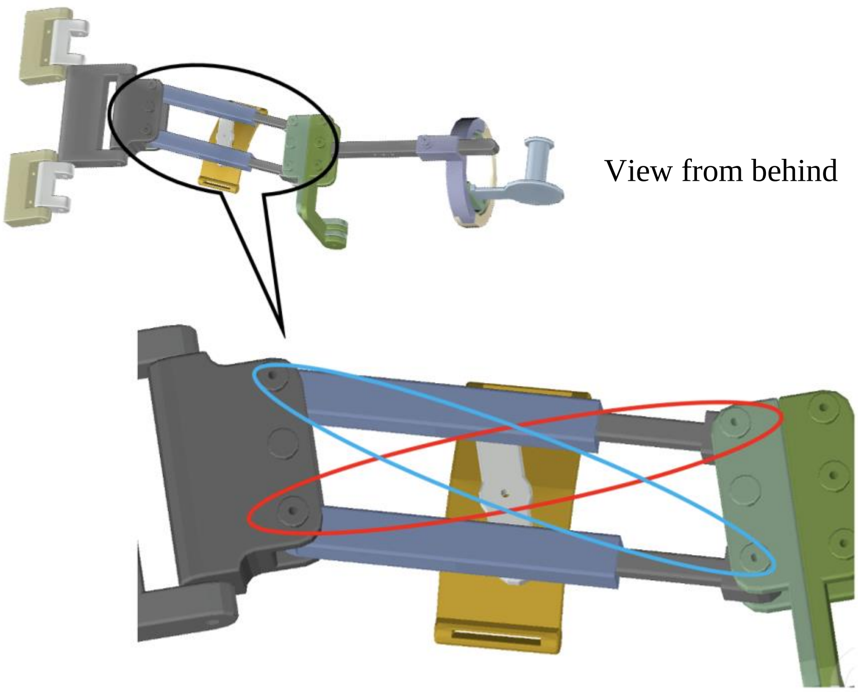


Figure 5 Elastic rubbers positions for shoulder flexion or shoulder extension assistance (AutoCAD 2023).

Assistance mechanism is shown in blue and resistance mechanism in red (see Figure 6), what translates into elbow flexion and extension.

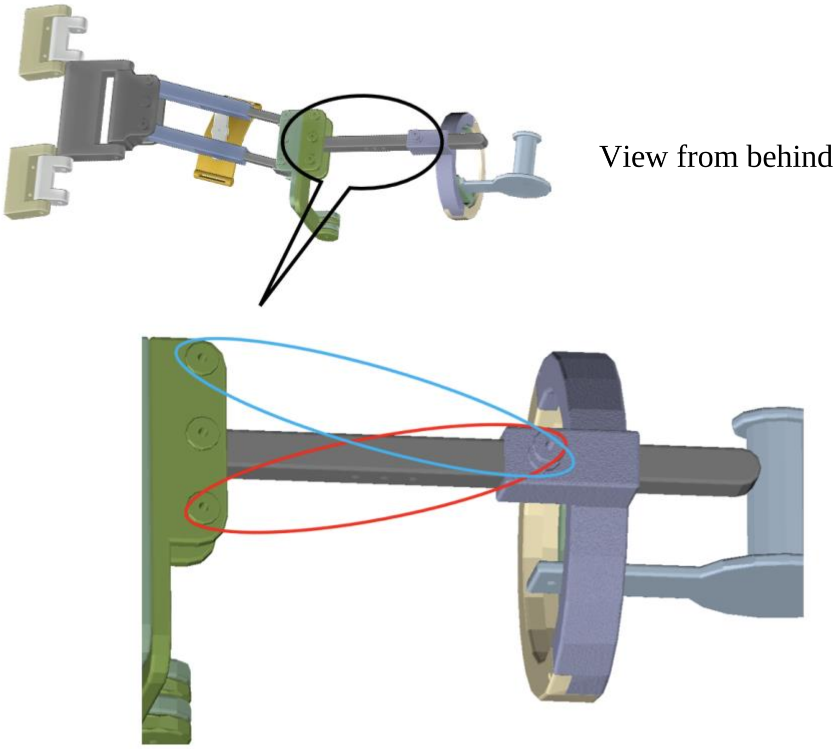


Figure 6 Elastic rubbers positions for elbow flexion or elbow extension assistance (AutoCAD 2023).

Elastic rubbers position for blocking elbow internal flexion (see Figure 7), for assisting patient forcing them elbow extension. This combination allows abolish the elbow internal flexion that many patients with CP have by default. Elastic rubbers always must be between middle lugs for avoiding interferences with shoulder or elbow flexoextension.

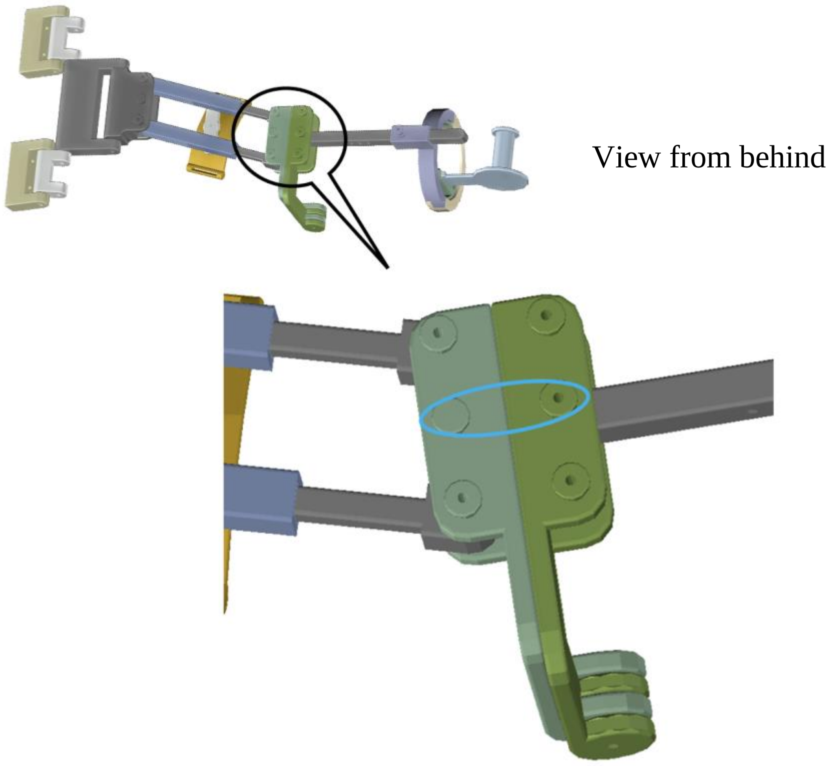


Figure 7 Elastic rubbers position for blocking an external rotation elbow position (AutoCAD 2023).

The main purpose of the elastic rubbers is to allow the exoskeleton to evolve in tandem with the patient's arm strength. If the user lacks the muscle strength to lift their arm during the first session, several rubber bands can be used to help. As the patient requires less assistance, the number of rubber bands used may decrease as the sessions progress. Once the user can lift and move their arm completely without assistance, elastic rubbers can be used in the resistance position.

1.4 Videogames

The POWERUP exoskeleton aims to integrate video games into the rehabilitation process as a supplementary rehabilitation component. These specially designed video games provide interactive activities that focus on enhancing motor skills and promoting functional recovery. By incorporating gamification elements, the rehabilitation experience becomes more enjoyable and motivating for patients, leading to increased participation and progress in therapy sessions. The inclusion of video games adds an innovative and dynamic aspect to the rehabilitation program, creating an immersive and stimulating environment where patients actively engage in their own recovery.

In the field of upper limb rehabilitation, several systems have utilized video games and various human-computer interfaces. Two notable examples are [35] (See Figure 8):

- The InMotion2 system [36], a commercial version of MIT-MANUS, has been used successfully in children with upper limb hemiplegia caused by cerebral palsy. The technology demands users to move their arms and shoulders while interacting with a 2D video game that needs them to reach for things on the screen. Positive results were assessed, and families reported improvements in daily activities.
- Haptic Master system [37], created in cooperation with the New Jersey Institute of Technology, this system comprises a custom-built gimbal with several degrees of freedom and force control. It has been employed in augmented reality environments with children with cerebral palsy, providing an interesting and interactive therapy experience.

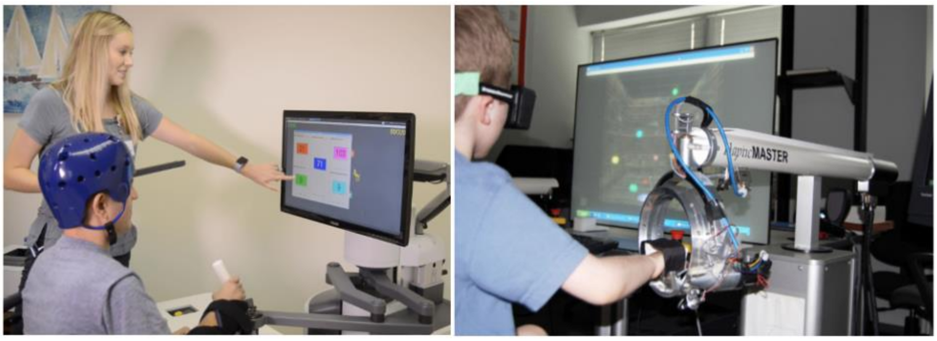


Figure 8 InMotion2 [36] (left), Haptic Master (right) [37].

1.5 Objective

The primary aim of this study is to prepare assembly and usage guides for the POWERUP upper limb passive exoskeleton. Additionally, usability and satisfaction analysis of the exoskeleton will be conducted, along with its validation through focus groups in both real and virtual reality environments.

To evaluate the proposed guidelines, a survey was conducted involving two physiotherapy students from the CEU University for the assembly and setup and a group of clinical professionals (physiotherapists and occupational therapists) to evaluate functional aspects of the use from their subjective perspective. The setup was evaluated by 2 students who assembled the exoskeleton using the provided manuals and later completed questionnaires to assess their experience during assembly and usage. The sessions took place in June at the San Pablo CEU University.

Furthermore, the use of the exoskeleton underwent evaluation in focus group sessions conducted by clinical specialists from the Neuroped rehabilitation center and the María Isabel Zulueta special needs school (Madrid, Spain). These sessions aimed to assess the practical functionality and effectiveness of the exoskeleton in real-life scenarios.

Following the trials, a data analysis was performed using all the collected data to draw conclusions regarding the accessibility of the manuals and identify areas for mechanical, functional, and ergonomic improvements.

The ultimate objective of the POWERUP project is to make the technical documents available online at the website www.exopowerup.com, allowing them to be printed and used in daycare centers and rehabilitation facilities once they have been validated and are fully functional.

The next section will provide a description of the materials, clinical trials, and methodology undertaken to achieve these objectives.

2 MATERIAL AND METHODS

In this section, the POWERUP platform will be explained, which includes the exoskeleton, the videogames research and the focus groups realized. Following, the clinical trials will be described, including the centers involved and the participants in the study, their characteristics, and explanation of how the sessions were. The final subsection will explain the methodology for analyzing the results data.

2.1 Materials

2.1.1 POWERUP analysis

The POWERUP, is a passive orthosis that has been designed to enhance upper limb rehabilitation in children with different motor disabilities implying upper limb limitations like Cerebral Palsy. This research project is supported by funding from the Spanish Ministry of Science and Innovation and is being developed by the Bioengineering research team at San Pablo CEU University in Madrid, Spain [38-39].

The design of the exoskeleton was developed according to clinical and functional criteria established by the clinicians at the Institute of Functional Rehabilitation La Salle in Madrid, Spain. Its primary purpose is to facilitate elbow and shoulder movements while providing stability. Additionally, it aids in controlling the flexion and extension of these joints while maintaining the wrist and hand in a neutral position.

The exoskeleton is constructed entirely using 3D printing technology, utilizing PLA filament derived from renewable and organic sources. This choice of material not only ensures a lightweight and cost-effective solution but also allows for easy replication, enabling wider access to this rehabilitation device. Recognizing the user-friendliness importance, next phase of the project involves creating clear instruction manuals, enabling individuals to assemble and use the exoskeleton independently without the need for technical assistance.

To facilitate the creation of comprehensive assembly and use manuals for the POWERUP exoskeleton, two powerful software tools were employed: AutoCAD and Autodesk Inventor.

AutoCAD [40], a widely recognized tool in the fields of engineering and industrial design, renowned for its capability to generate 2D and 3D models, provided a platform for visualizing the different components of the exoskeleton. AutoCAD enabled to gain a deeper understanding of the exoskeleton's structure, spatial relationships, and overall functioning. By examining the virtual representation of the exoskeleton, they were able to accurately document the assembly process and articulate the necessary steps concisely.

In parallel, Autodesk Inventor [41], a powerful computer-aided design (CAD) software widely embraced in the industry, played a vital role in the optimization of the exoskeleton's design. By subjecting the original design to analysis, different areas were identified for improvement and fine-tuning. This process involved remodeling various pieces of the exoskeleton based on the insights and recommendations gathered.

2.1.2 Evaluation scales

A systematic literature research was conducted following the PRISMA guidelines [42]. Google Scholar was used for searching relevant studies published within the last 10 years. The search terms used included "exoskeleton," "instruction manual," "satisfaction," "usability," and "evaluation". Additionally, Mendeley [43], a reference management software, was employed to facilitate the organization and citation of research papers, making the process of creating bibliographies more efficient.

Usability evaluation

By employing the PRISMA approach, which ensures a comprehensive examination of usability validation scales in comparable contexts, a search yielded approximately 2,000 results. After removing duplicates, the remaining articles were screened based on their titles and abstracts to assess their relevance to the research topic. This screening process reduced the number of articles to 500.

Next, specific criteria was applied for relevance, the selection narrowed down to the ten most significant papers that met the following requirements: they had to be scientific publications, that evaluated exoskeletons of upper limbs, and were intended for rehabilitation or assistance. The intention was to identify scales suitable for assessing the usability of the POWERUP exoskeleton instruction manual.

This review revealed a body of literature supporting the use of the System Usability Scale (SUS) [44] for evaluating the usability of diverse technologies, including medical devices and software applications. Although several studies have focused on applying SUS to assess the usability of different assistive devices, such as exoskeletons [45-47], none of them specifically addressed the validation of their instruction manuals. The SUS, originally developed by Brooke in 1996, serves as a widely utilized tool for evaluating system usability and comprises 10 statements rated on a five-point scale ranging from "Strongly Disagree" to "Strongly Agree."

Satisfaction Evaluation

In line with PRISMA methodology, this review identified a body of literature supporting the use of the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) [48] scale to assess user satisfaction in various domains, including the use exoskeletons [49-50]. However, there are limited studies specifically investigating the use of this scale to assess the assembly and setup of assistive devices. These two aspects, specially the latter one, are considerably important because they can put at risk the use of the device.

The QUEST 2.0 scale is a standardized questionnaire consisting of 12 items rated on a 5-point satisfaction scale, accompanied by a comment section to gather additional user feedback. This scale assesses satisfaction across multiple dimensions, including the adjustability and dimensions of the exoskeleton, its weight, safety, durability, ease of use, comfort, and effectiveness. Its comprehensive nature makes it a suitable tool for evaluating the satisfaction of exoskeleton instruction manuals.

2.1.3 Virtual reality scenarios

Virtual reality involves interactive simulations that provide users with opportunities to engage in virtual environments that resemble real-world objects and events.

Due to its unique attributes that offer realistic and motivating opportunities for active learning, these technologies have been increasingly utilized in pediatric rehabilitation in recent years, as they have become more accessible and affordable. As a result, they have gained popularity among healthcare professionals working in rehabilitation [51-52].

Based on the aforementioned concept, a search was conducted to identify various games that could prove beneficial in rehabilitation sessions. The objective was to find interactive experiences that have target specific therapeutic goals. By incorporating gaming elements into the rehabilitation process, it becomes more enjoyable and motivating for the patients undergoing therapy. We can categorize the games into different groups:

- Simulation and virtual experiences: Hand Physics Lab [53] provides a virtual environment where users can interact with virtual objects, promoting fine motor skills and hand-eye coordination. Curious Tale of the Stolen Pets [54] encourages problem solving and cognitive skills.
- Sports and physical activities: games like Just Hoops [55], Sports Scramble [56], and Dance Central [57] provide opportunities for users to engage in sports, exercise, and dance moves. These games focus on improving motor skills, coordination, balance, and overall fitness.
- Other games like ForeVR Darts [58], The Climb [59], and Dash Dash World [60] offer challenging, competitive gameplay that promotes goal setting, focus, and perseverance.

The aim is to assets of virtual reality for rehabilitation purposes and ensure it is adapted to the cognitive, motor, and emotional capabilities of the patient within the context of specific therapeutic goals.

2.1.4 Real scenarios

To assess the performance of the POWERUP exoskeleton, various focus groups were conducted with experts from different specialized centers. By engaging specialists from diverse backgrounds, the focus groups provided a valuable feedback and insights regarding the exoskeleton's performance. The primary objective was to identify potential enhancements in the exoskeleton's mechanical, functional, and ergonomic aspects when used in real-world scenarios.

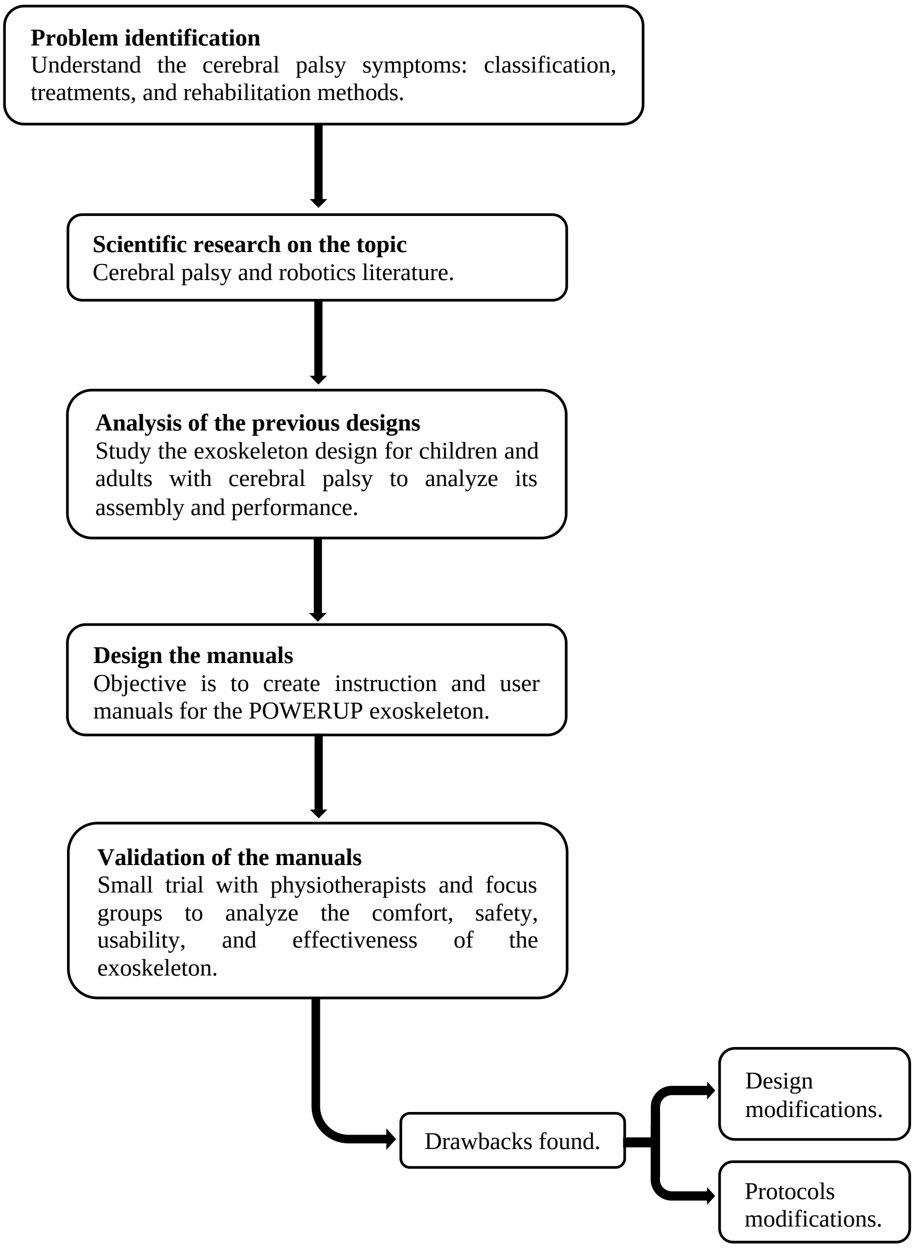
The insights gathered from these sessions were aimed at further implementation to improve exoskeleton rehabilitation capabilities.

To assess exoskeleton performance in real-world conditions, the use of BlazePod [61], a reactive light training system, was explored as a potential assessment method. This approach aimed to investigate the advantages of integrating interactive training techniques with the exoskeleton.

By incorporating BlazePod into the testing process, the goal was to create a dynamic and engaging rehabilitation experience, as the reactive lights provide visual stimulation, measure reaction time, and could test coordination when used in conjunction with the exoskeleton.

2.2 Methodology

The following section will discuss the methodology used during the development of this project, showing the different steps that have been followed for the development of the exoskeleton's manuals, form the gathering of information, the design of the manuals, and the process of validation and clinical trial.



2.2.1 Assembly design and set up

This project builds upon a prior exoskeleton developed under the POWERUP initiative, aimed at assisting individuals with cerebral palsy.

The primary goals of this project are to develop user-friendly instruction manuals, these manuals are designed to enable anyone to easily assemble and operate the exoskeleton, providing clear explanations of its mechanics and functionality in both assistive and resistive modes. The aim is to make the assembly and usage of the exoskeleton accessible to individuals without the need for technical assistance.

Additionally, the project aims to identify potential limitations in both the design of the manuals and the exoskeleton itself, and to propose alternative solutions for further evaluation, with the objective of enhancing previous designs.

The starting point involved conducting a comprehensive study on cerebral palsy, considering its significant impact on neuromotor function. The research was conducted to explore the various exoskeleton options available, with a specific emphasis on upper limb exoskeletons.

In the next step, the POWERUP exoskeleton was thoroughly examined to comprehend its assembly procedure and sequence, aiming to identify the most straight forward approach for explaining it and outlining its subsequent usage. To achieve this, the AutoCAD tool was employed, allowing for optimal visualization of the different components and perspectives of the exoskeleton. Based on the analysis, an initial set of manuals was developed, comprising two main components:

- Assembly Instructions Manual (See Annex 1): This guide adopted a friendly style, following the technical manual of leader companies e.g. IKEA [62], this minimalist approach emphasize simplicity and clarity in conveying the assembly process of the exoskeleton.
- User Manual (See Annex 2): In the search for existing exoskeleton manuals examples, the Apex exoskeleton user manual [63] was chosen as a reference due to the low number of exoskeleton user manuals accessible and the lack of 3D exoskeletons discovered. The manual was

chosen because, like POWERUP, it is a passive exoskeleton, but APEX is designed to help workers reduce back strain and lower the risk of musculoskeletal ailments during working days. Despite the fact that other manuals were considered, the Apex Exoskeleton Manual stood out as an example, offering a good instructional design and user-friendly material. The manual designed, provides a detailed explanation of the mechanics, correct positioning, and functionality of the exoskeleton. It stands out that the operation of the exoskeleton is subject to the placement of the elastic bands, resulting in two different modes:

- Assistance mode, the exoskeleton supports and assists movement, making tasks easier.
- Resistance mode, the exoskeleton creates a challenging environment that promotes muscle activation and strength development.

In this way, users can maximize the benefits of the exoskeleton by selecting the appropriate mode based on their specific needs and goals.

2.2.2 Design of protocols of use in clinical scenarios

Following the development of the assembly and use manuals, a testing phase was carried out. In order to assess their effectiveness, various evaluation methods were explored, leading to the creation of questionnaires that targeted the usability of both manuals and user satisfaction (See Annex 3).

The evaluation process encompassed two distinct scenarios. Firstly, physiotherapists at San Pablo CEU University engaged in the assembly and independent familiarization of the exoskeleton only through the aid of the manuals. Their experiences were then evaluated to measure the manuals' usability in facilitating the assembly and usage processes.

Additionally, focus groups were organized to gather further insights and feedback. These sessions enabled participants to share their perspectives on the manuals and contribute to the overall assessment of their usability and effectiveness. The evaluation process encompassed two distinct scenarios: virtual reality and real-world environments.

Real task scenario

During the initial clinical stage, a one-month trial period was provided in collaboration with the Neuroped Integral Pediatric Neurorehabilitation Center [64] and the Maria Isabel Zulueta Special Education Center [65], in which patients performed daily life movements and participated in interactive sessions that involved direct interaction with real goal-directed manipulative tasks while wearing the exoskeleton. A focus group was then held to obtain information and feedback on their experience. Specific needs were identified during this process, such as requirements for various improvements in anatomical fit, ergonomics, and enhanced comfort, among other aspects.

To test it, the centers received the BlazePod kit (See Figure 9), a reactive light training system used for various purposes, including improving reaction time, agility, coordination, and cognitive skills. The system consists of small wireless LED modules that can be placed in different locations. These pods are controlled via a mobile app, allowing users to customize and create interactive, light-based workout routines.

These sessions were intended to provide a dynamic and engaging environment for patients, allowing them to actively participate and experience the benefits of combining play with exoskeleton technology.

Figure 9 BlazePod kit [61].

Virtual reality scenario

In the second scenario, multiple Focus Group meetings were held, involving a comprehensive analysis of different virtual reality applications. Several criteria were considered when selecting games for an effective rehabilitation therapy. These requirements included the adaptability to individual abilities, an intuitive interface, targeted rehabilitation exercises, clear visual and auditory feedback, immersive and motivating elements, as well as the capability to monitor and record data.

For these reasons, it was decided in collaboration with specialized health professionals to select the following games to test their use with the exoskeleton.

Among the applications studied, Hand Physics Lab stood out as an interesting tool, which allows users to engage with physics-based challenges and puzzles using hand gestures and motions. The game promotes hand-eye coordination, motor skills, and spatial awareness through tasks such as manipulating objects and solving puzzles. Players use their own hands, to control virtual hands within the game environment (See Figure 10).

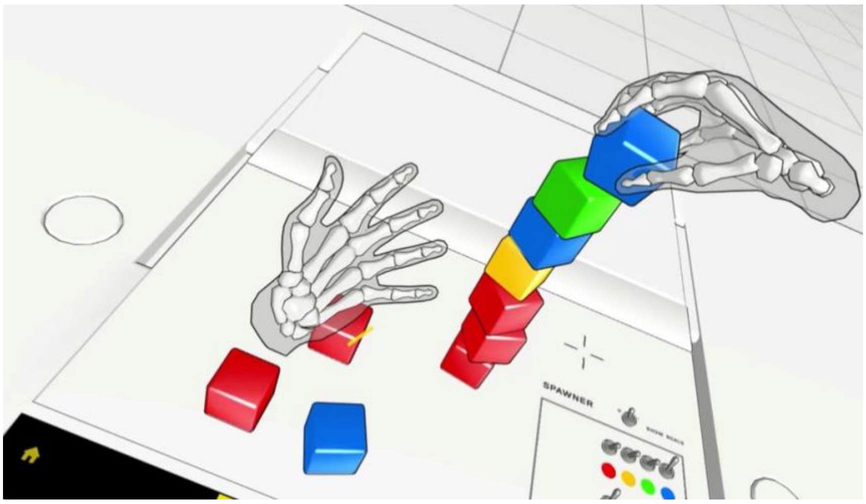


Figure 10 Virtual reality game Hand Physics Lab [53].

Another game of interest was The Climb, a virtual reality game focused on navigating and conquering climbing challenges using hand movements and coordination. This game targets upper body strength and coordination, crucial for children with cerebral palsy. In this case, motion controllers are needed to track and replicate players' arm movements in the virtual environment (See Figure 11).

Figure 11 Virtual reality game The Climb [59].

To play these games with the POWERUP exoskeleton, it is necessary to properly fit the exoskeleton to the user's arm and hand. The user can wear the exoskeleton while holding the motion controllers or with their own hands. The Oculus glasses capture the movements of the user's hand, and the exoskeleton provides support or assistance in executing those movements.

2.2.3 Study design and discussion of the validation protocol

The aim of this project is, as stated above, to validate the proposed instruction and user manuals for the POWERUP exoskeleton. For this validation, a series of tests based on the scales of usability (SUS) and satisfaction (QUEST 2.0) are carried out (See Annex 3). Both scales are widely known and used in the validation of technical aids such as the one proposed, but according to the research carried out, no specific literature has been found on the validation of manuals of assembly.

All in all, the final protocol encompassed an investigation into the user satisfaction and usability of the exoskeleton across different scenarios. It involved two main components: a manipulative game that relied on a series of buttons, and a virtual reality scenario utilizing different games with the Oculus glasses. Throughout the tests, the users were required to maintain a seated posture with a straight back and their knees bent at a 90-degree angle. The aim of this protocol was to gather valuable insights regarding user experience and gauge the exoskeleton's effectiveness in various interactive environments.

Once the exercises were performed, the usability and satisfaction tests, mentioned before, were conducted to identify areas for improvement. When feedback was received, appropriate changes were made to the manuals to create new versions of them, so the results were more satisfactory in order to be more easily understood and provide valuable information for identifying specific areas in need of refinement and guide the implementation of necessary improvements.

The last step was to determine whether the exoskeleton worked properly for use in the rehabilitation of patients with cerebral palsy. This verification process was carried out with a meeting with the professionals of the Neuroped and Maria Isabel Zulueta centers, in which some improvements were proposed by the professionals and others were observed. Based on the information provided, some changes were made following these indications. These improvements will be of great importance to ensure its usefulness for future patients who use it.

3 RESULTS

This section presents the results obtained based on the methodology explained above. Manuals for the assembly and use of the exoskeleton, feedback from specialists and technicians, and case studies carried out in various settings were evaluated.

3.1 Manuals evaluation results

To assess the assembly and usage of the exoskeleton, surveys were conducted with two voluntary participants, who were Physiotherapy students from San Pablo CEU University. These individuals had no previous familiarity with the exoskeleton or its operation.

3.1.1 Usability scales results

Following the methodology, the evaluation of these manuals was conducted using the SUS (System Usability Scale). After the completion of the surveys, the collected data was analyzed according to the following procedure:

1. For each participant, the score assigned to the odd questions (Q1, Q3, Q5, Q7, Q9) was subtracted from 5.

2. For each participant, 1 was subtracted from the score assigned to the even questions (Q2, Q4, Q6, Q8, Q10).

3. The obtained scores were then added together.

4. The sum was multiplied by 2.5 to calculate the total raw score.

5. To determine the average usability, the total raw score was divided by the number of participants.

The final result is a value between 0 and 100, which indicates the average usability of the system evaluated using the SUS questionnaire. Higher values indicate greater usability perceived by the participants.

Assembly manual results

Regarding the results related to the assembly manual (See Table 4) the overall score for the exoskeleton was of 75 out of 100 in the scale.

Table 4 Assembling manual results.

Question	User 1	User 2	Sum
Q1: Complexity	1	3	4
Q2: Simple	4	4	8
Q3: Technical support needed	2	2	4
Q4: Well explained	4	4	8
Q5: Irregularities	1	2	3
Q6: Universal	5	5	10
Q7: Time-consuming	2	2	4
Q8: Safety	5	5	10
Q9: Require previous knowledge	2	1	3
Raw score	77.5	72.5	150
Total			**75**

The results indicate a consistently high rating, with users agreeing with the simplicity of the manual. They also found that the manual was easy and intuitive, without requiring extensive prior knowledge. Regarding specific areas:

- Complexity: User 2 rated the complexity as moderate, indicating potential difficulties in the assembly process. This was associated with design errors that obstructed the easy fitting of the components and narrow holes that posed challenges for screw insertion.
- Technical Support Needed: Both users expressed a moderate need for technical support, suggesting the requirement for additional assistance

or clarification, particularly in areas where component fitting was challenging.

- Irregularities: User 2 reported encountering some irregularities in the manual, indicating potential confusion or lack of clarity regarding the differentiation between the internal and external parts of the exoskeleton during arm assembly.

On the positive side:

- Simplicity: Both users rated the simplicity of the manual highly, indicating that the assembly process is considered easy to understand.
- Well explained: Both users also rated the clarity of the instructions highly, suggesting that the manual provides clear explanations of the steps to follow.
- Universality: Both users rated the universality of the manual highly, indicating that they consider it applicable to a wide range of users.

In summary, users found the manual relatively easy to comprehend and well explained. However, areas for improvement were identified regarding complexity, the need for technical support, and potential irregularities. Addressing these aspects could further enhance usability and the user experience.

User manual results

Regarding the results related to the user manual (See Table 5) the overall score for the exoskeleton was of 90 out of 100 in the scale.

Table 5 User manual results.

Question	User 1	User 2	Sum
Q1: Complexity	1	1	2
Q2: Simple	5	5	10
Q3: Technical support needed	1	1	2
Q4: Well explained	5	5	10

Q5: Irregularities	1	1	2
Q6: Universal	5	5	10
Q7: Time-consuming	1	1	2
Q8: Safety	5	5	10
Q9: Require previous knowledge	1	1	2
Raw score	90	90	180
Total			**90**

The assessment of the user manual for the exoskeleton, based on the collected data using the SUS scale, produced highly favorable outcomes. Users expressed that the manual was straightforward, well-elaborated, and applicable to a wide range of individuals, demonstrating its ability to offer adequate guidance and self-sufficiency. The manual garnered excellent ratings for its clarity, ease of comprehension, and absence of any inconsistencies or ambiguities. Overall, the user manual proved to be effective in assisting users in comprehending and utilizing the exoskeleton, thus significantly contributing to a positive user experience.

3.1.2 Exoskeleton satisfaction scale results

Regarding the results from the satisfaction scale (See Table 6) the overall score for the exoskeleton was of 4.125 out of 5 in the scale.

Table 6 Satisfaction scale results.

Question	User 1	User 2	Mean
Q1: Dimensions	4	4	4
Q2: Weight	4	5	4.5
Q3: Easy to adjust	5	5	5
Q4: Safety	5	5	5
Q5: Durability	3	3	3
Q6: Easy to use	4	5	4.5

Q7: Comfortability	3	3	3
Q8: Effectiveness	4	4	4
Total			**4.125**

The results indicate a consistently high rating, with users expressing agreement regarding the lightweight nature of the exoskeleton. They also found the use of the exoskeleton to be easy and intuitive, requiring minimal prior knowledge. Additionally, there was consensus among users regarding the safety of the exoskeleton.

However, there was a noticeable trend regarding user comfort, which received a lower rating. Users specifically mentioned difficulties when performing elbow extension due to the piece colliding with their body, and discomfort caused by the velcro arm straps chafing the skin in the comments section.

In terms of durability, the overall score was 3, as the plastic construction of the exoskeleton tends to produce friction-induced noises. These noises create the impression of fragility among the users.

Lastly, in terms of effectiveness, users commented on the significant assistance provided by the sensation of weightlessness created by the rubber bands. This feature was deemed valuable for assisting the patients in their rehabilitation process.

3.2 Specialists' and technicians' considerations

After evaluating the exoskeleton's efficacy in rehabilitating children with cerebral palsy, specialists from the Neuroped Integral Pediatric Neurorehabilitation Center and the Maria Isabel Zulueta Special Education Center, identified several key considerations for improving the exoskeleton. These considerations include:

- Hand comfort: During exoskeleton use, discomfort was observed in the hand area due to the edges of the piece rubbing against the patients' hands, causing friction and reluctance to fully engage with it.
- Shoulder joint stability: The shoulder joint was found to lack stability, posing challenges for certain patients as they exhibited compensatory

movements during exercises, preventing them from utilizing the exoskeleton effectively.

- Height adjustment: An issue was noted regarding the exoskeleton's height, as it did not lower enough to achieve proper patient positioning, impacting the overall usability of the device.
- Arm piece adjustability: The arm piece was found to be non-adjustable, limiting its suitability for patients with varying sizes and proportions.
- Elbow extension limitation: During elbow extension, patients encountered contact with the articulated piece, indicating the need for modifications to ensure a smoother range of motion.

These considerations, identified by the specialists, highlight specific areas that require attention and improvement in order to enhance the functionality and ergonomics of the exoskeleton for children with cerebral palsy.

3.3 Case studies

In addition to the previously mentioned assessments of the exoskeleton's mechanics and functionality, tests were conducted to evaluate its performance in different scenarios, including virtual reality (VR) and real-world environments.

This approach allowed researchers and specialists to collect valuable information and data on exoskeleton performance, its potential benefits for patients in different settings, and conclusions for next steps.

3.3.1 Virtual reality games review according to methodology

Specialists from the Maria Isabel Zulueta Special Education Center conducted testing on with the proposed games and drew the following conclusions:

- Games that required the use of controls presented limitations in patient handling, as not all patients were able to use them effectively, and the detection of movements was more sensitive. When combined with the exoskeleton, detecting arm and hand movements proved challenging, making it impossible to use them together in games like The Climb.

- The top-performing game exhibited when used in conjunction with the exoskeleton and virtual reality glasses was Hand Physics Lab, particularly in the game's initial levels. These levels were designed to be easily completed and involved tasks such as moving blocks or pressing buttons. Specialists emphasized that the game could be customized to accommodate each patient's specific needs, including adjusting the height and enabling seated gameplay, making it accessible for wheelchair users. The immersive nature of the game, combined with the use of the patients' own hands instead of external controls, provided a more engaging experience.

All the physiotherapists agreed, regardless of the game used, that the employment of this new form of rehabilitation served as a motivating factor for the patients in a controlled environment.

3.3.2 Goal-directed task

In the following case study, experts were asked about utilizing BlazePod technology to practice goal-directed tasks suitable for real-world scenarios when combined with the exoskeleton to facilitate rehabilitation exercises. The objective was to evaluate whether integrating BlazePod technology with the exoskeleton could offer additional benefits to patients, enhance their overall rehabilitation progress, and assess the exoskeleton's performance in such tasks.

During the testing phase, in the Focus Group the professionals carried out tests with an individual with cerebral palsy. The subject was encouraged to interact with the reactive lights by pushing the illuminated targets strategically placed in various locations. The objective of this activity was to evaluate the level of difficulty of the buttons in order to study the feasibility of using it in therapy sessions and thus provide a dynamic and interactive experience that would encourage children to carry out the activities.

However, the trial results revealed certain limitations. It was observed that the sensitivity of the pods was inadequate, as the sensors were small and positioned only in the center of the button. Consequently, the individuals were unable to exert enough force to activate the buttons, resulting in inaccurate detection. Therefore, it was concluded that the BlazePod system, designed primarily for sport-related games, was not suitable for this particular context of rehabilitation exercises with the exoskeleton.

4 DISCUSSION

Based on the received evaluation, there are specific areas that require attention in order to further refine the design of the exoskeleton and the accompanying manuals. Overall, the exoskeleton design enables the intended movements of the upper extremity, although certain limitations exist in some aspects.

4.1 Exoskeleton improvements

Regarding the adjustability of the exoskeleton, a significant issue arises concerning the lack of height regulation, making it challenging to use the device effectively for smaller patients or those requiring a lower backrest during sessions.

One potential solution involves cutting the metal bars of the television support by approximately 10 cm, thereby allowing for greater adjustability. However, an obstacle in implementing this solution is the presence of a stop on the bars, preventing further reduction in height if a lesser adjustment is required (See Figure 12).

Figure 12 TV support solution.

Moving forward with the issues related to adaptability, concerns were also raised about the adaptation of the exoskeleton to the arms of smaller children to address this issue, as a proposed solution, it was suggested to modify the existing telescopic arm designed for adults to make it suitable for children. This modification would involve the incorporation of a screw mechanism, allowing for size adjustments by utilizing various available holes in the component (See Figure 13).

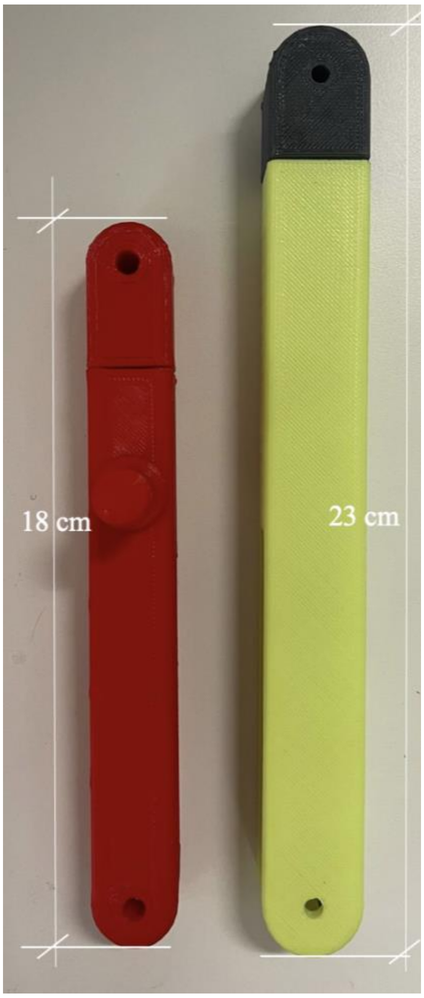


Figure 13 Child (left) and adult (right) telescopic arm comparison.

Another proposed improvement aims to address the issue of high assembly time for the exoskeleton. Currently, the pieces' holes, through which bars or screws need to be inserted, are not adequately sized, leading to the need for manual drilling to enlarge them. This delay is attributed to design flaws rather than the precision of the 3D printers, as confirmed through discussions with the technicians.

To solve this problem, it has been determined that all the holes should be approximately 2mm larger than the screws to ensure a proper fit. Consequently, the decision was made to enlarge all the holes uniformly. For instance, the insertion of the bar through pieces 3 and 4 proved to be quite challenging (See Figure 14), but the issue solved by increasing the size by 2 mm (See Figures 15 and Figure 16).

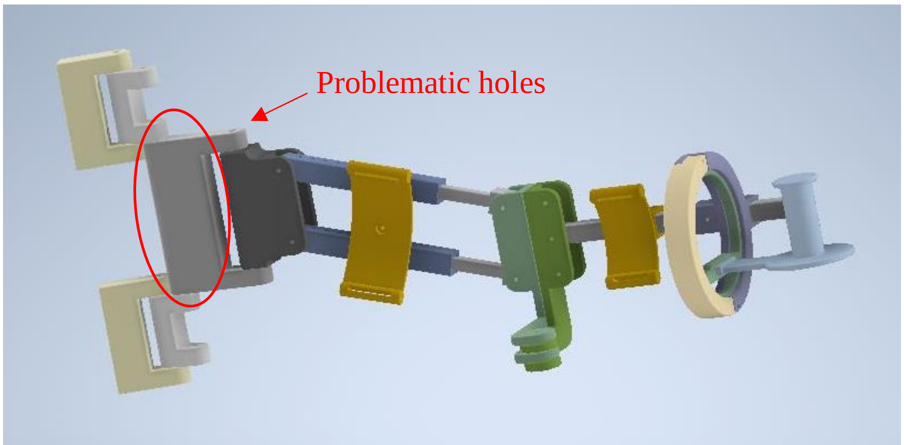


Figure 14 Example of problematic holes in the POWERUP exoskeleton (Autodesk Inventor Professional 2023).

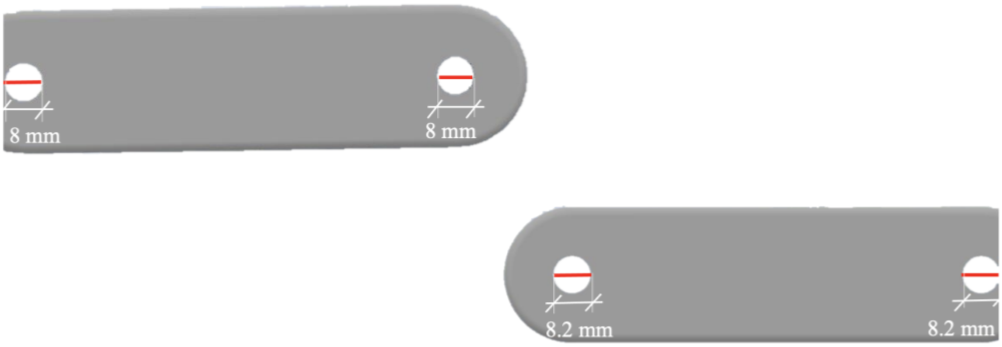


Figure 15 Increase in size of piece 3 (Autodesk Inventor Professional 2023).

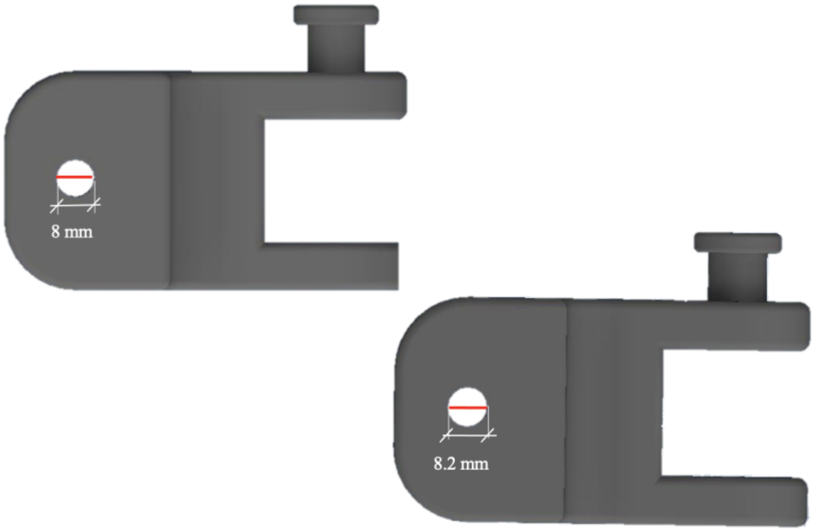


Figure 16 Increase in size of piece 4 (Autodesk Inventor Professional 2023).

In addition to the mentioned improvements, there are other enhancements that have been considered regarding the gathered feedback. One crucial aspect to address is the replacement of the current elbow piece, which has been identified as causing collisions when the elbow is fully extended. In order to solve this matter, a previously developed elbow piece design was recovered (See Figure 17), which effectively eliminate the collision problem. However, due to concerns with the design of the protrusions for fastening the rubbers, further refining would be required in future works.

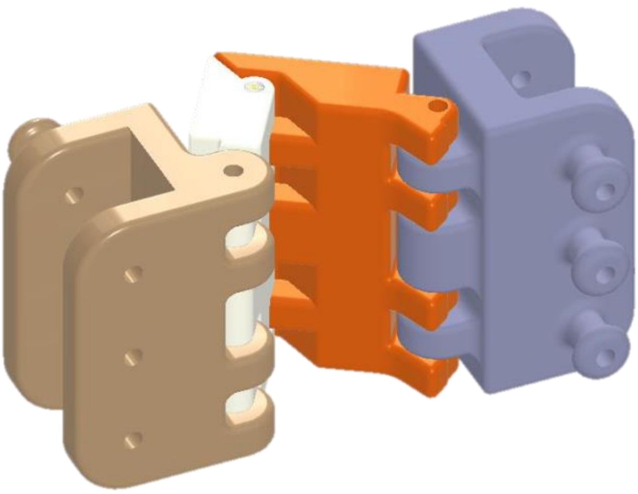


Figure 17 Elbow piece recovered [66].

Furthermore, discomfort has been observed in the hand area due to friction caused by the edges of the piece rubbing against the patients' hands. To enhance comfort, it is proposed to employ elastic straps with velcro for holding electrodes (See Figure 18). These straps are commonly used in physiotherapy and are also low cost.

Figure 18 Elastic straps with velcro for holding electrodes [67].

4.2 Manuals improvements

After examining the usability and satisfaction outcomes of the two manuals, it was found that while the results were generally satisfactory, certain modifications were implemented based on the gathered feedback. Firstly, specific clarifications were added to certain steps to clearly indicate piece orientation should be internal or external to the arm, as there were cases where this caused confusion. Secondly, a video demonstration was created to provide a step-by-step assembly guide for enhanced clarity. This video is accessible on the PowerUp Exoskeleton website (See Figure 19).

Figure 19 Exopowerup web page [38].

4.3 Alternatives in clinical scenarios discussion

After the conducted tests and in light of the unsatisfactory outcomes mentioned in the previous section, a search for alternatives to BlazePod was carried out, leading to the identification of the Portable light up reaction wall game (See Figure 20) as the most viable alternative within this specific context. Several factors validate this selection. Firstly, the game exhibits a targeted design for children with disabilities, featuring a larger surface area equipped with multiple touch-sensitive panels, thereby ensuring enhanced accessibility for these individuals. This attribute effectively resolves the limitations encountered with the insufficient sensitivity of BlazePods' sensors.

Figure 20 Portable light up reaction wall game [68].

In relation to the virtual reality scenario, the subsequent phase will involve further assessment of the exoskeleton with a larger user base and conducting additional game-based tests. The objective is to investigate whether the exoskeleton effectively contributes to rehabilitation by assisting users in successfully achieving the designated game tasks.

5 CONCLUSIONS

The aim of this project was to create and evaluate assembly and usage manuals for the POWERUP exoskeleton, with the goal of assisting in the rehabilitation of individuals with upper limb neuromotor disorders. The designed manuals were a significant step towards the final project, enabling anyone to assemble and use the exoskeleton independently, without requiring external assistance. Furthermore, design modifications were implemented to enhance the simplicity and efficiency of the assembly process.

Regarding the surveys carried out, the users gave the manuals high ratings in three categories: "simplicity," "well-explained," and "universality." However, the exoskeleton received lower ratings in the categories of "ease of fit," "comfort," "effectiveness," and "durability." Although there is a certain level of satisfaction among users, it is evident that adjustments need to be made to enhance the user experience and address the existing issues in the exoskeleton.

Additional testing of the exoskeleton is required to further refine its design and enhance its overall performance. Furthermore, the effectiveness of the new modifications needs to be verified to ensure a satisfactory improvement. Once these validations are conducted, the second phase will begin, involving testing the exoskeleton with the intended target patients. Reassessments of the manuals will be necessary after the implementation of these changes in the exoskeleton design.

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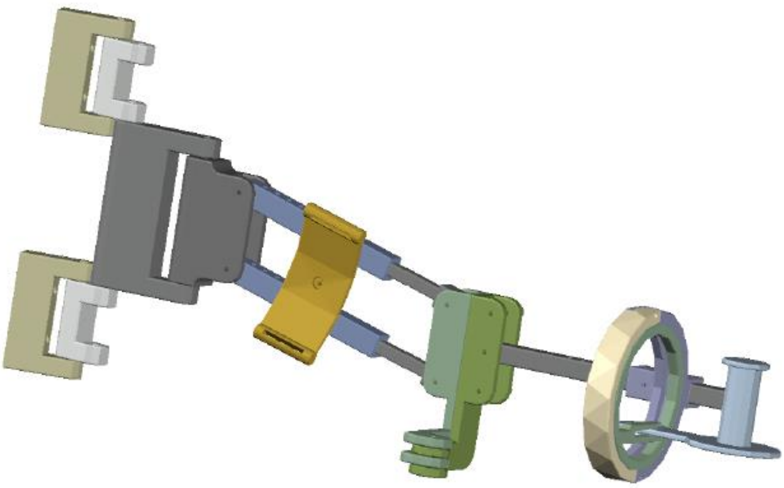
7 ANNEXES

ANNEX 1: Assembly manual

POWERUP

Assembly manual



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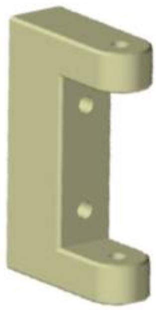

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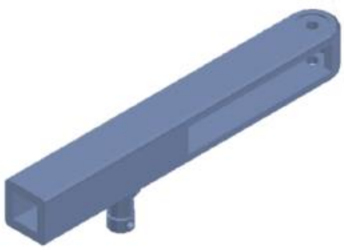

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2x

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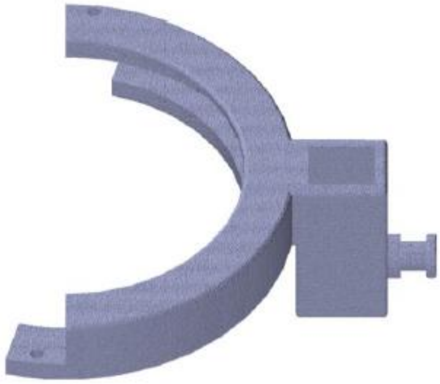

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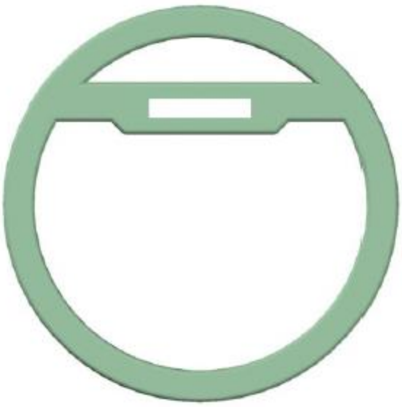

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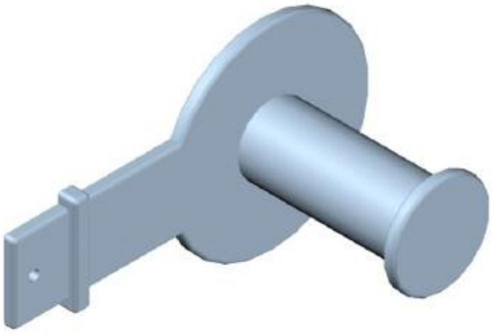

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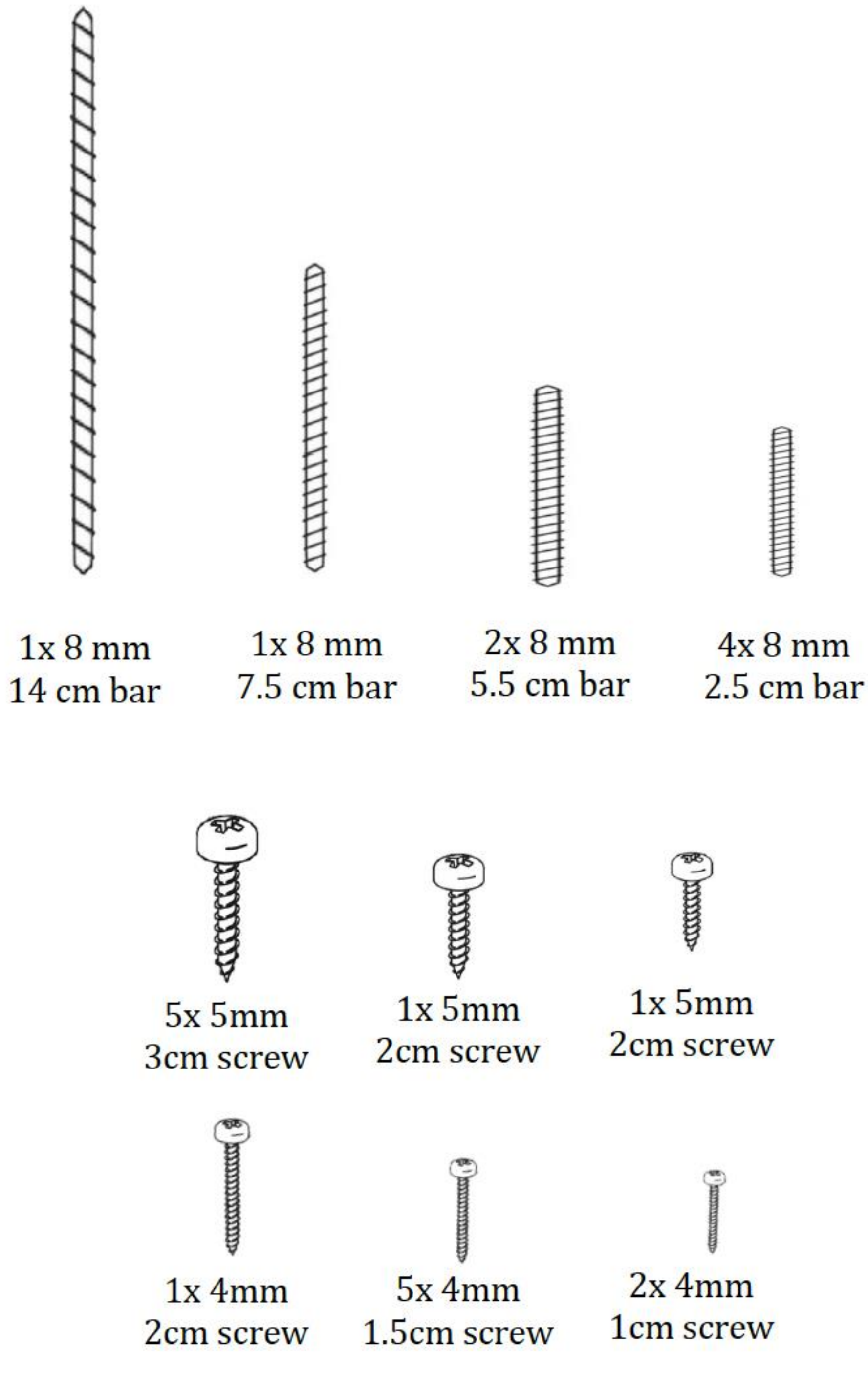
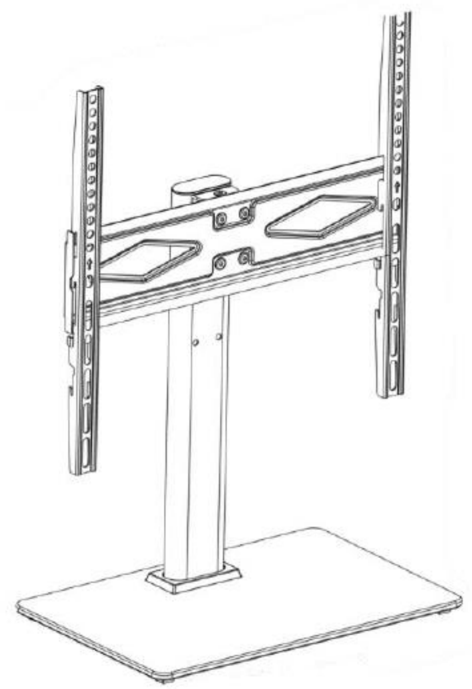

1x 8 mm
14 cm bar
1x 8 mm
7.5 cm bar
2x 8 mm
5.5 cm bar
4x 8 mm
2.5 cm bar
5x 5mm
3cm screw
1x 5mm
2cm screw
1x 5mm
2cm screw
1x 4mm
2cm screw
5x 4mm
1.5cm screw
2x 4mm
1cm screw

14x Ø8 mm

12x Ø5 mm

8x Ø4 mm



TV support

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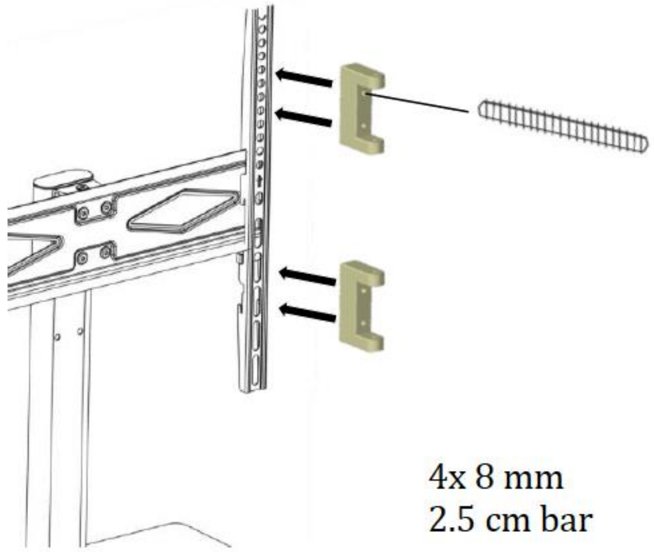

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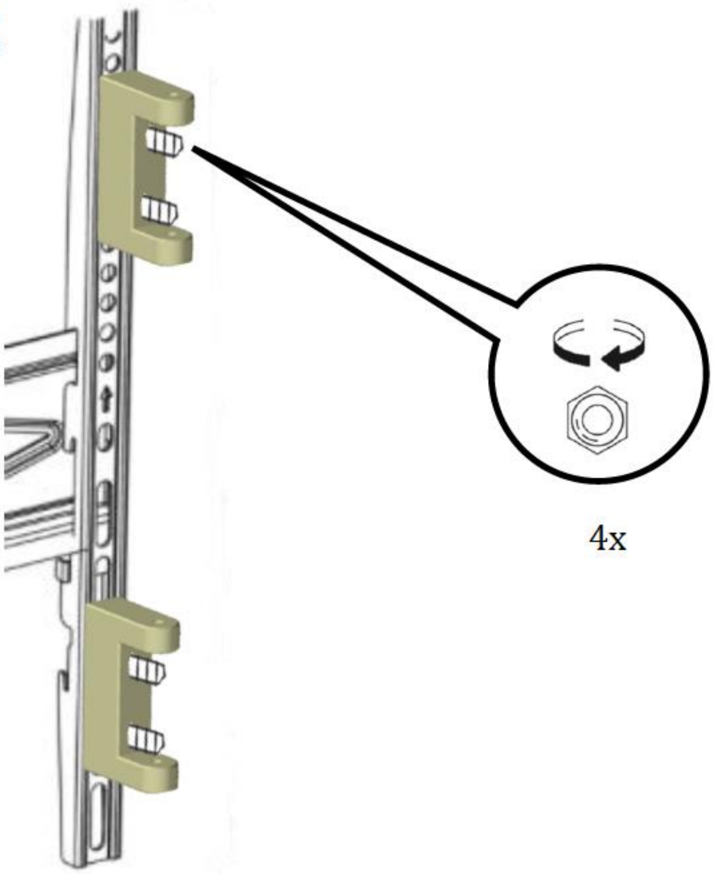

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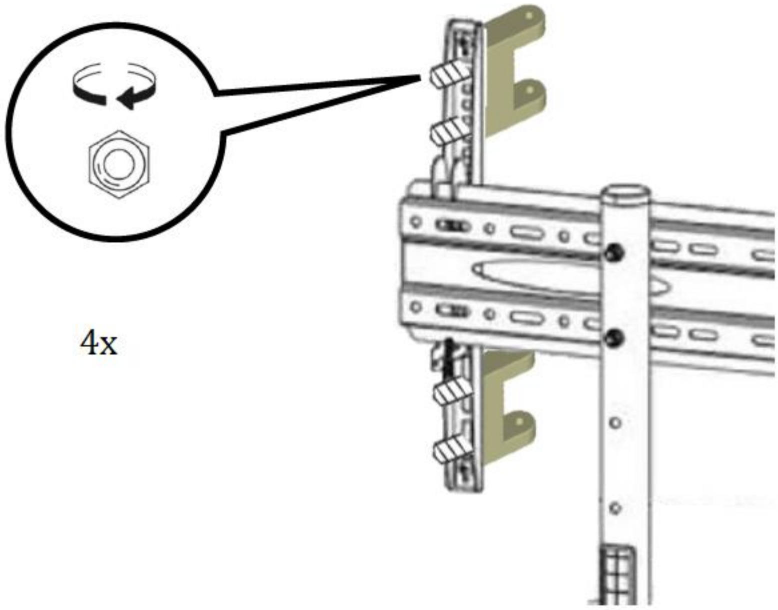
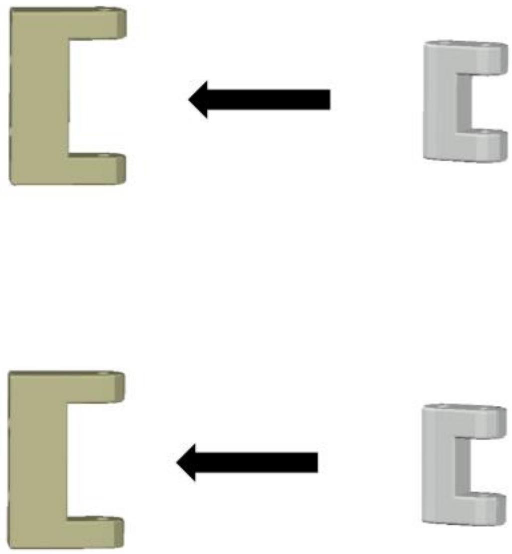


4 without TV support



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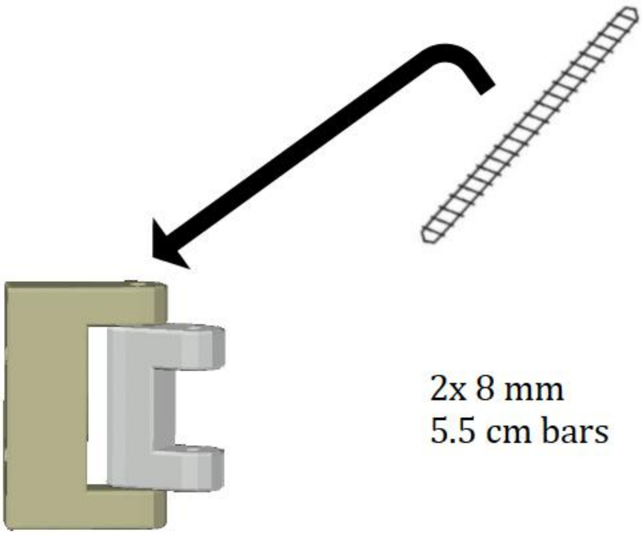
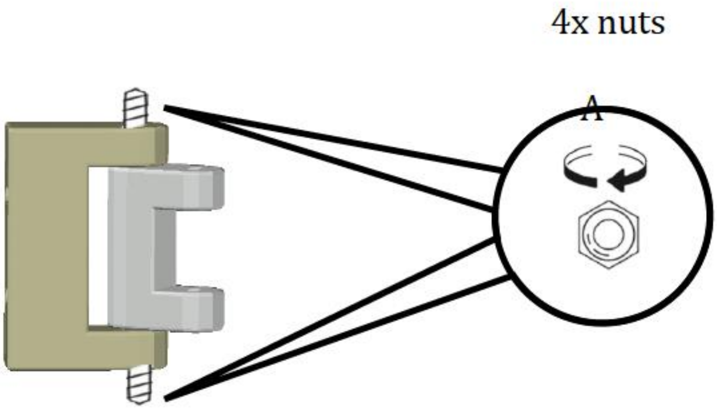
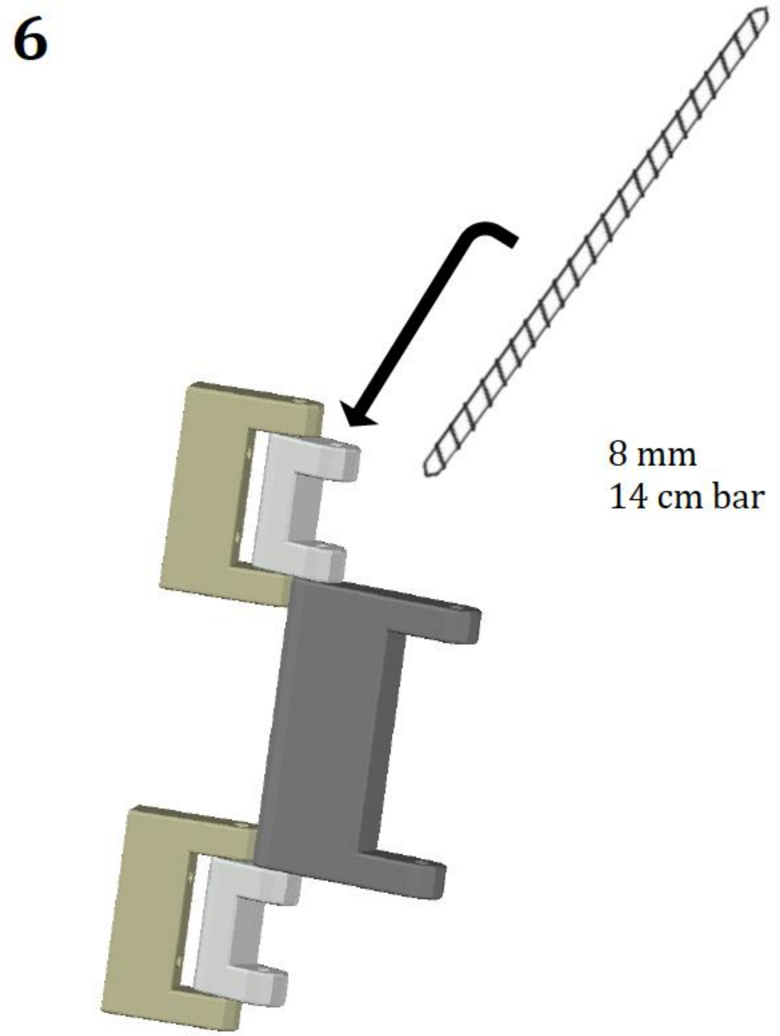
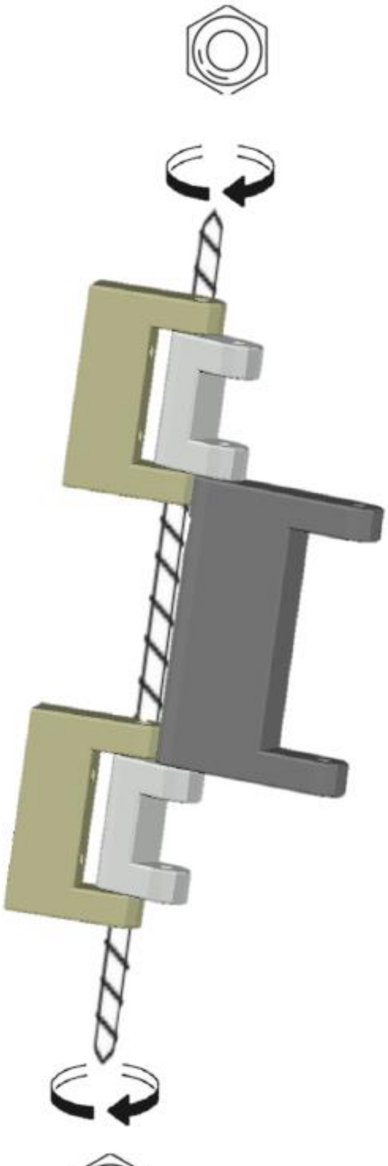




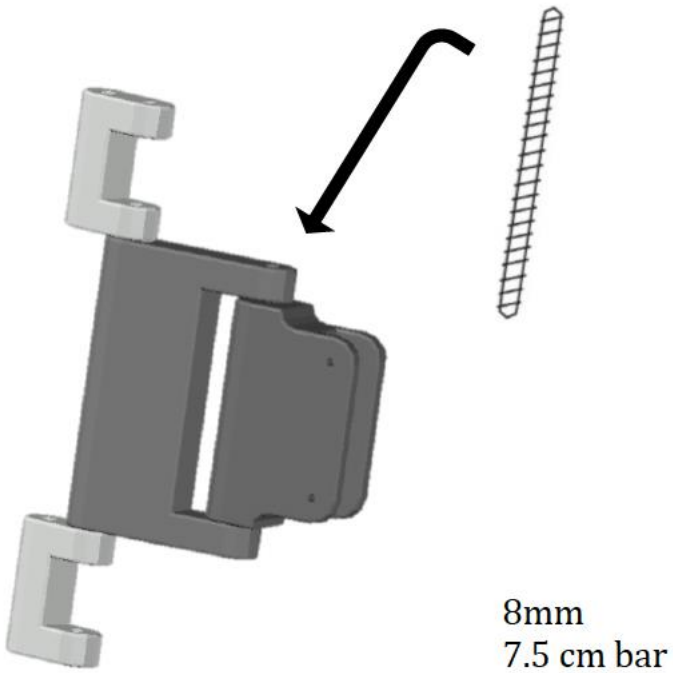

6
8 mm
14 cm bar

7



8

Internal part view



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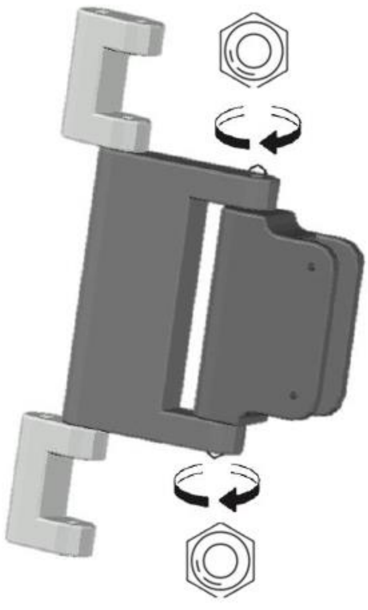

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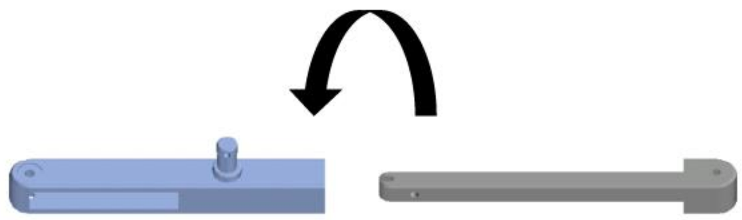

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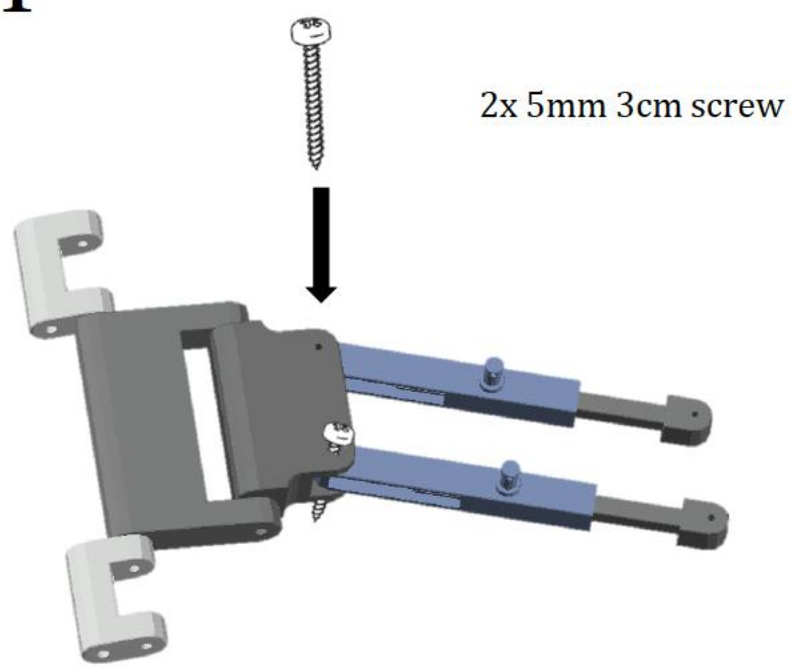
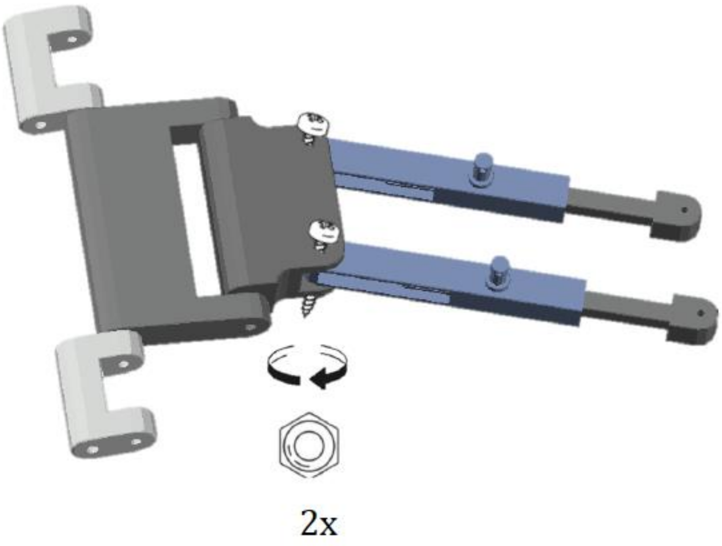
11



Internal part view

12



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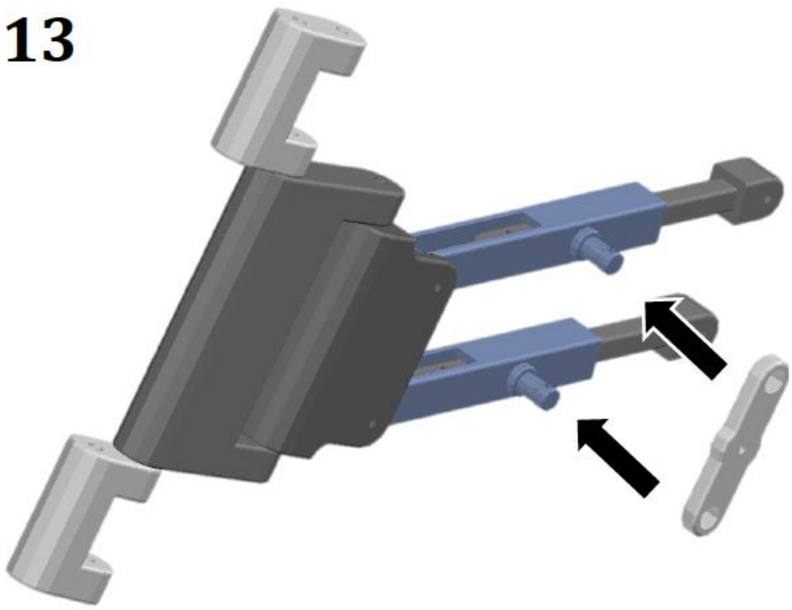

Internal part view

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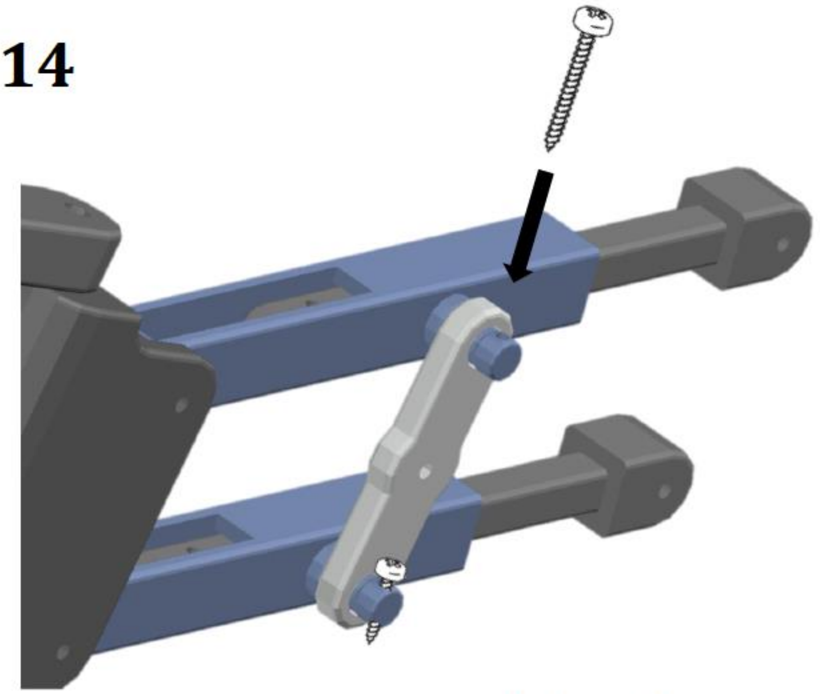

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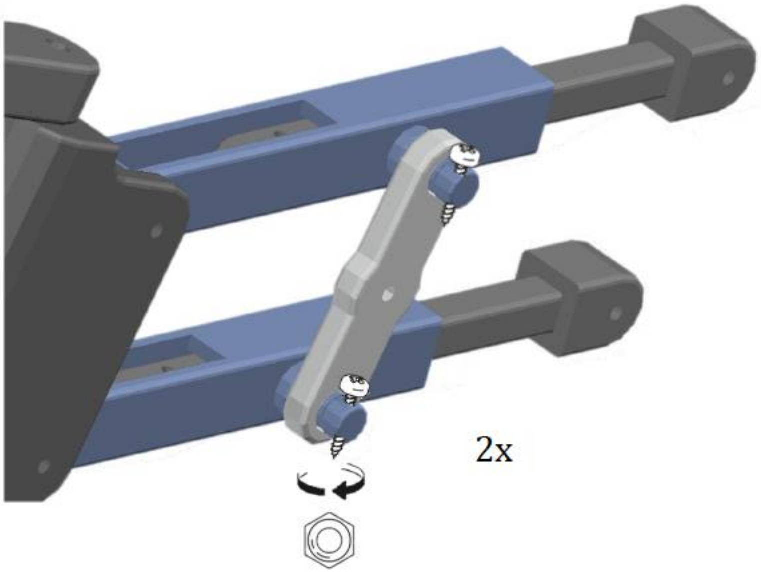

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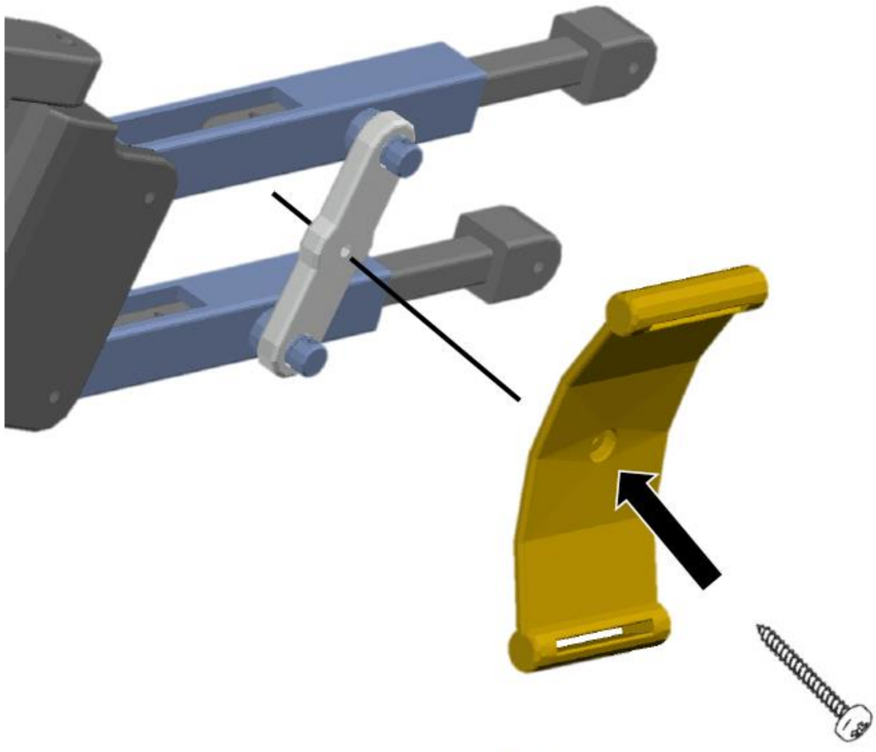
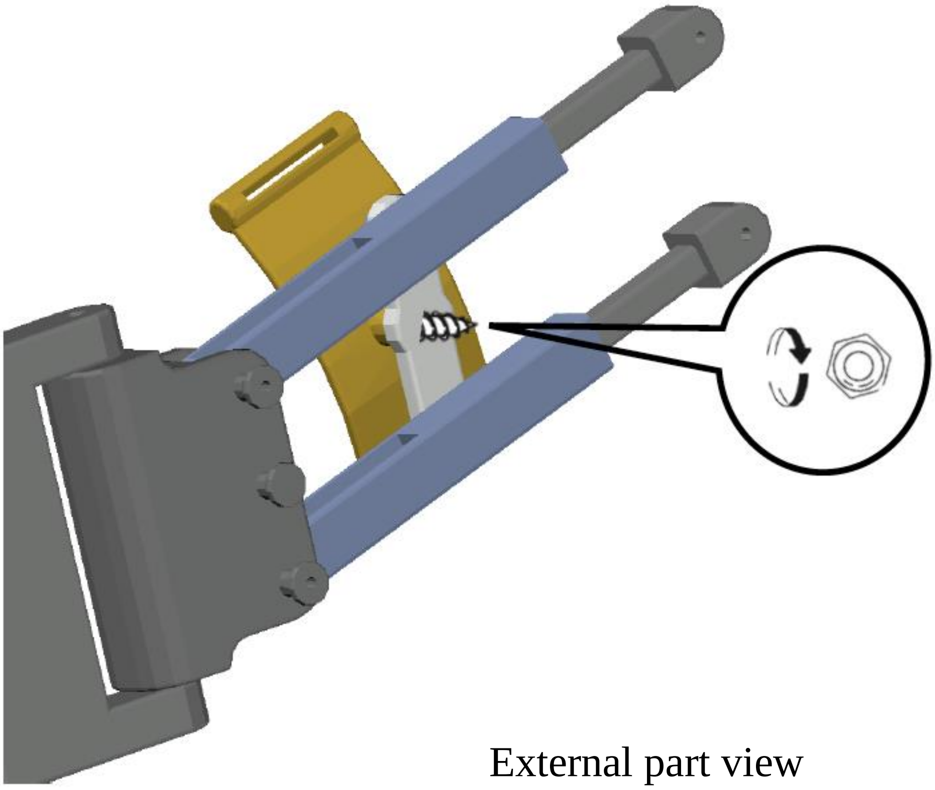


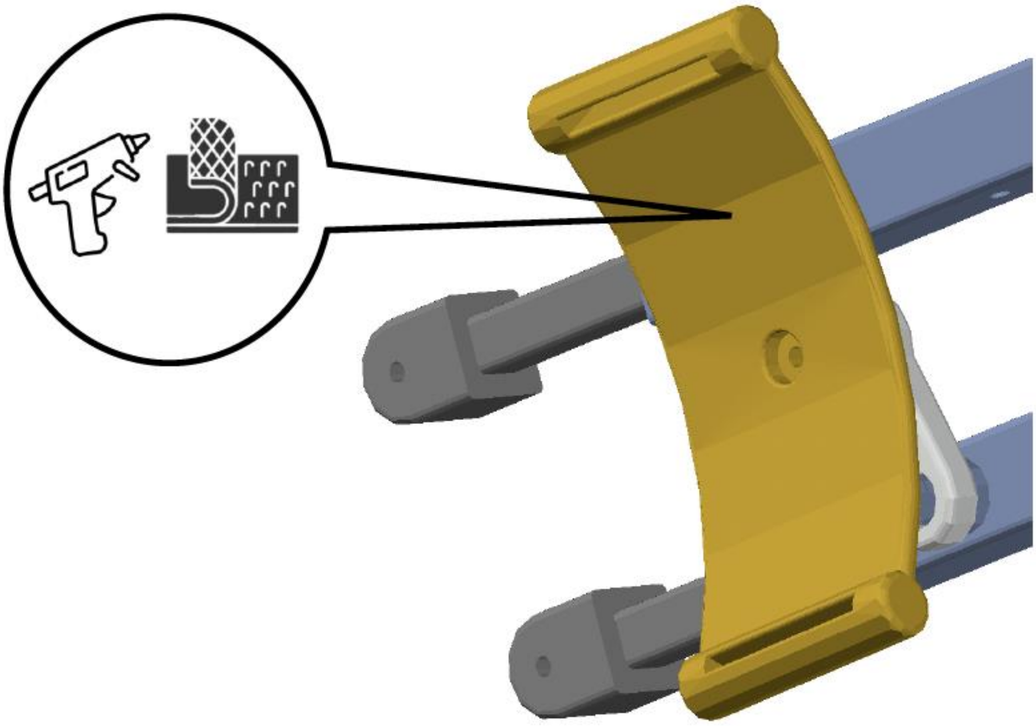
4 mm
1.5 cm screw

17



External part view

18



Stick velcro tape

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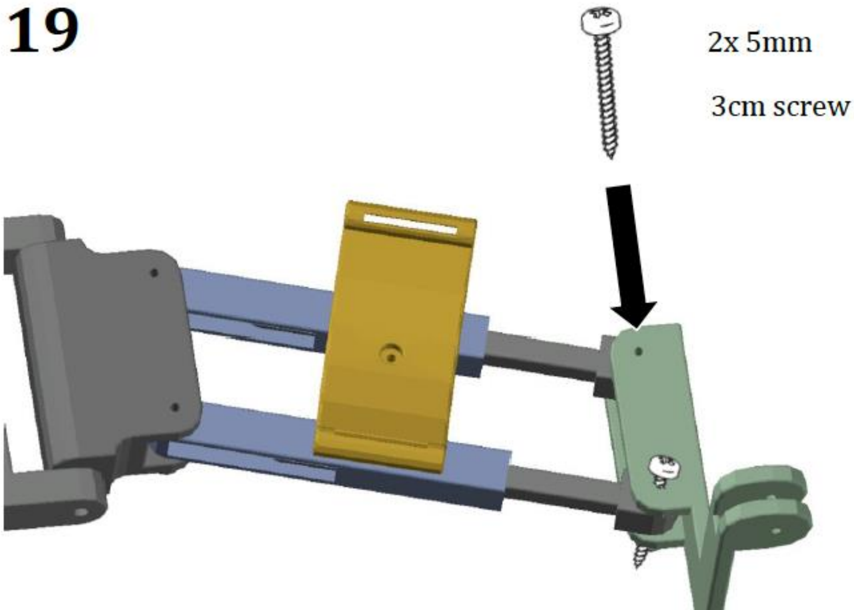
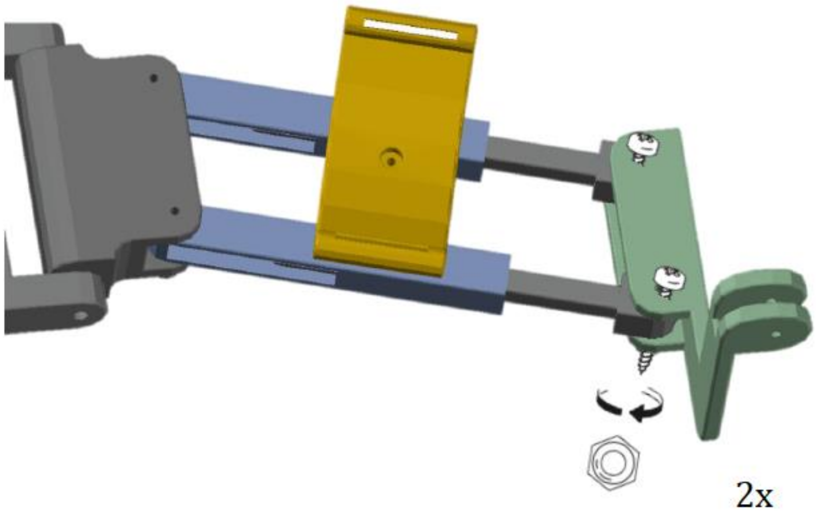


Internal part view

20



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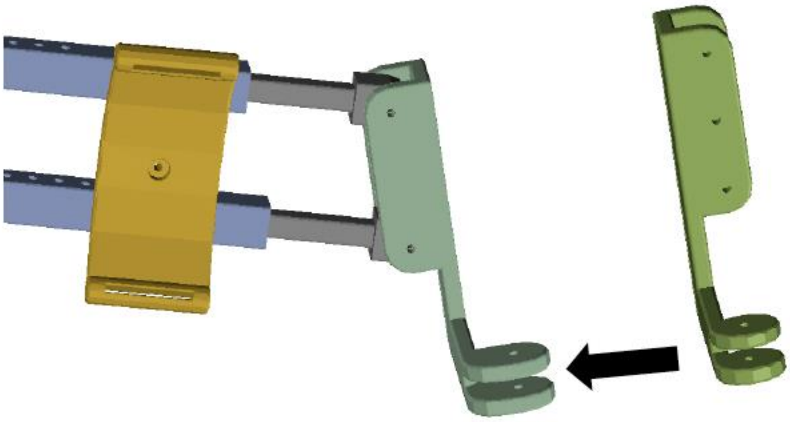

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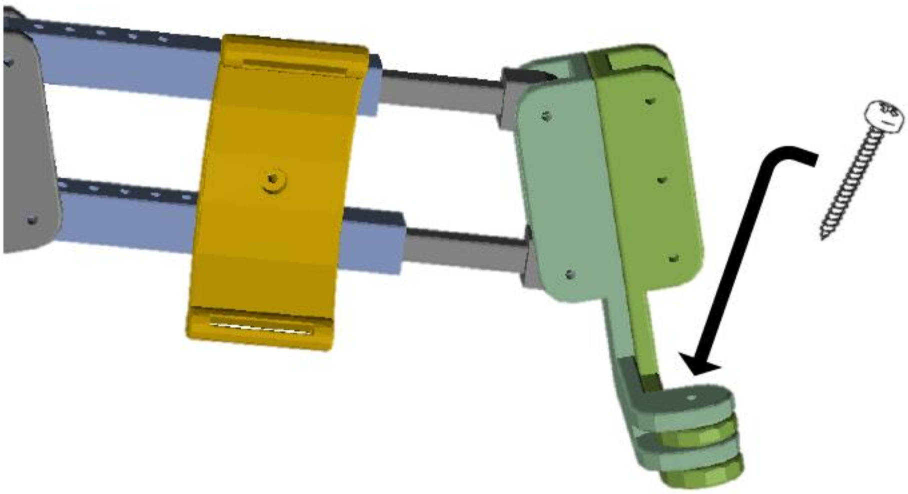

4 mm
2 cm screw

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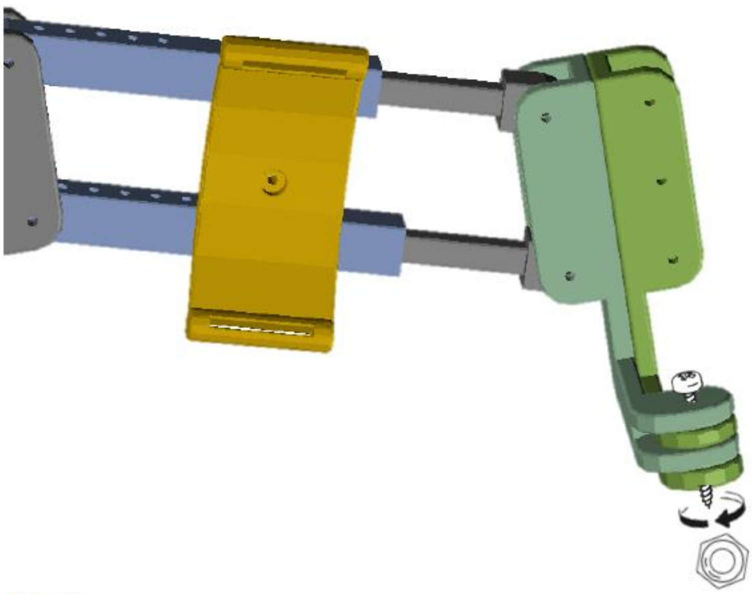

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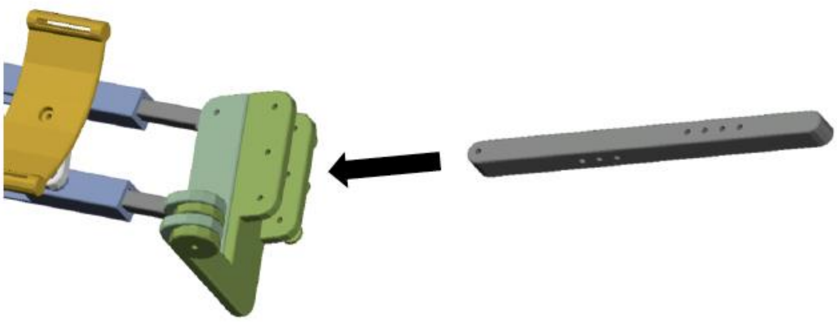

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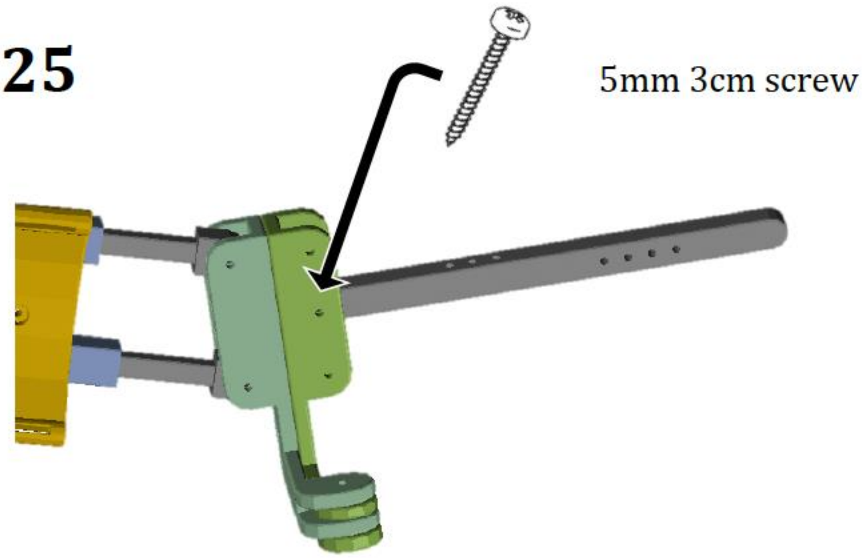
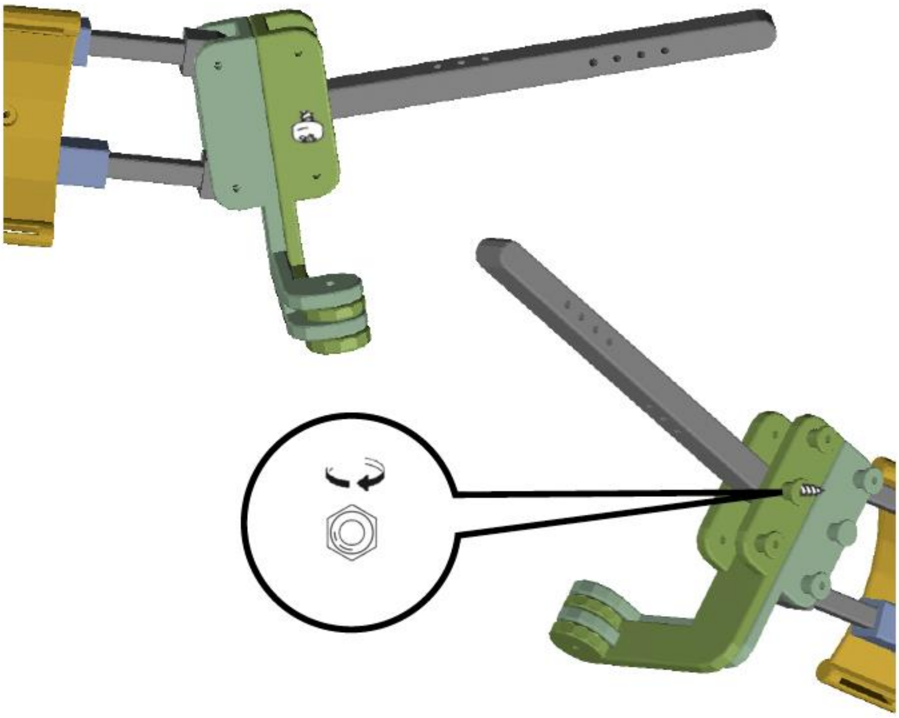


26

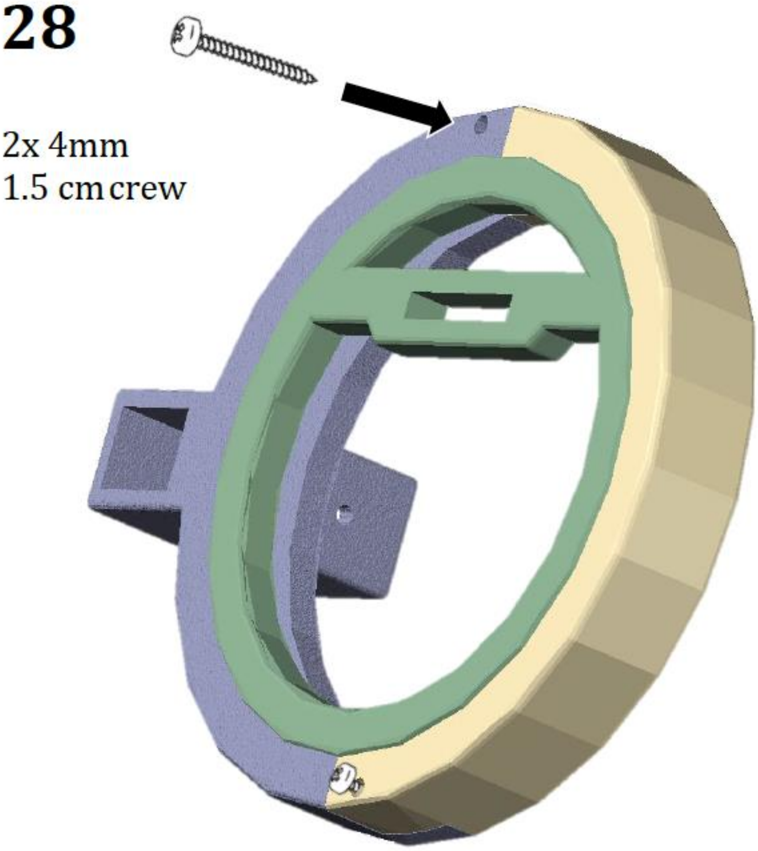
Internal part view



External part view

27

28



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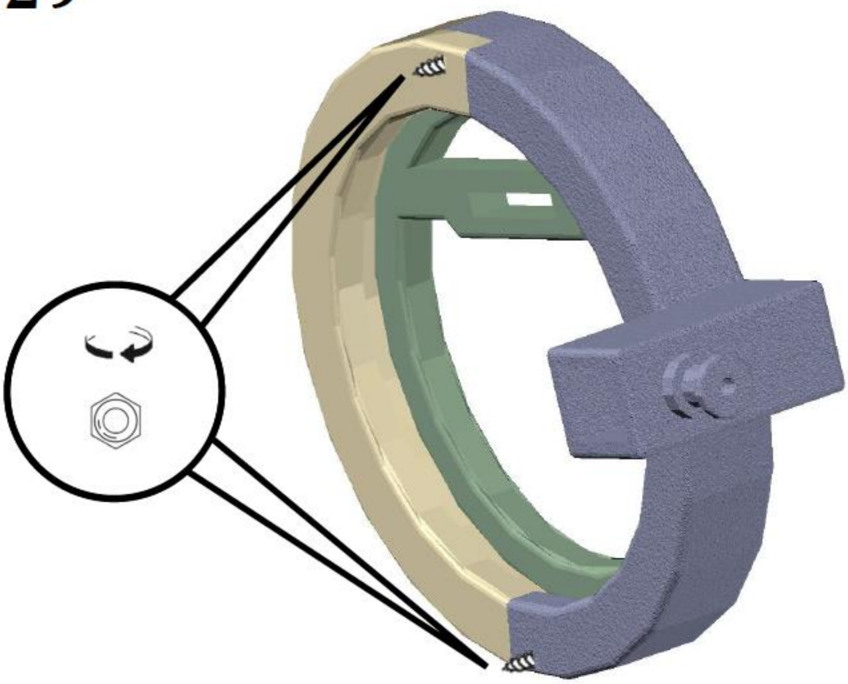
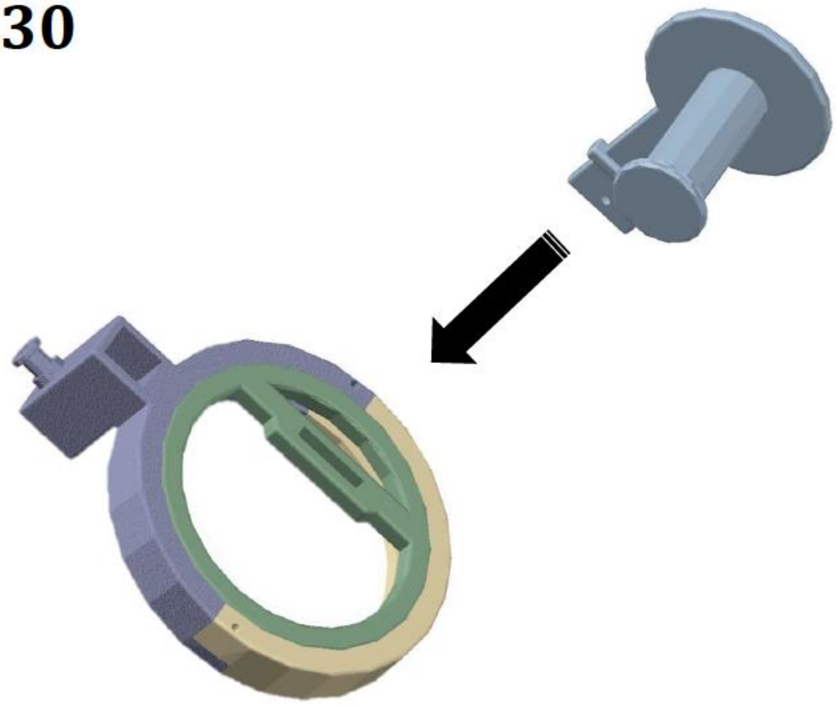
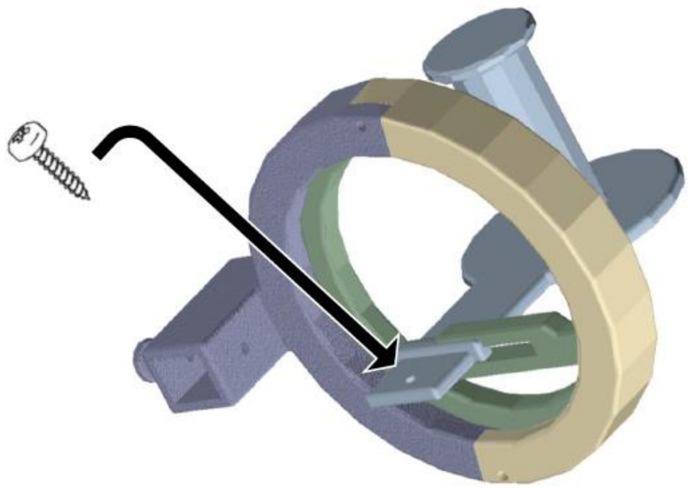


30

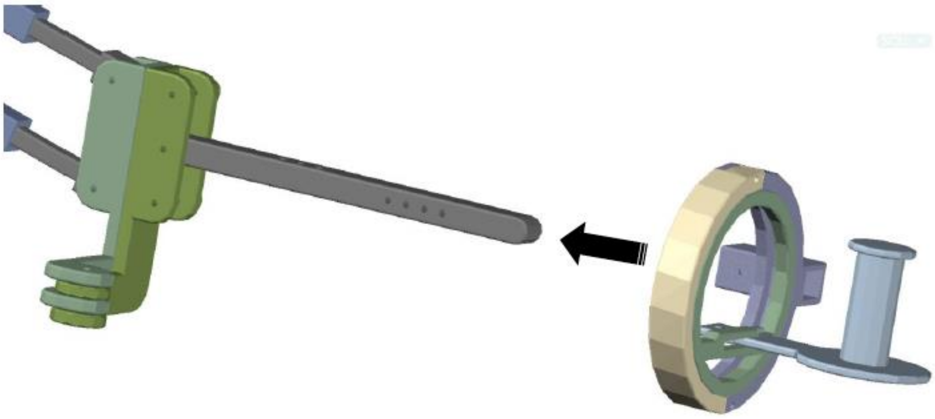


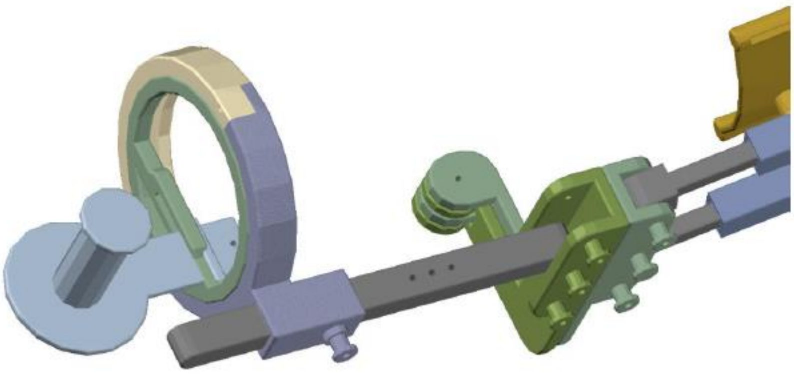
5mm
0.5 cm screw



View from behind

31 Internal part view

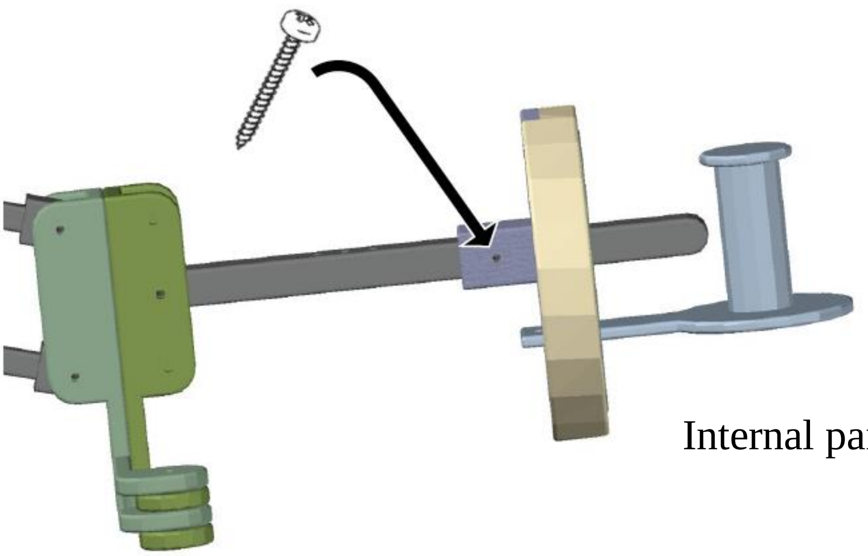




View from top

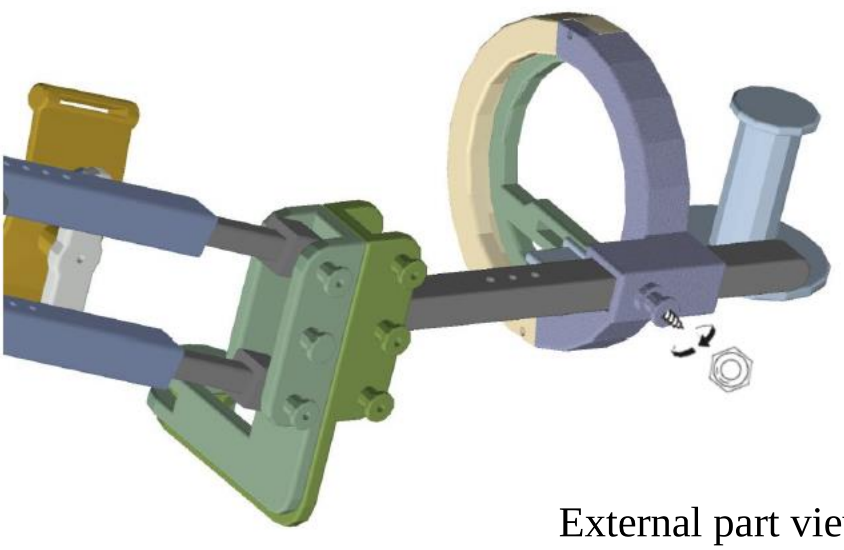
32

5mm 3cm screw



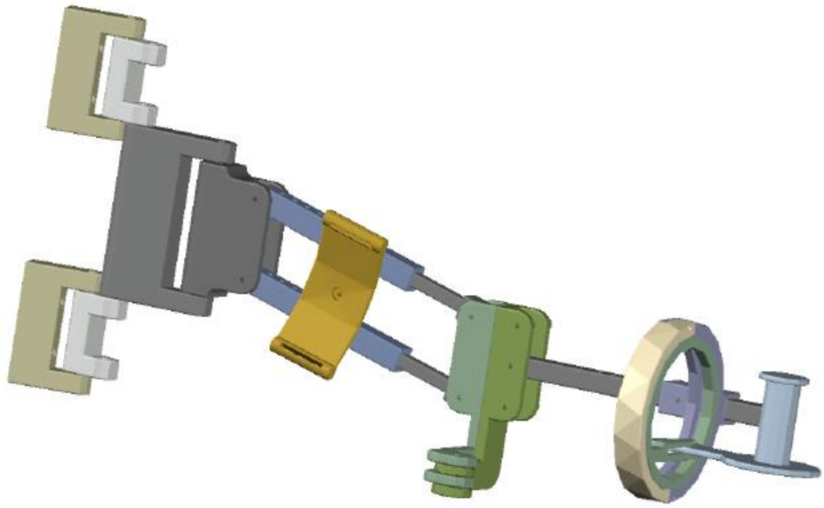
Internal part view

33



External part view

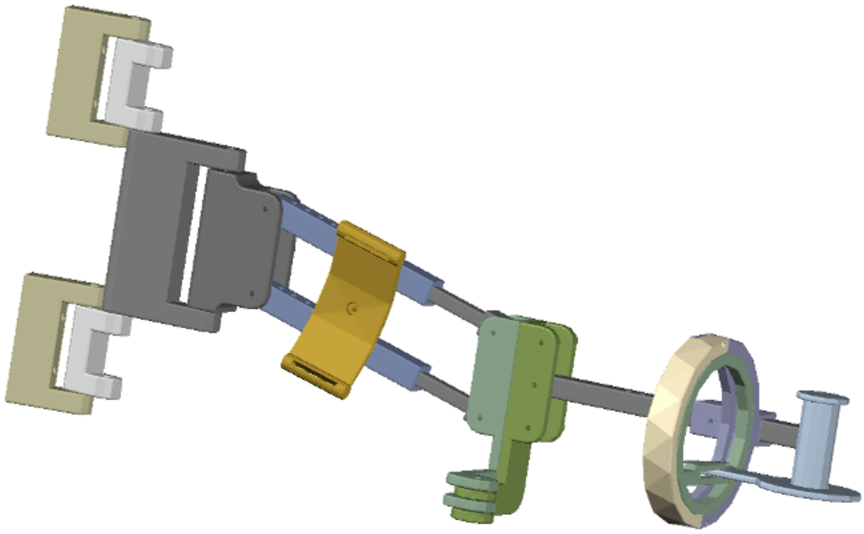
Complete assembly



ANNEX 2: User manual

POWERUP

User Manual



CEU

User manual of the POWERUP exoskeleton

The POWERUP platform consists of an orthosis for promoting the upper limb rehabilitation of patients with Cerebral Palsy.

Research project funded by the Spanish Ministry of Science and Innovation and developed by the Bioengineering research team of San Pablo CEU University in Madrid (Spain).

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    1.1 Parts and performance ……………………………………... 5
2. How to put on ……………………………………………………….... 7
3. How to use ………………………………………………………….... 10

1 About the POWERUP exoskeleton

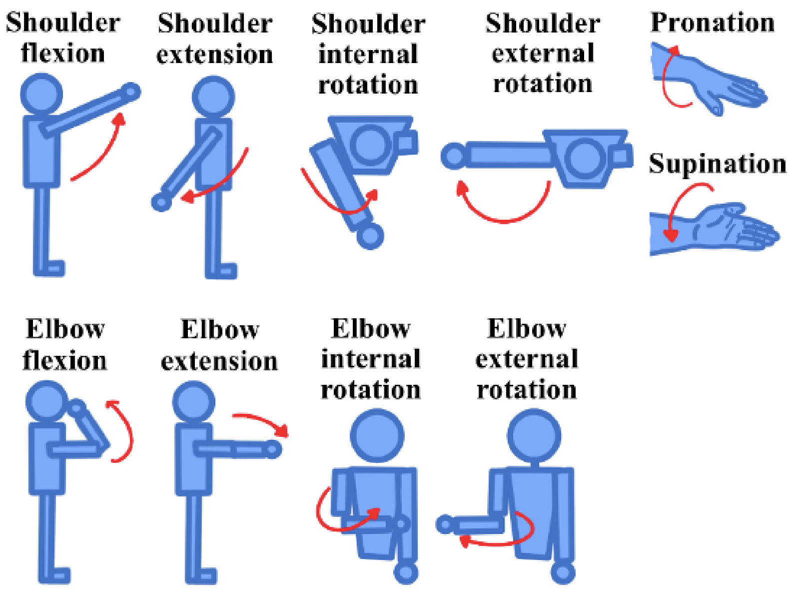
The POWERUP setup consists of an upper-limb exoskeleton designed to enable users with limited motor functions to perform rehabilitative movements and improve their range of motion in daily activities.

The POWERUP system consists of four modular components: shoulder/back, arm, forearm, and hand.
By utilizing bars, anchors, and elastic straps, physiotherapists can easily customize the device's width, height, and length to match the user's body measurements. Furthermore, the modular design facilitates simple and quick assembly.

The exoskeleton offers five degrees of freedom, enabling the following movements:

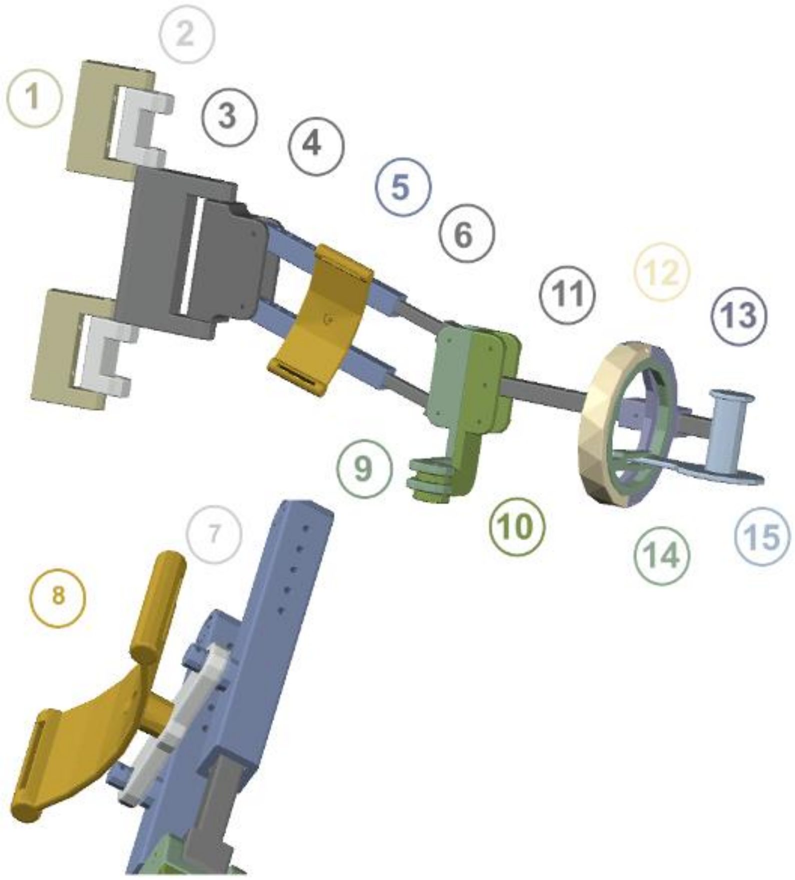
- Shoulder extension and flexion
- Shoulder internal and external rotation
- Pronosupination of the arm
- Elbow flexion and extension
- Elbow internal and external rotation

The device is entirely 3D printed using PLA filament, a lightweight and cost-effective thermoplastic derived from renewable and organic sources. This manufacturing method ensures the exoskeleton is lightweight, affordable, and easy to reproduce.



Movements allowed.

1.1 Parts and performance



Parts 5 and 6 are extensible so they can be adapted to any user. Depending on the patient's size, different measurements are required.

Although there are two versions of the exoskeleton, one for the right arm and one for the left arm, the idea is that only one arm can be rehabilitated with the device during a therapy session.

Do not use both exoskeletons at the same time, even if you change the arm later.

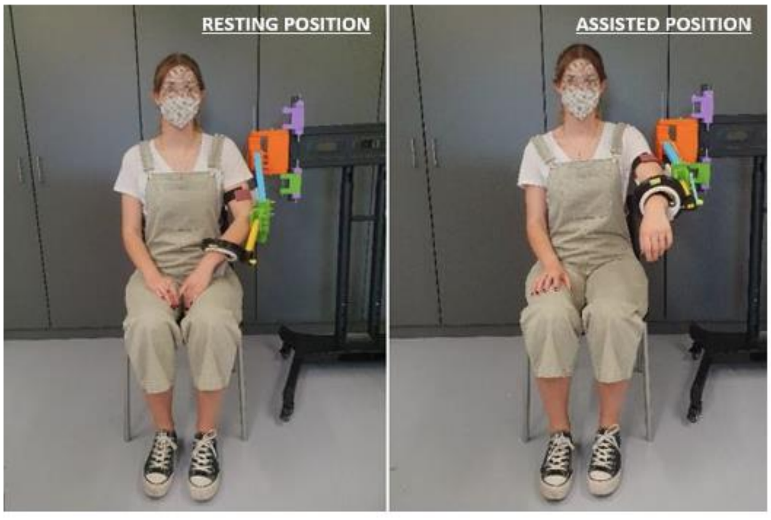
2 How to put on.

Always, sessions require from patient:

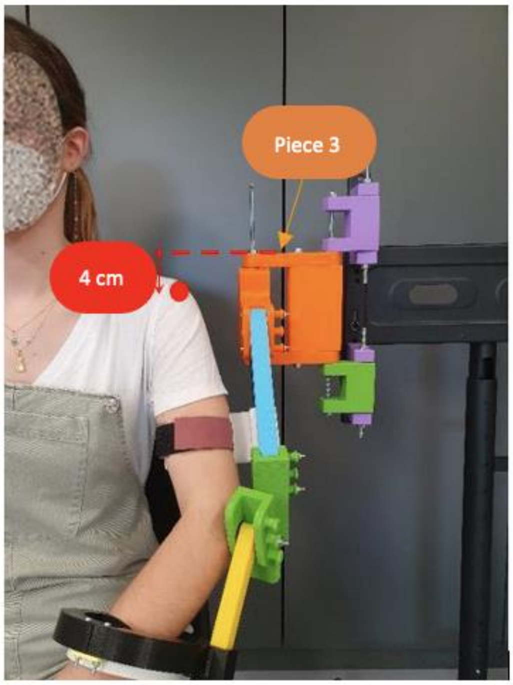
- Sited with straighten back.
- Knees bent 90 degrees and
- Feet flat on the floor or on a solid and smooth surface

Both arms are symmetric, so references were set to assure comfortability on the posture.

For testing, if the exoskeleton was correctly attached, patient on resting position should be comfortable and with no shoulders dealignment. Also, comfortability must be present on not resting position when using elastics rubbers to raise arm to the new assisted resting position.



Upper piece 3 should be approximately 4 centimeters above shoulder's height.



For a good coupling of the exoskeleton with the patient, piece 3, should be aligned with back.

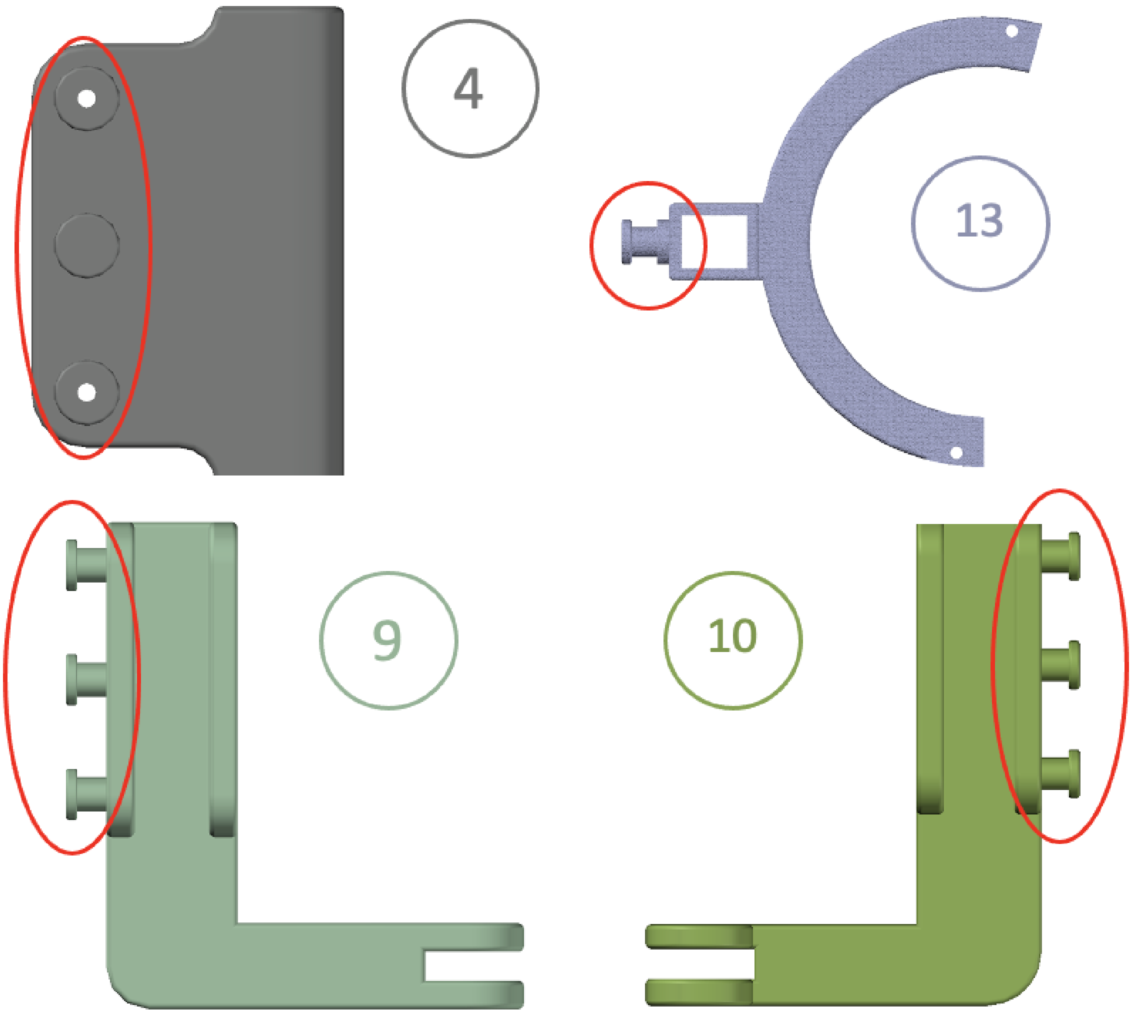
Upper arm support colocation is important for avoid contact between ribs and piece 5 (upper arm support) and for avoid shoulders dealignment.

- If velcro attaches are extremely closer to the elbow, lifting movements would result hampered.
- If velcro attached are extremely closer to the shoulder, descending movements would result hampered.

Once exoskeleton was completly attached and patient in a comfortable position, practique exercises could took place.

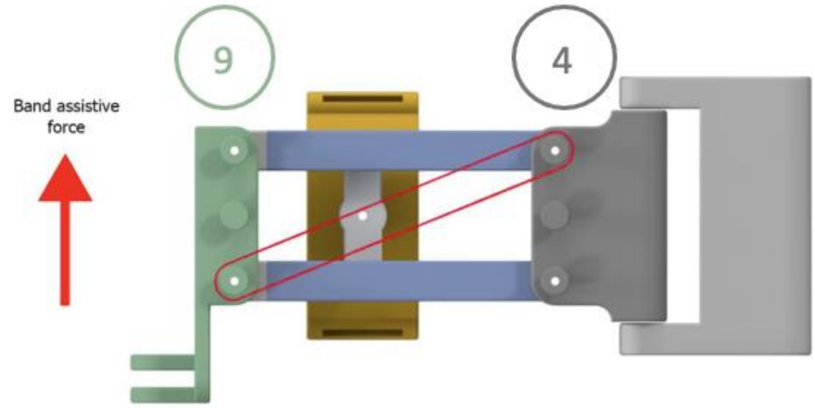
3 How to use.

There are multiple settings depending on how the elastic bands are positioned.
As we can see, in the pieces 4, 9 and 10 there are three protuberances, and in the piece 13 there is one protuberance.

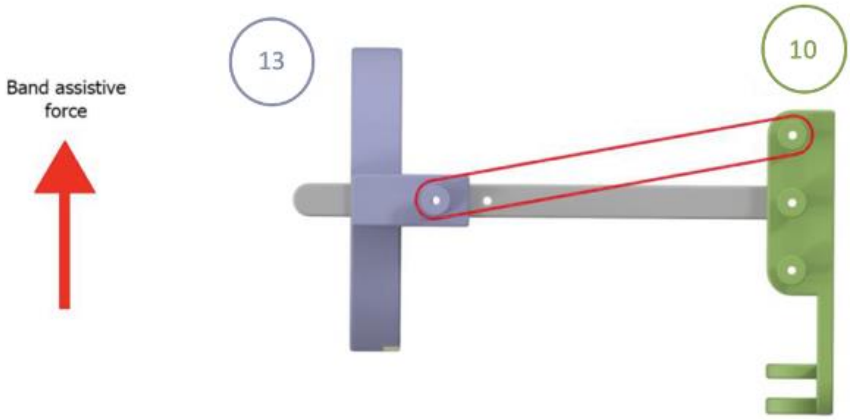


Depending on how the elastic bands are placed around these protrusions, different configurations of the exoskeleton are achieved, these can be assisting or resisting the movement:

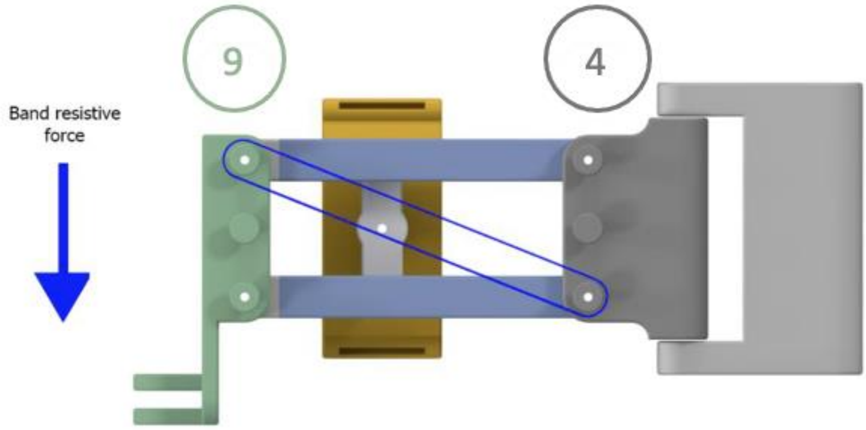
- Assistive configuration
    - Arm segment: Bands are placed at the upper attachment point of piece 4 and the lower attachment point of piece 9, this will cause an up force opposite to the gravity pull downwards.



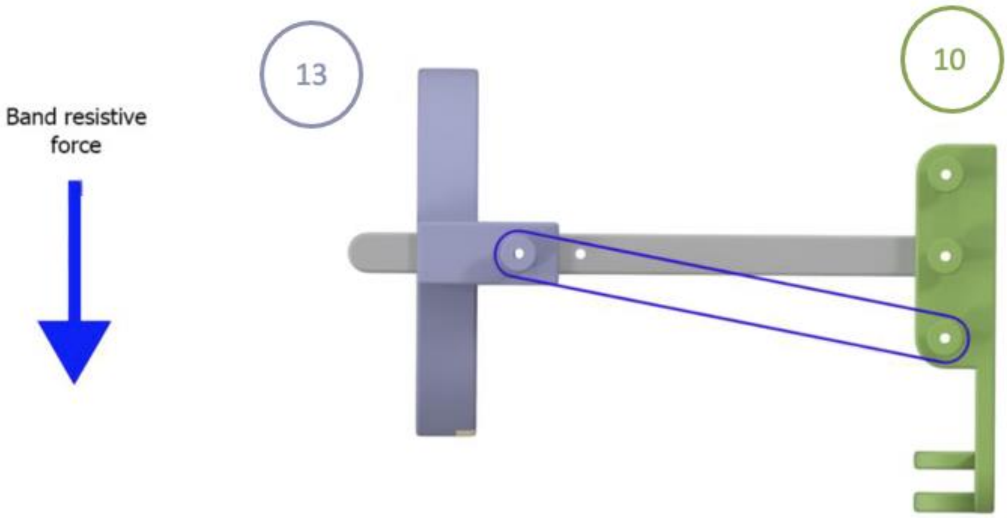
    - Forearm segment: Bands are place on the upper attachment point on piece 10 then an upper force will be produced, at piece 13 in this case there is only a fixed point.



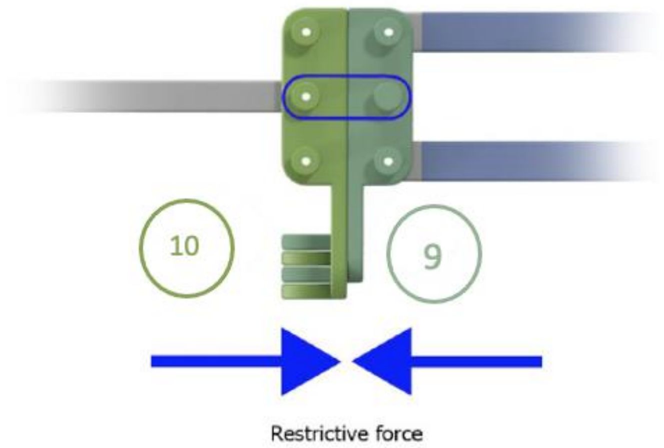
- Resistive configuration:
    - Arm segment: Bands are placed on the lower attachment point of piece 4 and the upper one of piece 9 then a downward force will be produced which will be added to the gravitational pull increasing the apparent weight of the upper limb.



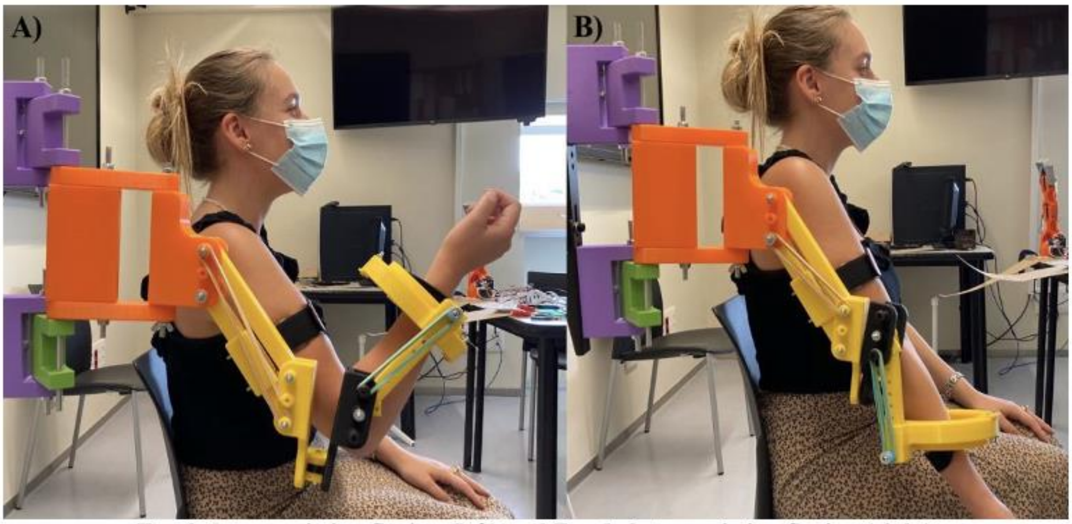
    - Forearm segment: Bands are placed on the lower attachment point of piece 10 then a resistive force is produced, the attachment at piece 13 is the same.



- Elbow segment
  - Assistive configuration to prevent the elbow internal flexion: Middle attachment point in pieces 9 and 10 is used to create an opposite force when flexing the forearm.



It is usually needed to place several elastic bands to be able to assist or resist the patient's arm significantly. But it is **not possible to quantify how many bands are necessary for each activity** a priori, as it depends on external factors, such as the patient's height and weight, the strength of the user, the problem or dysfunction that needs to be worked on. **A physiotherapist is responsible for and supervises the therapeutic prescription of the use of these modes.**



Exoskeleton assisting flexion (left) and Exoskeleton resisting flexion (right)

ANNEX 3: Questionnaires

Please indicate your level of agreement or disagreement with the following statements based on your experience in ASSEMBLING the POWERUP exoskeleton.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
I would like to use the POWERUP exoskeleton more often.	○	○	○	○	○
it seems to me that this instruction manual is more complicated than it should be.	○	○	○	○	○
I find the manual simple and easy to use.	○	○	○	○	○
II need technical support to assemble this exoskeleton.	○	○	○	○	○
I think the manual works well and is well explicated.	○	○	○	○	○
I think there are many irregularities in the manual.	○	○	○	○	○
I think most people could assemble this exoskeleton.	○	○	○	○	○
I think this assembly is very time-consuming.	○	○	○	○	○
I feel safe using this manual.	○	○	○	○	○
I think there are a lot of things to learn before the exoskeleton can be assembled.	○	○	○	○	○

SUS Assembly Manual

SUS Use Manual

Please indicate your level of agreement or disagreement with the following statements based on your experience with the POWERUP exoskeleton.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
I would like to use the POWERUP exoskeleton more often.	○	○	○	○	○
It seems to me that this user manual is more complicated than it should be.	○	○	○	○	○
I find the manual simple and easy to use.	○	○	○	○	○
I need technical support to use this exoskeleton.	○	○	○	○	○
I think the manual works well and is well explicated.	○	○	○	○	○
I think there are many irregularities in the manual.	○	○	○	○	○
I think most people could use this exoskeleton very quickly.	○	○	○	○	○
I think this manual is very time-consuming.	○	○	○	○	○
I feel safe using this exoskeleton.	○	○	○	○	○
I think there are a lot of things to learn before I can use this exoskeleton.	○	○	○	○	○

Evaluation of User Satisfaction with the POWERUP exoskeleton.

QUEST 2.0 survey

Technology device ____

Username ____

Date of evaluation ____

How long have user been using the device ____________________________

Age _______________ Gender ______________________________________

Pathology ____

Social security system ____

Observer ____

The aim of this survey is to assess your satisfaction with de devices you use and related services. The survey consists of 12 questions.

- For each of them, please mark your level of satisfaction (how pleased you are with the device and related services) using the following scale from 1 to 5.

1	2	3	4	5
Not satisfied at all	Not very satisfied	More or less satisfied	Satisfied	Very satisfied

- Please circle the number that best describes your level of satisfaction for each of the 12 questions.
- Do not leave any questions unanswered.
- For each question with which you state that you are not very satisfied, please write it in the comments section.

Thank you for your cooperation.

1	2	3	4	5
Not satisfied at all	Not very satisfied	More or less satisfied	Satisfied	Very satisfied

POWERUP EXOSKELETON

How satisfied (happy) are you with:

1. The dimensions (size, width, length) of the exoskeleton? Comments:	1 2 3 4 5
2. The weight of the exoskeleton? Comments:	1 2 3 4 5
3. The adjustability (graduation, securing) of the parts of the exoskeleton? Comments:	1 2 3 4 5
4. Safety and the possibility of the exoskeleton not hurting you? Comments:	1 2 3 4 5
5. The durability (duration and resistance to use) of the exoskeleton? Comments:	1 2 3 4 5
6. The ease of use ("wearing") of the exoskeleton? Comments:	1 2 3 4 5
7. The comfort of the exoskeleton? Comments:	1 2 3 4 5
8. The effectiveness of the exoskeleton in solving the problem for which you are using it? Comments:	1 2 3 4 5

FURTHER QUESTIONS

1. What is your overall level of satisfaction with the exoskeleton? Comments:	1 2 3 4 5
2. What is your overall level of satisfaction with the services provided for the exoskeleton? Comments:	1 2 3 4 5

Below you will find the list of the same 12 satisfaction questions. **PLEASE SELECT THE THREE QUESTIONS** that are most important to you and mark them with an x in the 3 boxes of your choice

☐ 1. Dimensions

☐ 2. Weight

☐ 3. Adjustment

☐ 4. Security

☐ 5. Durability

☐ 6. Ease of use

☐ 7. Comfort

☐ 8. Effectiveness

☐ 9. Delivery service

☐ 10. Repair and maintenance

☐ 11. Professional assistance

☐ 12. Continuous service

Please rate your appreciation of the satisfaction and usefulness of the exoskeleton for the observed patient: (Using the same score)

1	2	3	4	5
Not satisfied at all	Not very satisfied	More or less satisfied	Satisfied	Very satisfied