



Kaunas University of Technology

Faculty of Electrical and Electronics Engineering

Technical University of Cartagena

School of Industrial Engineering

Design of the Automatic Actuation System of a Hexapod Robot for Medical Applications

Bachelor's Final Degree Project

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Supervisors

Cartagena, Kaunas 2020



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Industrial Electronics and Automation Engineering (5071)

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Design of the Automatic Actuation System of a Hexapod Robot for Medical Applications

Declaration of Academic Integrity

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Pedro Serrano Montesinos

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4. Project's Structure. *The content is concretized together with supervisor, considering the format of the final project, which is listed in 14 and 15 points of Combined Description of Preparation , Defence and Keeping of Final Projects Methodical Requirements*

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4.2 Select proper technological equipment for the hexapod robot design

4.3 Analyse possible risks and hazards, that can occur while exploring the system

4.4 Compose and describe control algorithm of the hexapod robot for medical applications

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Show component assembling schemes and explain them

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Summary

The initial objective of this end-of-grade work was the development of the TL-Hex hexapod robot automatic actuation system, designed for medical applications at the "Texas Scottish Rite Hospital for Children" (TSRHC) in Dallas, Texas, US. However, due to the health crisis suffered due to the global pandemic by the COVID-19, the objectives of this project were modified, being diverted towards a work that would provide the necessary information to continue with the development of the action system in future works.

The initial work plan consisted of analysing the requirements of the actuators, and then studying the different possible forms of automation; motorising the existing ones while respecting the current structure of the system, looking for complete adaptable actuators or any other solution that has the least possible impact from a mechanical point of view. For this automation, the previous developments made in the end of degree work "Sensorization of a parallel robot for medical applications", carried out by Laura Valdez Vidal in 2018, would be used. Once the different possibilities had been studied, experimental tests would be carried out in order to check that the studies carried out were valid and thus draw conclusions that could meet the objective of this work.

However, after the declaration of the state of alarm that prevented the university from conducting experimental tests, and the closing of borders that caused the components acquired for the project not to be received, the project was reoriented in order to be able to add value to the project that was established with the available material. These subsequent contributions are based on the energy dimensioning of the system based on the analysis carried out prior to the state of alarm and available information, the study in terms of regulations because it is a medical product, and the study of the control system of the motors used in the actuation system.

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Santrauka

Pradinis šio darbo tikslas buvo sukurti automatinio valdymo sistemą „TL-Hex Hexapod“ robotui, skirtam medicinos reikmėms „Texas Scottish Rite Hospital for Children“ (TSRHC), Dalaso mieste, Teksaso valstijoje, JAV. Tačiau dėl pasaulinės pandemijos, susijusios su COVID-19, šio projekto tikslai buvo pakeisti, nukreipiant į darbą, kuris suteiktų reikiamos informacijos, siekiant tęsti sistemos plėtrą būsimuose darbuose .

Pradinį darbo planą sudarė pavarų reikalavimų analizė, o vėliau skirtingų galimų automatizavimo formų tyrimas; motorizuojant esamus, gerbdami esamą sistemos struktūrą, ieškant pritaikomų pavarų ar bet kokio kito sprendimo, darančio mažiausią įmanomą poveikį mechaniniu požiūriu. Šiai automatizacijai bus naudojami ankstesni pokyčiai, padaryti baigiamajame darbe „Lygiagrečiojo roboto jautrumas medicininėms reikmėms“, kurį atliko Laura Valdez Vidal 2018 m. Išnagrinėjus skirtingas galimybes, bus atlikti eksperimentiniai bandymai, siekiant patikrinti atliktų tyrimų pagrįstumą ir padaryti išvadas, kurios galėtų atitikti šio darbo tikslą.

Tačiau paskelbus karantiną, buvo uždrausta universitete atlikti eksperimentinius bandymus, o uždarius sienas, projekto metu įsigyti komponentai nebuvo gauti, projektas buvo perorientuotas, kad būtų galima sukurti pridėtinę vertę. Šie paskesni įnašai yra pagrįsti sistemos energijos išmatavimais, pagrįstais analize, atlikta prieš pavojaus signalo būseną ir turima informacija, tyrimu, atsižvelgiant į reglamentus, nes tai yra medicinos produktas, ir į sistemos valdymo sistemos tyrimą. varikliai, naudojami paleidimo sistemoje.

Serrano Montesinos, Pedro. Diseño del Sistema de actuación automático de un robot hexápodo para aplicaciones médicas. Trabajo de fin de grado. / Supervisores Miguel Almonacil Kroeger, Julio José Ibarrola Lacalle, Virginijus Baranauskas; Universidad Tecnológica de Kaunas, Facultad de Ingeniería Eléctrica y Electrónica; Universidad Politécnica de Cartagena, Facultad de Ingeniería Industrial Campo y área de estudio (campo de trabajo del grupo): ingeniería electrónica y eléctrica, ciencias de la tecnología, ingeniería.

Palabras clave: robot hexápodo, sistema de control.

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Resumen

El objetivo inicial del presente trabajo de fin de grado era el desarrollo del sistema de actuación automático del robot hexápodo TL-Hex, diseñado para aplicaciones médicas en el “Texas Scottish Rite Hospital for Children” (TSRHC) en Dallas, Texas, US. Sin embargo, por la crisis sanitaria sufrida debida a la pandemia global por el COVID-19, los objetivos de este proyecto se vieron modificados, desviándose hacia un trabajo que aportase información necesaria para continuar con el desarrollo del sistema de actuación en futuros trabajos.

El plan inicial de trabajo consistía en analizar los requerimientos de los actuadores, para después estudiar las distintas formas posibles de automatización; motorizando los existentes respetando la estructura actual del sistema, buscando actuadores completos adaptables o cualquier otra solución que tenga el menor impacto posible desde el punto de vista mecánico. Para dicha automatización se utilizarían los desarrollos previos realizados en el trabajo de fin de grado “Sensorización de un robot paralelo para aplicaciones médicas”, realizado por Laura Valdez Vidal en 2018. Una vez estudiadas las distintas posibilidades, se realizarían pruebas experimentales con el objetivo de comprobar que los estudios realizados eran válidos y así sacar unas conclusiones que pudieran responder al objetivo de dicho trabajo.

Sin embargo, tras la declaración del estado de alarma que impedía acudir a la universidad para realizar pruebas experimentales, y el cierre de fronteras que hizo que no se recibieran los componentes adquiridos para el proyecto, se reorientó el proyecto para poder aportar valor al proyecto que estaba establecido con el material disponible. Estas aportaciones posteriores se basan en el dimensionado energético del sistema en base al análisis realizado previo al estado de alarma e información disponible, el estudio en cuanto a normativas por ser un producto sanitario, y el estudio del sistema de control de los motores utilizados en el sistema de actuación.

INDEX OF CONTENTS

ÍNDICE DE FIGURAS	12
CHAPTER 1	15
1. INTRODUCTION	15
1.1. Framework	15
1.2. Motivation.....	15
1.3. Objective of the Project	16
CHAPTER 2	17
2. STATE OF THE ART	17
2.1. Introduction to parallel robots.....	17
2.2. TL-Hex robot	18
2.3. TL-Hex Robot Actuators	20
CHAPTER 3	23
3. ACTUATOR SELECTION.....	23
3.1. Pneumatic actuators	23
3.2. Hydraulic actuators	24
3.3. Electric Actuators	24
3.3.1. Direct current (DC) motors.....	25
3.3.2. Alternating Current Motors	27
3.3.3. Stepper motors.....	29
3.4. Engine proposal	31
CHAPTER 4.....	33
4. ENERGY CONSUMPTION AND BATTERY SIZING.....	33
4.1. Preliminary considerations	33
4.2. Component analysis.....	34
4.3. Functioning	38
4.4. Battery selection	48
CHAPTER 5.....	49
5. HEALTH REGULATIONS AND RISK MANAGEMENT PLAN	49
5.1. Standardization for CE marking.....	50

5.2. Risk management study.....	52
5.3. Risk management plan.....	53
5.4. Risk assessment	56
5.5. Risk control.....	58
5.6. Pre-marketing and after-sales documentation.....	59
5.7. Risk management plan tables	60
CHAPTER 6.....	68
6. ACTUATOR CONTROL AND SIMULATION	68
6.1. Modeling and simulation of DC engine	69
6.2. Modeling and simulation of Stepper motor.....	76
7. CONCLUSIONS AND FUTURE DEVELOPMENT LINES	82
8. BIBLIOGRAPHY	84

ÍNDICE OF FIGURES

Figure 1. Parallel robot and its fundamental parts.....	17
Figure 2. Serial robot (a) and parallel robot (b).....	18
Figure 3. Platform designed by Gough to test tires	18
Figure 4. Hardware of TL-Hex robot	19
Figure 5. Example of a screen for the analysis of the surgery.....	20
Figure 6. Actuator sizes and design.....	20
Figure 7. Mounting the actuators on the brackets	21
Figure 8. Built- in clip types.....	21
Figure 9. Fig. A: Quick adjustment mark. Fig. B: Function of the adjusting screw. Fig. C: Gradual adjustment mark	21
Figure 10. Location of the mounting bolts in their holes	22
Figure 11. TL-Hex system correctly mounted.....	22
Figure 12. Climbing robot with pneumatic actuators for maintenance and fumigation of palm trees	24
Figure 13. Parts of a DC motor	26
Figure 14. Working principle of a DC motor	27
Figure 15. Synchronous motor with DC-excited rotor	28
Figure 16. Asynchronous motor with short-circuited winding.....	28
Figure 17. Two stator coils excited to double the number of motor steps	30
Figure 18. Variable reluctance motor with toothed rotor and stator	30
Figure 19. DC motor connection diagram	31
Figure 20. Wiring diagram for motor nema 17	32
Figure 21. Design diagram	33
Figure 22. Nema 17 engine torque-pps curve.....	35
Figure 23. Actuator design of FDP Linear actuator design for robotic prosthetic devices.....	36
Figure 24. Current/time curve of the actuator in the above-mentioned TFG	36
Figure 25. Arduino Nano module.....	37
Figure 26. Comparative Arduino working normally and in sleep mode	37
Figure 27. Code to put one of the pins in sleep mode	37
Figure 28. Information flow between the Wifi module and Arduino.....	38
Figure 29. Prescription page 1	39
Figure 30. Prescription page 2	40
Figure 31. Prescription page 3	40
Figure 32. Prescription page 4	41
Figure 33. Comparative of engine consumption (mWh).....	46
Figure 34. Comparison of microcontroller consumption (mWh).....	46
Figure 35. Comparison of Bluetooth, Wifi and memory consumption (mWh)	46
Figure 36. Comparative consumption of Sensors (mWh)	47
Figure 37. Steps up to the commercialization of a product	51
Figure 38. Representation of the relationship between hazard, sequence of events, dangerous situation and damage	52
Figure 39. Risk management scheme according to ISO 14971	53

Figure 40. Engine modeling general scheme.....	68
Figure 41. Location of the motor in the actuator.....	69
Figure 42. Control loop for the system formed by the DC motor.....	69
Figure 43. Electromechanical diagram of the DC motor.....	70
Figure 44. DC motor modeling system with its electrical circuit and load.....	72
Figure 45. Engine input parameters (sub-system engine and driver).....	72
Figure 46. Circuit with driver function (speed demand block).....	73
Figure 47. System controller (closed-loop controller block).....	73
Figure 48. Sensor providing rotor data (w-block).....	74
Figure 49. Labels to show the simulation data (speed and position block).....	74
Figure 50. Configuration parameters of the motor and driver subsystem.....	75
Figure 51. Simulation of DC motor operation.....	75
Figure 52. Closed control loop for the stepper motor.....	76
Figure 53. Schematic for step motor with two phases and three teeth.....	76
Figure 54. Equivalent circuit of the two phases of the stepper motor.....	77
Figure 55. Stepper motor shaft; Mechanical part of the model.....	78
Figure 56. Block diagram modeling the stepper motor.....	78
Figure 57. System designed for stepper motor simulation.....	79
Figure 58. Position controller.....	79
Figure 59. Position controller in pulse generator block.....	79
Figure 60. Engine configuration according to the manufacturer's datasheet.....	80
Figure 61. Driver Configuration.....	80
Figure 62. Stepper motor operation simulation.....	81

ÍNDICE OF TABLES

Table 1. Advantages and disadvantages according to the type of actuator	25
Table 2. Comparison of DC and AC motors	29
Table 3. DC motor specifications	31
Table 4. Stepper motor specifications	32
Table 5. Electrical data of the components.....	42
Table 6. Consumption of the components according to the proposed scenario	43
Table 7. Tools and requirements for medical certification in the major WHO Powers .	49
Table 8. Qualitative analysis of risk management.....	55
Table 9. Semi-quantitative estimate of the probability of occurrence of a risk case.....	57
Table 10. Qualitative estimation of severity by the occurrence of a risk	57
Table 11. Risk assessment matrix	58
Table 12. Model table for risk management plan.....	59
Table 13. Risk Management Plan; Energy Hazards	61
Table 14. Risk management plan; Biological hazards	62
Table 15. Risk management plan; Environmental hazards	63
Table 16. Risk management plan; Human and use-related hazards	66
Table 17. Risk management plan; Hazards associated with design	67

CHAPTER 1

1. INTRODUCTION

1.1. Framework

The aim of this project is to advance the design of a robot hexapod for use in medical applications. It aims to advance the design of the system of action of the robot, an energy study for possible use with batteries and a regulatory study for the application in the health field.

This robot has been created to serve as a base for some orthopedic surgery and traumatology treatments. It currently uses manual actuators consisting of two telescopic aluminium tubes that allow the elongation of the system to be adjusted with a spring loader, giving the system the possibility of making a quick or gradual precise adjustment according to the needs of the treatment. The automation of these actuators is intended to provide greater control of the treatment, allowing the doctor to program the movements according to the needs of each patient.

Following the line of research initiated by the Department of Systems Engineering and Automation with the FDP of Laura Valdez Vidal consisting of the sensorization of the present robot, the aim is to achieve fully automated operation of the system in the future.

1.2. Motivation

Health comes first. This is an affirmation that, although it may seem exaggerated, is confirmed by observing how among the most important news that have occurred during the last century are included even before studies such as the theory of relativity or the appearance of the computer, several related to medicine, such as the discovery of penicillin or the identification of the AIDS virus.

Given the importance of health in our lives, it is also important to mention another fundamental term: research. Research is something that is essential in the development of humanity, which has allowed people to make their lives longer and more comfortable.

As a result of the research, engineering arises, which consists of the application of all kinds of techniques and knowledge to achieve the greatest effectiveness in the desired goal. The presence of engineering in medicine is more and more remarkable, something that can be observed with the appearance of new specialities such as biomedicine. This fact is not surprising, since the contributions of engineering can generate great benefits in any field of work, since as has already been seen in other sectors in industry, it can make any work faster, simpler, more efficient and more precise.

Thus, as a future engineer, it is a great motivation to carry out this work, allowing to apply the knowledge obtained during my time as a student, especially in electronics and robotics, to try to improve the life of the users of the system, and to facilitate the work of the specialized doctor by improving a widely studied treatment that has already helped many people. In addition, it will be a privilege to have the help of people with experience and knowledge such as UPCT and KTU professors to best carry out this project and grow as an engineer.

1.3. Objective of the Project

As mentioned above, the final objective of the work is the development of the TL-Hex robot's automatic actuation system, thus trying to facilitate the work of the specialist and improving the results in the treatment of future patients. To achieve this goal, procedures must be followed that lead to the end of the objective. The following is a description of the objectives set before the appearance of the health crisis and the changes that were developed to be able to contribute value while maintaining the final objective.

- Study of the parallel robot and its application in orthopedic surgery and traumatology operations.
- Gathering information on the most suitable actuators and the requirements necessary for their application in the health sector.
- Selection, acquisition and assembly of the actuators in the robot.
- Design and development of the control system for the actuators.
- Carrying out experimental and calibration tests.
- Analysis of the results obtained and feasibility of the developments made.

These were the initial objectives of the project, which could be developed as presented below until the selection of the possible actuators for the robot. It is worth mentioning that with the closing of the borders, the purchases to carry out the tests were not received and it was necessary to redirect objectives.

- To be able to size one of the parts that could limit the automation of the system due to weight and lack of power, the batteries, it was decided to carry out an energy study of the system.

- In order to have a guide to take into account regarding sanitary requirements, it was decided to carry out a study analyzing the existing regulations and a risk management plan was drawn up.

- In order to have previous knowledge in the control of the selected motors, control tests with the MATLAB simulator were proposed.

CHAPTER 2

2. STATE OF THE ART

2.1. Introduction to parallel robots

As previously mentioned, this TFG follows the line of research initiated with the end-of-degree work "Sensorization of a parallel robot for medical applications" by Laura Valdez, in 2018. Therefore, given that in this TFG we can find a more in-depth analysis of parallel robots, the Stewart platform and the TL-Hex robot and their applications in medicine, this work will provide an introduction to understanding hexapod robots both in their operation and applications, and in particular for the field of medicine and will focus on the development of the actuators, as this is the fundamental objective of this work.

To understand the robot on which the study is focused, it must be classified as a parallel hexapod robot designed for medical applications, in particular the field of traumatology.

A parallel robot (fig. 1) is defined as one composed of at least two independent kinematic chains that join a base to an end effector forming a closed chain mechanism. In the following image the basic structure of a hexapod robot and its parts can be seen:



Figure 1. Parallel robot and its fundamental parts

Since the appearance of these robots in 1928 with the creation by James E. Gwinnett of a robot for the entertainment industry, their use has increased due to the work possibilities they offer, replacing in a wide field of activities their great rivals, the open chain robots. While serial robots are composed of an open kinematic chain that allows them to act in large fields of movement, as if it were a human arm, parallel robots allow greater strength and precision in the performance. The simile of the human body is a great way to easily understand the principle of performance of parallel robots with respect to the serial, where considering the torso as a fixed base, and the moving platform the element held by both hands, you can apply greater force and provide greater accuracy when moving an object with both hands at the expense of losing working field.

Other advantages of this type of robot are its high energy efficiency, as a result of its high load/power ratio, its high rigidity, low weight and high operating speeds compared to other types of robots. At the expense of these advantages, these robots present other characteristics that, depending on the application, can be disadvantages, such as the complicated kinematics of the mechanisms and the inexistence of a general dynamic model for these mechanisms as exists for serial robots.

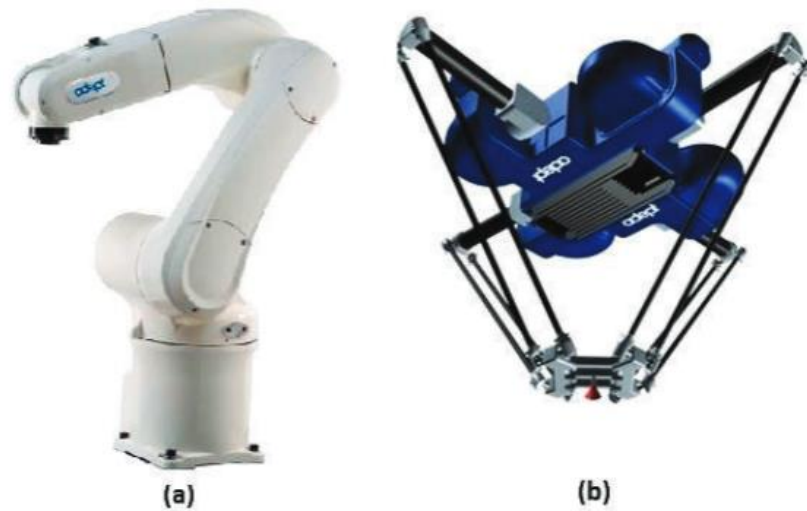


Figure 2. Serial robot (a) and parallel robot (b)

As mentioned above, the first parallel robot appeared in 1928, and in 1940 Willard L.V. Pollard presented the first parallel robot for industrial applications. As a relevant fact, in the 50's, it was when Eric Gough, an automotive engineer working for the Dunlop company, designed what would be the first robot that would use a platform with 6 degrees of freedom that employed a structure similar to that of the TL-Hex robot to test tires (fig. 2). However, it was in 1965 when the first scientific article was published introducing a parallel robot with 6 degrees of freedom, similar to the one used by Gough previously, in this case designed for flight simulation applications. For this reason, the robot model studied follows the model known today as the Stewart-Gough platform (fig. 3).

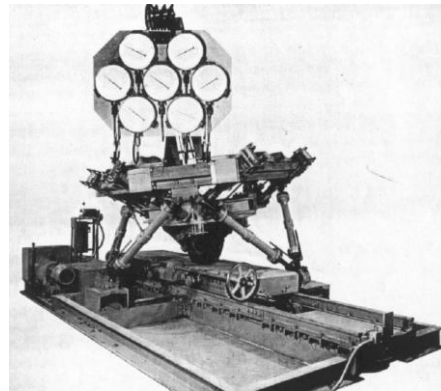


Figure 3. Platform designed by Gough to test tires

As for all the areas in which we can find hexapod robots, we highlight 4 in which they have a more relevant presence. Two are for applications in industrial robotics, such as pick and place operations and high-speed machining centres, and another two are for service robotics, such as robotic surgery and the development of rehabilitation and diagnostic devices.

2.2. TL-Hex robot

The TL-Hex robot, or "TrueLock Ring Fixation System," is a hexapod robot with a circular external fixation system developed at the Texas Scottish Rite Hospital for Children (TSRHC) in Dallas, Texas. It is a system marketed by the company Orthofix, which, in conjunction with a software developed

to facilitate the work of the specialist, is used to lengthen the extremities by means of metaphyseal and epiphyseal distraction, fix open and closed fractures, treat pseudoarthrosis of long bones and correct deformities or defects of bone or soft tissue. This method of treatment follows the approach of Gavril A. Ilizarov, a Russian researcher, who defended the biological principle of tension-stress based on the regeneration and growth of tissues during distraction.

When a treatment is carried out using the TL-Hex robot, a hardware is used that varies according to the pathology to be treated, and that must be assembled and used following established steps and software available to the specialist that helps to monitor progress and make an adequate analysis of it. In the FDP of Laura Valdez already mentioned, more extensive descriptions are given of both the components and the ways of assembling or using both the hardware and the software. In this work, a more summarized review is shown to help understand the system.

The system hardware consists of two supports, which would be the base and the final effector, which in this case would be the external circular, semi-circular or so-called foot plate supports, made of aluminium and stainless steel in a variety of sizes to suit clinical requirements. These supports are connected to the bones by Kirschner wires, and interconnected to each other by six struts. These props are the system's actuators, which will be automated in the project, and currently consist of two telescopic aluminium tubes, one inner and one outer, which are actuated by turning a nut and can be locked with a spring loaded system. These actuators consist of a joint at each end, which, based on the TrueLok fixing system, allows the connection of actuators and supports, building fixing blocks if necessary (fig. 4).

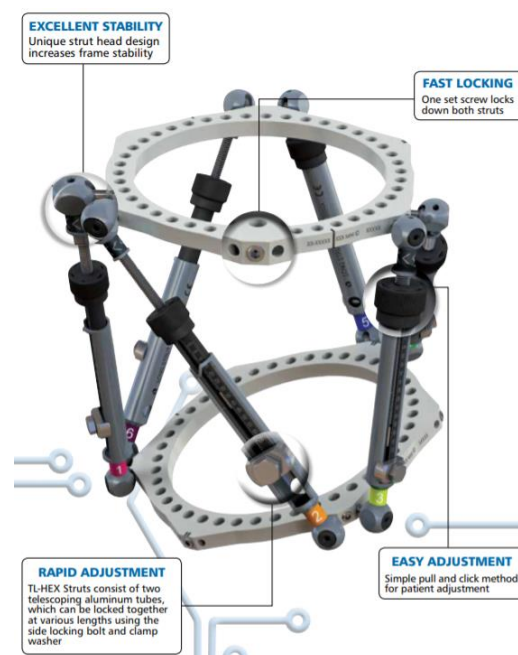


Figure 4. Hardware of TL-Hex robot

The software that helps the surgeon use the device can be found on the manufacturer's website (www.thlhex.com), and attempts to provide support before, during, and after surgery (fig. 5). Before starting the treatment, it is able to calculate a prescription to be reviewed by the doctor, it can show the method of mounting the system, as well as an interface to see how the treatment is going, allowing to analyze data on X-rays and create an appropriate plan for correction on Excel-type tables, helping the specialist to generate a more organized and precise treatment. The use of this software implies the use of a terminology adapted to the field of medicine on which it acts, so it will be necessary to be aware of the matter on which you are working.



Figure 5. Example of a screen for the analysis of the surgery

2.3. TL-Hex Robot Actuators

The actuators or "struts" of the TL-Hex, consist of two telescopic aluminum tubes, one outer (A) and one inner (B), which can be locked together through a fixing screw (C) and a clamping washer (D) (fig. 6). These components are compatible with the TrueLok fixing system. These actuators are available in 4 sizes, as shown in the table and providing an adjustment range from 45mm to 318mm.

Part Number	Description	Minimum Length	Maximum Length
50-10100	UltraShort	45mm	101mm
50-10200	Short	92mm	122mm
50-10300	Medium	114mm	184mm
50-10400	Long	158mm	318mm

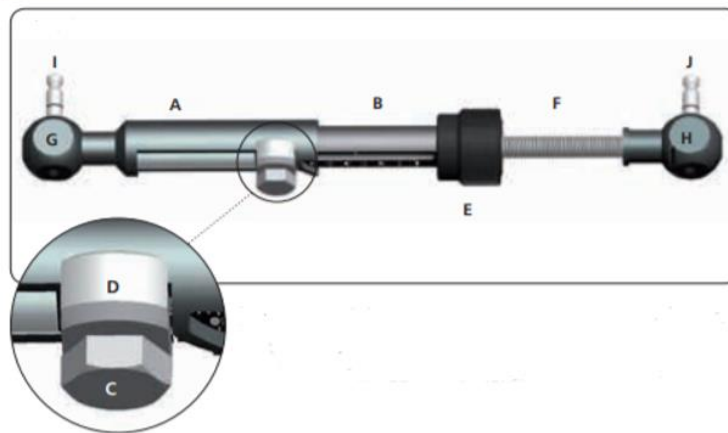


Figure 6. Actuator sizes and design

The inner tube is connected to a spring-loaded, black knurled adjustment knob (E), which is attached to a threaded rod (F) so that the rod moves with respect to the inner tube when the knob is turned. Each actuator is accompanied by two special seals (G) and (H), located one at the end of the lower tube and the other at the end of the worm. Each joint comes with two adapters (I) and (J) which can be placed in the holes intended for mounting on the rings that form the bases of the system as shown in the following figure (fig. 7):



Figure 7. Mounting the actuators on the brackets

Two different types of clips can be attached to the actuators, which remain in the system throughout the treatment and show the actuator number or setting direction, depending on the clip type chosen.



Figure 8. Built-in clip types

The movement of the system's actuators can be done quickly or gradually (fig. 8). The quick adjustment is made by loosening the clamping screw, sliding the inner tube with respect to the outside to the desired point, and re-adjusting the mentioned screw. This adjustment can be measured on the 1 mm scale on the inner tube with the orange line on the outer tube (Fig. 9A). Gradual adjustment is made by turning the adjustment screw, which generates a slight click every 0.5 mm of movement (Fig. 9B). The measurement of this displacement is carried out with the same scale as in the previous case, but using the 0.5 mm divisions and the green line for marking (Fig. 9C)



Figure 9. Fig. A: Quick adjustment mark. Fig. B: Function of the adjusting screw. Fig. C: Gradual adjustment mark

For the correct assembly of robot, it is recommended to follow the steps established by the manufacturer, as shown in the manual on its website (<https://abs.orthofix.it/db/resources/TL-1405-OPT-E0.pdf>), and which are as follows:

1. Selection of the external supports, the six actuators and the clips to be placed on the actuators.
2. Make sure that the locking screws have been pushed back to the stops.
3. Place the clips in the slot of the actuator.
4. Position the proximal ring bracket with the double line boss toward the surgeon and insert the #1 actuator into the left boss mounting hole.
5. Ensure that the bolt insertion line is completely tightened in the mounting hole.
6. While holding the #1 actuator in place, insert the #2 actuator mounting bolt into the right-hand hole of the same boss as shown in the following figure (fig. 10):



Figure 10. Location of the mounting bolts in their holes

7. Using an Allen key, tighten the locking screw so that the actuators are held in place.
8. Turning clockwise, skip a boss hole and repeat the procedure with actuators #3 and #4.
9. Repeat steps to position actuators #5 and #6. Confirm that the actuators have been placed in the proximal bracket in a clockwise direction.
10. Align the orientation tab of the distal mount with the proximal mount. Position the mounting bolts of the actuators #2 and #3 in the corresponding holes according to the steps above. Secure the actuators in position.
11. By turning clockwise, mount the actuators #4 and #5 and then the actuators #6 and #1 following the same procedure.
12. Make sure that the mounting is as shown in the figure below (fig. 11):



Figure 11. TL-Hex system correctly mounted

CHAPTER 3

3. ACTUATOR SELECTION

The aim of this project is to automate the actuators of the parallel hexapod robot. Therefore, firstly, an analysis of the requirements to be met by the solution to be developed will be carried out and different possibilities will be considered in order to compare the pros and cons of each option.

Based on the requirements established by Laura Valdez in the previously mentioned TFG together with the specialist Dr. Salcedo, the following key points could be set according to the needs for the automation of the actuators:

- The solution taken to automate the actuators must have a minimum impact on the system. Neither the operation nor the overall design of the system will be changed.
- The actuation system must be capable of providing lengths between 158 and 318 mm with a minimum accuracy of 1 mm, with higher accuracy always being favourable.
- The automation of the actuators can neither add excessive weight nor increase the volume of the robot, since it will be mounted on the patient's leg.
- The changes have to be adaptable to the existing system.
- Under no circumstances must the integrity of the patient or the medical team be compromised, respecting all the health and safety regulations.
- Communication between the control platform and the actuators must be wireless
- The aim is to offer a solution that does not hinder the movement of the actuators in any way, and so can continue to be adjusted by both the patient and the doctor as appropriate.
- Without making a thorough analysis, given the complexity that may be involved, it is considered that the force to be developed by the actuators will not be great. To reach this conclusion, the criterion is that in the current system, all the force is applied by two fingers operating a small diameter nut without effort.

After analyzing the characteristics that the selected solution must have for the automation of the actuators, possible solutions are presented along with the possible advantages and disadvantages of their use.

Analyzing the current robot system, there are mechanical actuators, this means that they have a mechanism that provides a force to move another device, in this case a nut operated by the person generates the telescopic movement of the system tubes. In order to automate the linear movement of the actuators, we proceed to study the types of actuating systems that could provide the necessary force to exercise such movement, taking into account that in any case an electronic part would be required to carry out the control. Depending on the source used to transmit the force, the actuators can be pneumatic, hydraulic or electric.

3.1. Pneumatic actuators

Pneumatic actuators base their operation on the movement of a piston with compressed air. The main advantages of these systems are their ability to generate linear or rotary work, their high operating speed or their high load capacity. This type of actuators, although present in parallel robots such as the REMO robot, to facilitate underwater movement operated remotely, or the Trepa robot of the photo (fig. 12), is discarded for the present application. The reason for discarding these actuators is

that none of their advantages are relevant for our system, since neither high speed nor high work force are required, while it would be a disadvantage in terms of weight and volume of the set to have to incorporate a tank to store the air, a motor to compress it and high maintenance for the proper functioning of the system. They are usually used in applications that require two states, for example, open and closed.



Figure 12. Climbing robot with pneumatic actuators for maintenance and fumigation of palm trees

3.2. Hydraulic actuators

Hydraulic actuators follow the same principle of operation as pneumatic actuators, however, the fluid used to generate the mechanical force is a liquid, such as water, or oil if high power is required in machines of great weight and size. The advantages of this type of actuators are the high power/load ratios, the accuracy, the frequency of response, the speed range, the smoothness at low speeds and, with respect to pneumatic systems, the higher force output with the same size. These types of systems will also be discarded for our applications since their disadvantages outweigh their advantages. Among the disadvantages are the need for maintenance to avoid possible leaks, the complexity of the installation and, as in the previous case, the weight and volume provided by the motors to compress the liquids or the tanks to store them.

3.3. Electric Actuators

Finally, the third type of actuators to be considered would be electric, the simplest of the above, as they use electrical energy as a source to transform the rotary movement of the motor into linear movement. This type of actuators are the most used in robotics, especially in applications whose main requirements are accuracy and repeatability. We find actuators with direct current, alternating current and stepper motors.

Finally, it was decided to choose this type of actuators to carry out the automation of the TL-Hex system due to the number of advantages they present and which are explained below:

- Simplicity of the control circuit, with only an electric motor without the need to add any extra equipment. This will save inaccuracies and maintenance, providing a system that facilitates greater speed, load and life.
- The operation of the system will not be affected by external factors such as environmental temperature or pollution, as it happens in hydraulic and pneumatic systems.

- The connection between the motor and the servo is simplified, using only electrical cables to transmit the signals, and not oil pumps, pipes or other more complex accessories.
- Compared to pneumatic actuators they can be used in applications where compressed air is not suitable.
- Control of position, speed and torque is easier to automate, which is ideal for the application.
- This type of actuator is highly energy efficient, up to 90%, which is not achieved with any other type.
- Although it is not fundamental for the present design, the speed of movement is very fast and the load capacity covers a wide range reaching great values.
- Due to the simplicity of the structure, they can be designed to operate in places with defined spaces and their useful life is longer.
- Their applicability is higher, which is of interest for medical applications, where a lot of requirements have to be met.

ACTUATOR TYPE	ADVANTAGES	DISADVANTAGE
PNEUMÁTIC	<ul style="list-style-type: none"> - Low cost - Speed - Simplicity - Robustness 	<ul style="list-style-type: none"> - Special installations - Noise
HYDRAULIC	<ul style="list-style-type: none"> - Speed - High load capacity - Stability against static loads 	<ul style="list-style-type: none"> - - Special installations - - Difficult maintenance - - High cost
ELECTRIC	<ul style="list-style-type: none"> - Precise and reliable - Silent - Easy control - Easy installation and maintenance 	<ul style="list-style-type: none"> - Limited power

Table 1. Advantages and disadvantages according to the type of actuator

As mentioned above, among the electric actuators there are widely used direct current (DC) motors, with different types depending on how the magnetic field is generated, alternating current (AC) motors, which can be classified into synchronous and asynchronous, and step motors, which can be permanent magnet, variable reluctance and hybrid. We also find other results from recent research such as solenoid valves or shape memory alloys like nitinol. Next, we will present the characteristics of each of these, to see which ones are suitable for the present project.

3.3.1. Direct current (DC) motors

Direct current motors are the first electric actuators to appear, as developments after the appearance of the dynamo in 1866 by Werner von Siemens, an invention with which it shares the fundamental

characteristics and operating principle. Their purpose is to convert electrical energy into mechanical rotational energy. Its operation follows the criterion of a spiral of conductive material immersed in a magnetic field, on which by applying a potential difference between its terminals an electric current will start to circulate and therefore, what is known as Lorentz force is generated. The two basic components of this type of motor, the rotor and the stator, fulfil the function of a spiral and a magnet that creates the field respectively.

The rotor is one of the main parts of the motor, and is basically a rotating electromagnet induced by the stator. It consists of a shaft that supports a set of coils wound on a magnetic core that rotates within the magnetic field generated by the stator. This magnetic set will be mostly formed by stacked sheets, thus reducing hysteresis losses.

The stator is the other fundamental part, and it is basically an electromagnet that induces the rotating force on the rotor. It consists of a casing or yoke, in which either the coils or the permanent magnets that generate the magnetic field are placed.

Between the two components mentioned we find the air gap, a space with high magnetic reluctance due to the fact that there is only air in it, and which we will try to reduce as much as possible to minimize losses.

The gas connector is the connection area between the rotor and the stator. It is mounted on the rotating shaft and must have as much slurry as the rotor has coils.

The brushes, which are located in the commutator, are the most critical component of the motor and will account for most of the maintenance as they ensure electrical contact between the gas and the circuit that provides the current (fig. 13).

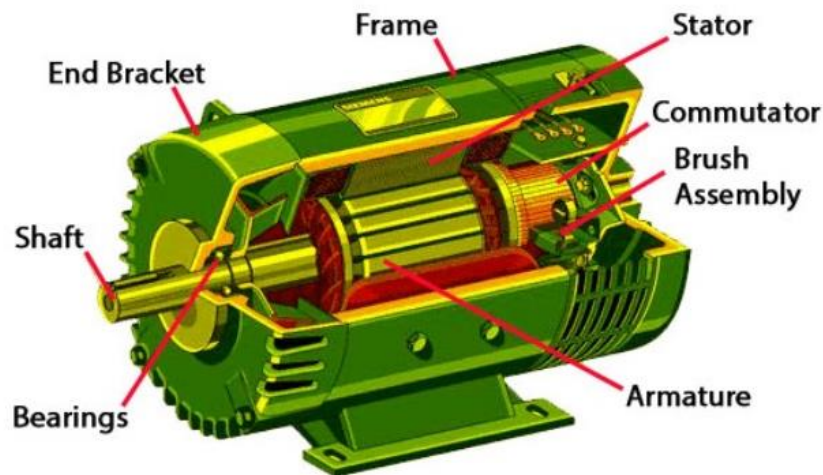


Figure 13. Parts of a DC motor

Following Hans Christian Oersted's discovery that when a spiral with current flowing through it is placed near a compass (magnet) it moves (fig. 14), DC motors make use of the relationship between electricity and magnetism to function. A fixed magnetic field provided by the stator is maintained, and an electric current is circulated through the rotor coils, which in this type of motor will always have the same direction of entry and exit thanks to the contact of the brushes with the commutator, as can be seen in the figure. In this way, as formulated by Lorentz's law, when a current circulates through a conductor immersed in a magnetic field, the so-called Lorentz force ($F=B*L*I*\text{sen}(\phi)$) is generated, perpendicular to the plane formed by the magnetic field and the current and will produce the movement. There are many types of DC motors, such as the series type, shunt type, compound

excitation, permanent magnet or brushless motor among others, which using the basic DC motor scheme add variations that can provide advantages for certain tasks.

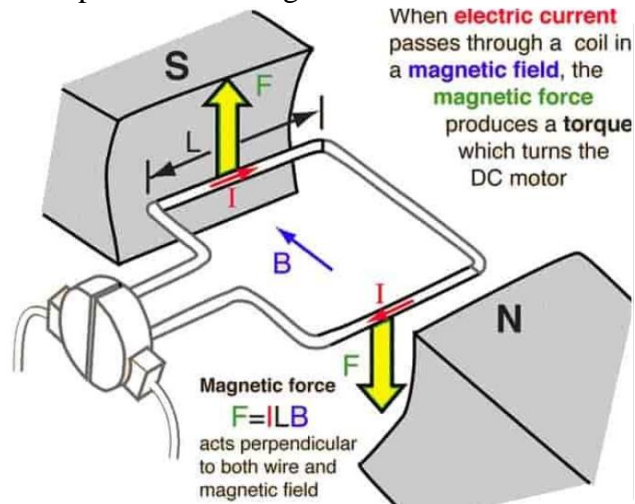


Figure 14. Working principle of a DC motor

The fundamental advantages of this type of motor are the variety of speeds, its high starting torque, the flexibility of the torque-speed characteristics, the possibility of working with energy from batteries or non-hazardous voltage sources, the possibility of reversing the direction of travel and its easy control. However, they have disadvantages such as their price, although more and more contained, the maintenance of certain parts, the need for a dc/ac converter if we connect them to the electrical network or the noise when they work continuously.

3.3.2. Alternating Current Motors

This type of engine was created in its simplest form in 1886, by Galileo Ferraris and Nikola Tesla. Like direct current motors, they transform electrical energy into mechanical rotational energy, using, however, alternating current as the source. In this case, operation is based on energy transformation by means of variable magnetic fields. In general, as in the previous cases, they are made up of a stator (inductor) and a rotor, which, depending on their structure, can be classified as synchronous or asynchronous motors.

The stator is made up of a set of stacked plates on which three windings are wound and through which the current circulates, offset by $2\pi/(3P)$, with P being the number of pairs of machine poles. When alternating current flows through these windings, a rotating magnetic field is generated, which will cause the rotor to move. The rotation speed of the magnetic field depends only on the frequency of the source and the number of poles and is calculated from the form; Synchronism speed = $120 * \text{electrical frequency} / \text{number of poles}$.

The rotor type generates the above mentioned distinction between synchronous and asynchronous motors.

Synchronous motors follow the principle of a magnet mounted on a shaft that follows a rotating magnetic field. In this way, the rotor must have a permanent magnetic field, which will be achieved either by making it a magnet itself or by installing coils in it through which direct current circulates, which will follow the rotating magnetic field of the stator (fig. 15).

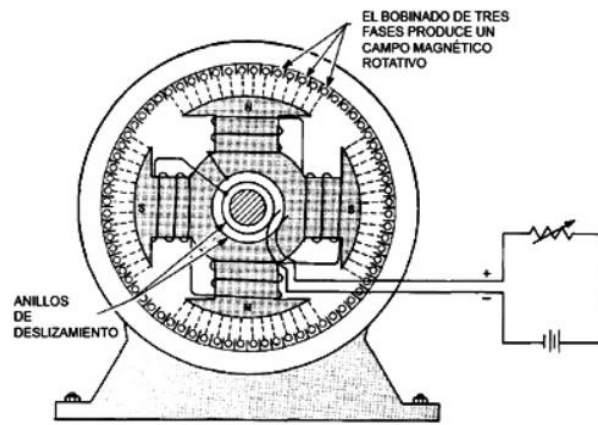


Figure 15. Synchronous motor with DC-excited rotor

Asynchronous motors are so called because the speed of the rotor does not correspond to the synchronous speed of the stator. In this case, the rotor conductors are short-circuited, so there is no way to connect this structure to the outside. These motors are also known as induction motors, and this is because a rotating magnetic field is generated when current flows through the stator conducting elements, which in turn induces a magnetic field in the rotor. The interaction of these two fields causes the rotor to move, which cannot have the same speed as the field that generates it. This difference in speed is described by a concept called slip; $\text{Slip} = (\text{synchronism speed} - \text{real speed}) / \text{synchronism speed}$ (fig. 16).

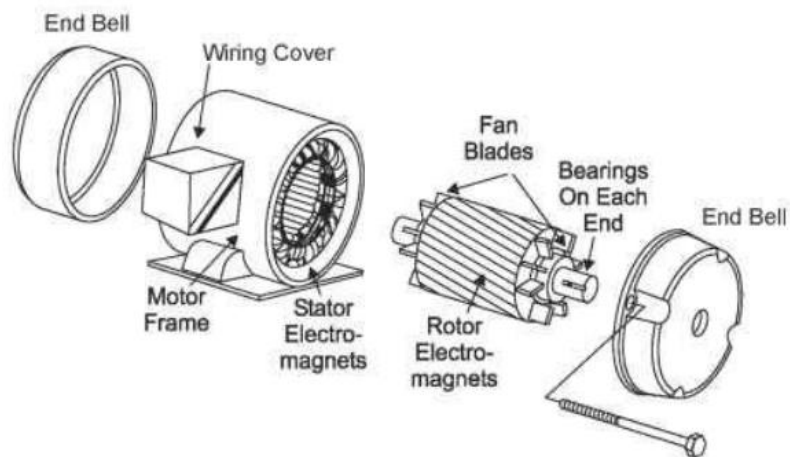


Figure 16. Asynchronous motor with short-circuited winding

Synchronous motors are more expensive, less robust and require more maintenance than asynchronous motors, however, they have the main advantage that the electrical characteristics of the rotor's electrical circuit, such as voltage and current, can be modified from the outside.

The advantages of alternating current motors are their simple design, ease of maintenance, cost and durability, and all the advantages derived from alternating current, such as easy transport, the wide range of voltages through the use of the transformer or the ease of converting this into direct current with an alternator. The disadvantages of these are the complexity of controlling them, their high starting torque and the impossibility of storing alternating current in batteries.

ASPECT	ENGINE TYPES	
	DIRECT CURRENT	ALTERNATING CURRENT
ADVANTAGES	<ul style="list-style-type: none"> - They can work in reverse, i.e. they can transform electrical energy into mechanical energy and in turn act as electrical energy generators - Increased flexibility for speed and torque control - Speed easily controlled by varying the voltage - Reversible direction of rotation - Easy programming for varying speeds over time - Acceleration and deceleration can be controlled - Dynamic braking can be obtained by reversing the polarity of the current as the motor rotates 	<ul style="list-style-type: none"> - Simpler design and use in most industrial devices - Structurally simpler and easier to maintain - Voltage can be easily varied without major losses with transformers - Great possibilities as a result of the type of energy - Price and duration - Can be adapted to direct current with rectifiers
DISADVANTAGES	<ul style="list-style-type: none"> - Maintenance - Worst size/power ratio - Complex wiring requirements for large jobs 	<ul style="list-style-type: none"> - High starting torque - Energy storage - Control

Table 2. Comparison of DC and AC motors

3.3.3. Stepper motors

Stepper motors could be defined as brushless DC motors. They convert electrical energy in the form of pulses, which are appropriately supplied by a controller, into rotor turns of a certain angle depending on the capacity of the rotor. As already mentioned, we distinguish between permanent magnet, variable reluctance and hybrid motors, each with a certain construction and characteristics. As in DC or AC motors, they basically consist of a stator that will support a variable number of windings depending on the motor, to which the current pulses that will generate a magnetic field will be applied, and a rotor that varies according to the type of motor.

Permanent magnet motors are named after the type of rotor used. Thus, by feeding the stator coils sequentially, the rotor follows the generated magnetic field. As many angular divisions as windings can be found, or these divisions can be doubled by making the turns have an intermediate point where they can be placed by exciting two coils in a row at the same time, as shown in the figure. These motors have a fundamental advantage, which is that they have a so-called holding torque, which keeps the rotor stopped in a certain position even if the stator is not energized (fig 17).

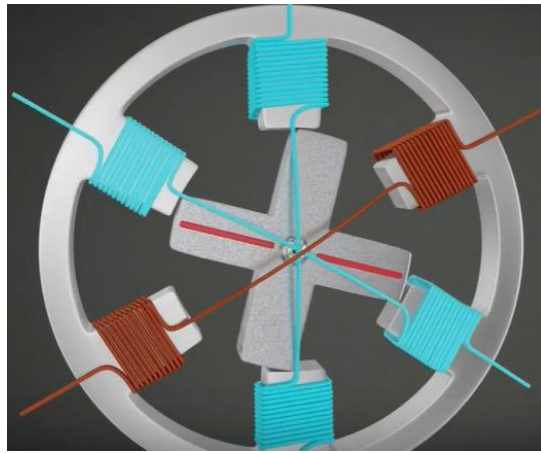


Figure 17. Two stator coils excited to double the number of motor steps

In variable reluctance motors (fig. 18), we find a ferromagnetic toothed rotor, together with a wound stator to which a toothed surface similar to that of the rotor is added as shown in the figure. The movement of these motors is based on the attraction of the stator and rotor poles to positions with minimum magnetic reluctance and, therefore, a higher magnetic flux while supplying the coils with sequential pulses through a controller. As in the previous case, the resolution of the motor can be improved by moving it half a step. These motors have a faster response than the previous ones because they have a lower inertia in the rotor, although they are not able to generate the holding torque.

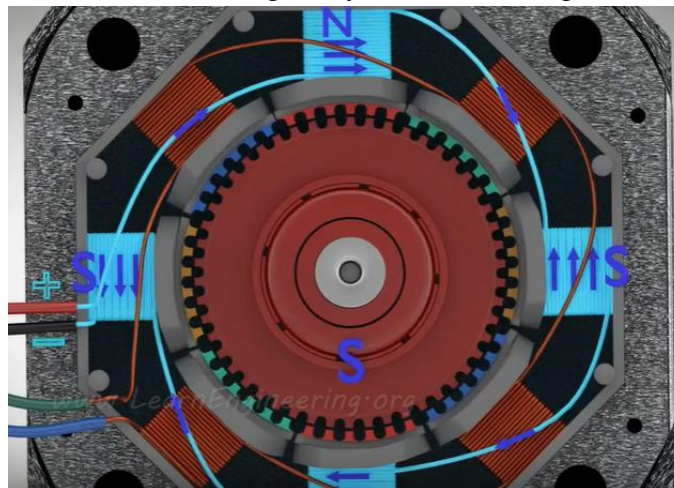


Figure 18. Variable reluctance motor with toothed rotor and stator

Hybrid motors are a combination of the two types of motors mentioned above, with a toothed rotor and stator and a magnetized rotor. They have a high torque and precision, offering a wide range of angular displacements.

The advantages of this type of motor are the high torque at low speeds, the precision that can be achieved when turning the rotor, the possibility of blocking movement when the current stops flowing, its high efficiency, the possibility of establishing digital control and its simple and robust design. Among its disadvantages is that sometimes its rotation can be abrupt if a sudden impulse is generated, its cost is higher than DC or AC motors and the need to use a controller can make it more difficult to drive.

3.4. Engine proposal

Once the types of motors that could be adapted to the system have been analysed, taking into account the limitations, a DC motor with integrated encoder and another stepper motor, with their respective control systems, are purchased to carry out experimental tests incorporating them into the robot to obtain more specific data for automating the robot. As previously mentioned, these motors were not received, due to the closing of borders and alarm state suffered by the crisis of the COVID-19.

In the case of the DC motor with integrated encoder, a system was proposed based on the scheme in the figure from which the data required for analysis would be obtained.

The components required for this assembly would be a potentiometer, a battery, the DC motor with the basic features shown in the figure, the L9110S driver H-bridge and the Arduino Nano microcontroller.


DC MOTOR WITH ENCODER		
Voltage	DC 6 V	
No load speed	210 RPM; 0.13 A	
Maximum efficiency	2 kg*cm; 170 RPM; 2W; 0.6 A	
Maximum force	5.2 kg*cm; 110 RPM 3.1 W; 1.1 A	
Holding torque	10 kg*cm; 3.2 A	
Reduction ratio	1:34	

Table 3. DC motor specifications

Specifications and website for buying DC motor: https://www.banggood.com/CHIHAI-MOTOR-GM25-370-DC-Gear-Motor-6V-100210300RPM-Encoder-Motor-p-1016183.html?akmClientCountry=ES&p=PW041611183930201706&custlixnkid=316774&ID=519630&cur_warehouse=CN

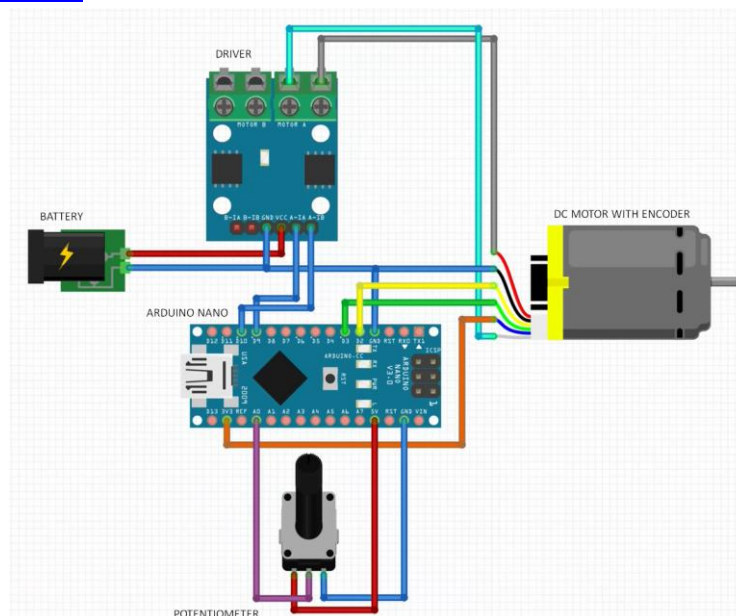


Figure 19. DC motor connection diagram

For the tests with the stepper motor, the scheme in the figure 19 would be used, using the nema 17 motor (fig. 20), a battery, the A4988 driver and the Arduino Nano microcontroller.

STEPPER MOTOR NEMA 17	
Number of phases	2
Nominal voltage	DC 3.6 V
Rated current	1.5 A/fase
Phase resistance	2.4 Ω /fase
Phase inductance	3.7 mH/fase
Holding torque	420 mN*m
Detent torque	15 mN*m
Rotor inertia	57.3 g/cm ²
Step angle	1.8°




Table 4. Stepper motor specifications

Purchasing website and engine specifications nema 17: <https://es.aliexpress.com/item/4000329570564.html?spm=a2g0s.9042311.0.0.330163c07DM0hC>

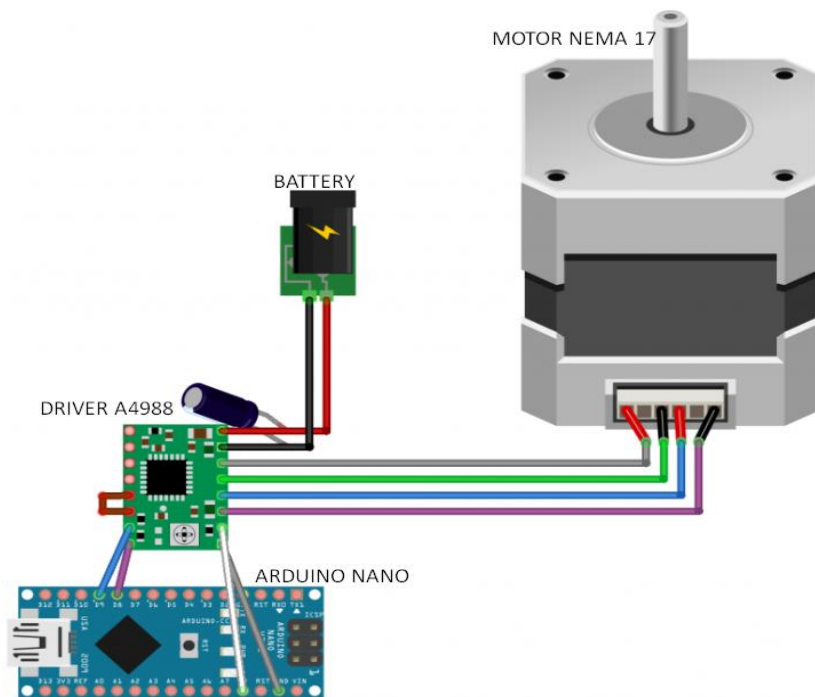


Figure 20. Wiring diagram for motor nema 17

In chapter 4, referring to energy consumption and battery sizing, in the section component analysis, a more detailed view is given of each component involved in the tests.

CHAPTER 4

4. ENERGY CONSUMPTION AND BATTERY SIZING

Next, a study of the energy consumption of the robot system will be carried out, in order to size the batteries to be incorporated into the robot and to check that the components studied could be adapted to the robot. This approach goes beyond selecting batteries that are more than compliant with consumption, since the analysis of the variables that may affect the system will make it possible to achieve the most appropriate operation possible and, therefore, greater well-being for the user (fig 21).

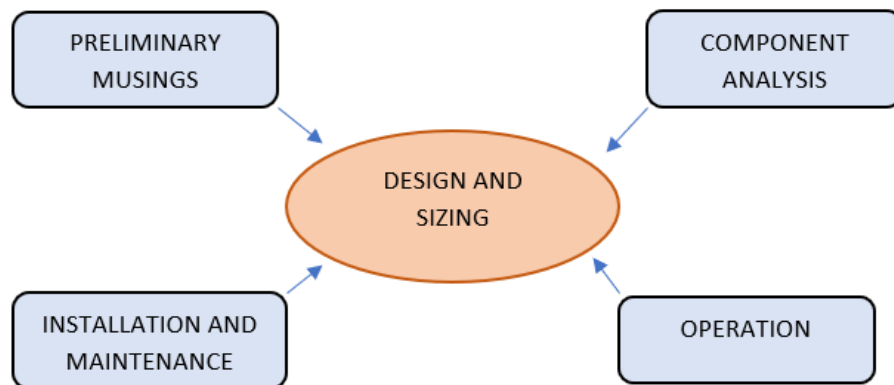


Figure 21. Design diagram

4.1. Preliminary considerations

It should be noted that, in the selection of the batteries for this project, we will find two main limiting factors, on the one hand their capacity, and in opposition, the weight, since if the values are exceeded in terms of necessary capacity, a weight will be added to the set which, together with the rest of the components necessary for the automation, may make it not viable to implement the improvements proposed in this project since they would result in a decrease in the quality of life of the patient that cannot be assumed.

First of all, it will be convenient to consider how the batteries work, what type of batteries can be better adapted to the system due to factors such as their composition, capacity, charge-discharge cycles or others that we will see next.

The batteries or electric accumulators, have their origin in 1800, when Alessandro Volta communicated to the Royal Society the invention of the battery. These are composed of a chemical element that reduces, and another that oxidizes. Its principle of operation is therefore based on a process of reduction-oxidation of two components. These, after a process of electrolysis, generate a flow of electrons between two electrodes generating electrical current.

Among the parameters to take into account of a battery we find the voltage, current intensity, charge capacity, electric charge, energy, resistance, mass, performance, charge and discharge constant and memory effect.

- The voltage is the first parameter that indicates whether the battery is fit for purpose, as it defines the work on the charging unit.
- The current refers to the unit of charge circulating per unit of time.
- The load capacity is the fundamental parameter of the battery, which is measured in Ampere-hours (Ah), that is, the amount of load that could be supplied during one hour. A related limiting factor is the maximum current, as it may be necessary at a certain time, such as the start of an engine, to supply current that the battery is not capable of supplying.
- The electrical charge, measured in coulombs, is measured by reference to the charging and discharging times.
- The energy that a battery can supply depends on its voltage and current and is measured in Wh (Watt hours), that is, power per unit of time.
- The internal resistance of a battery is not a fixed parameter, as it can vary with the age of the battery. This concept helps to model the chemical reactions that occur and is a parameter to take into account as it will create a decrease in the output voltage and a loss of performance.
- The efficiency is another determining factor, finding nowadays in most of the batteries values higher than 90 %.
- The charge and discharge constant is used to indicate the speed of charge and discharge at which the battery is not damaged.
- The memory effect, is an undesirable effect to take into account that will make the batteries lose charge capacity.

In the market it is possible to find different types of batteries, such as lead-acid, nickel-iron, nickel-cadmium, nickel-metal hydride, lithium-ion, fuel cells or high capacity capacitors. However, for the desired application the most interesting are the Lithium Ions. Among its advantages we find, the high energy density per unit of volume, its arrangement in rectangular plates of little thickness, a voltage per cell of 3.6 V, the lack of memory effect, its linear discharge, its low rate of self-discharge and that have been studied in depth. In addition, the factors against them are not determining for the robot, since the fact that they do not have to be submitted to extreme temperatures will be something normal since they will be incorporated to the robot that goes coupled in a person, a useful life of about 3 years is more than sufficient, its price already has been compared to the rest of batteries with similar benefits and the requirement of a security circuit to maintain the voltage during the load and the unloading within limits could be accepted.

4.2. Component analysis

The components to be evaluated for their energy consumption will be the actuators, the sensors used for the control and the microcontroller, to which the wifi or bluetooth module will have to be added and will increase consumption. The consumptions of the different options valid for each function will be compared in order to check if the energy point of view could be a determining factor when choosing certain components.

Following the study previously carried out on the actuators, the operation and consumption of the actuators will be analysed and compared with those that were to be tested before the COVID-19 crisis

made it impossible to carry out the tests, as they were the most suitable for the system following the assessments described above.

The selected DC motors have a voltage of 6 V, and a consumption of 0.13 A without load, 0.6 A at the maximum efficiency point and 1.1 A at the maximum load point.

The stepper motors nema 17, have a voltage of 3.6 V and two phases, with a nominal current of 1.5 A per phase. The power calculation for a stepper motor is somewhat more complex. In this case, the power is defined by the speed and inertia of the load, with the controller used playing a fundamental role in the optimisation. As an approximation for the power calculation, we can consider a stationary shaft with the specified current flowing as the maximum power condition for any shaft motor. Therefore, according to the formula $P=I^2 \cdot R$ (being the phase resistance 2.4 ohms) we obtain a power of 5.4 W per phase, and for having two phases, 10.8 W. On the other hand, the manufacturers provide the torque-pps curve (each pulse corresponds to 1.8°), from which we can obtain the mechanical power at the point of maximum load and maximum efficiency. From the formula $P(W)=T(N \cdot m) \cdot \omega(\text{rad/s})$ and the curve in the figure we obtain the mechanical power, giving values of 7.26 W at the point of maximum torque and 2.35 W at the point of minimum speed. The low speed points are taken because for this application very small speeds are used which are more than acceptable at 300-700 pps. Bearing in mind that the efficiency of these motors is usually around 80%, we obtain energy consumption values of 9.1 W for the maximum load point and 2.95 W for the minimum speed point, values that can be assumed seeing the approximation made previously. As we can see, it has a consumption approximately 50% higher than the DC motor, something that could be expected taking into account the low efficiency of these in comparison (fig. 22).

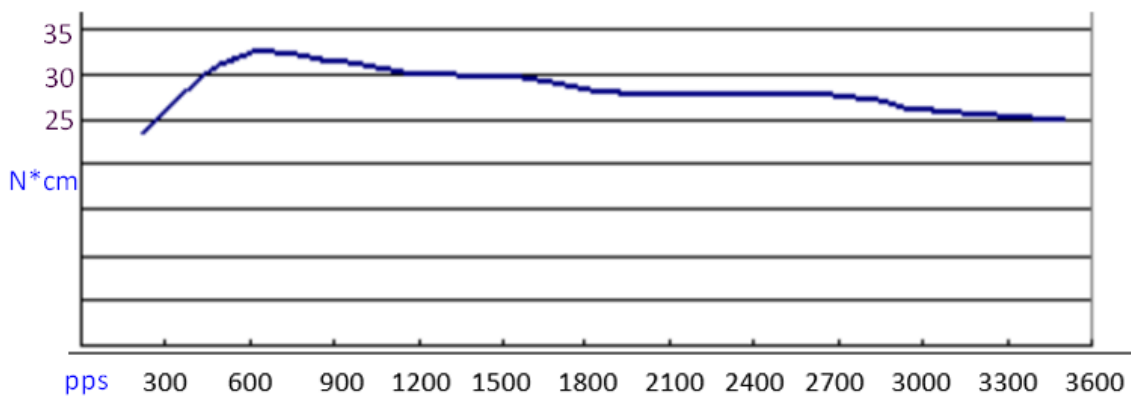


Figure 22. Nema 17 engine torque-pps curve.

In the case of engines, the consumption of these will depend largely on the influence of the controllers. For the stepper motor an A4988 controller was to be used, while for the DC motor the H-bridge L9110S. The mode of operation could vary depending on the way of programming, hence one of the advantages of automating the system. Therefore, evaluating consumption in this type of motor without an experimental analysis can be precipitated since we do not know what the working point would be, and as we can see in the TFG developed at the UPCT, "Design of linear actuators for robotic prosthetic devices" by Diego Cánovas Pérez, in 2020, the current consumed by an actuator with a function similar to ours in a load variation from empty to 200 gr, increased consumption by 25%, the increase in this linear, as shown in the work.

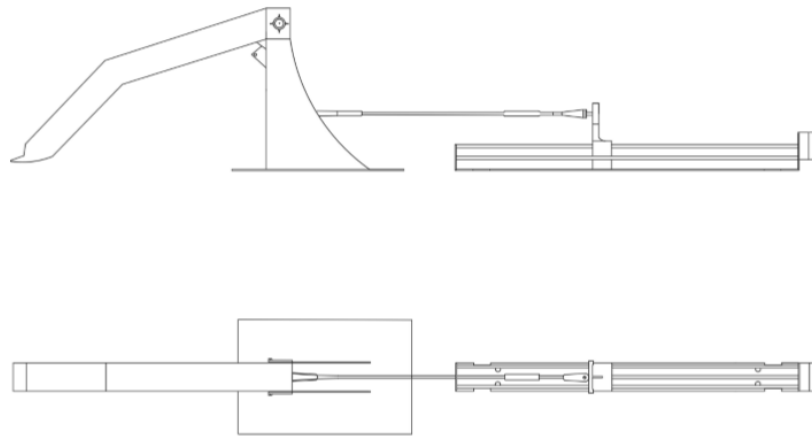


Figure 23. Actuator design of FDP Linear actuator design for robotic prosthetic devices

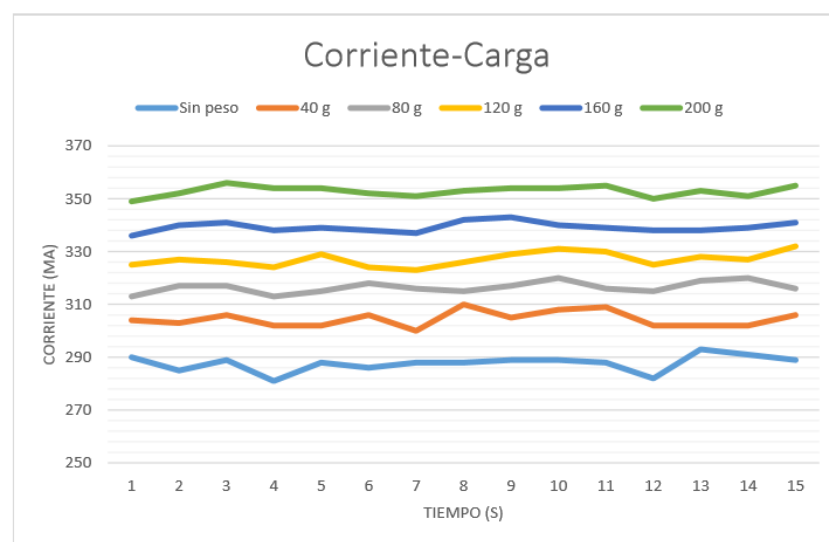


Figure 24. Current/time curve of the actuator in the above-mentioned TFG

As for the microcontroller used, the design was to be based on an Arduino Nano 33 BLE, which has a consumption of 15 mA. This alternative was previously contemplated because with the development of the technology, much more powerful and efficient microcontrollers have been created in short periods of time. This can be observed if we compare it with the previous TFG, which used an Arduino UNO Rev3, which has a larger size, being this another factor to take into account in our project, and a consumption of 46 mA, three times higher and to which we should add another 30 mA of the HC-06 bluetooth module, which in this case would not be necessary to use because the Arduino Nano itself already has a built-in Bluetooth module. The only energy consideration for the changeover would be the change from 5V of the Arduino Uno to the 3.3V of the Nano's (fig. 25) operation.

Web with Arduino Nano specifications: <https://store.arduino.cc/arduino-nano-33-ble?queryID=20117ed8cb1f0ddd16e5c7a13ce4c135>

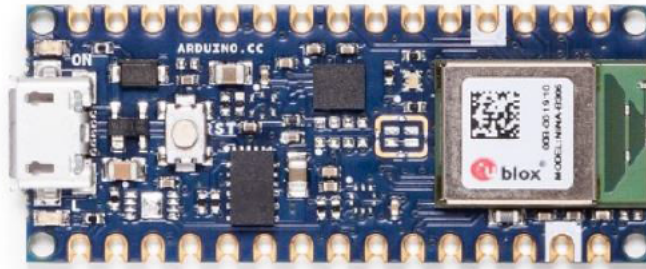


Figure 25. Arduino Nano module

The microcontroller will be needed to command the movement of the actuators, track them with the sensors, store the data, and transmit them via the Wifi or Bluetooth module to the desired platform. Therefore, it will not be necessary to keep it activated with its maximum consumption constantly. This can be achieved either by implementing an RTC (real time clock) or by implementing the Low-power-master library. Since the RTC requires the addition of additional components and increased consumption, and it is intended to have a system as safe and efficient as possible, it is considered convenient to use this library. With this library you go from a consumption of 15 mA in active mode to 5 mA in sleep mode as shown in the photo, where you compare consumptions and add the code to sleep one of the pins as an example (fig. 26).

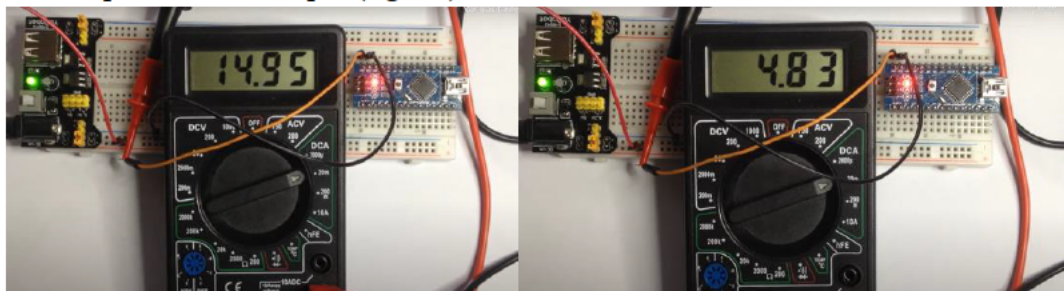


Figure 26. Comparative Arduino working normally and in sleep mode

```
#include "LowPower.h"
int LED = 13 ;
void setup()
{ pinMode(13, OUTPUT); }
void loop()
{ LowPower.powerDown(SLEEP_8S,
ADC_OFF, BOD_OFF);
digitalWrite(LED, HIGH);
delay(1000);
digitalWrite(LED, LOW);
}
```

Figure 27. Code to put one of the pins in sleep mode

Something that was not considered in the previous project, but that due to the interesting features it can provide should be presented, is a Wifi module, in order to improve the specialist-patient connectivity (fig. 28). The modules that we can incorporate for this purpose are diverse, although the most typical are the ESP8266 and the ESP32. Both have a consumption of 80mA at 225mA maximum

with a voltage of 3 to 3.6V. In addition, it should be considered that these modules can be used as microcontrollers.

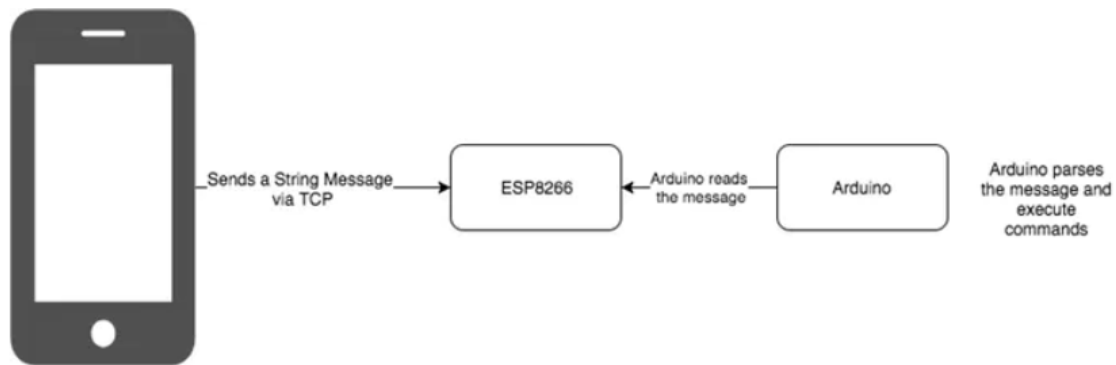


Figure 28. Information flow between the Wifi module and Arduino

An EEPROM memory is used to store data, which allows programming and deleting data with electrical impulses at more than acceptable speeds given the system requirements. One of the advantages is that when disconnected from the battery it keeps the data, so it would only consume battery for reading and writing. Taking as a reference the EEPROM 25AA1024, with 1024 Kbits of memory, we observe consumption values of 5 mA at 5.5V for writing and 7 mA at 5.5V for reading. These reduced values are due to the use of low power CMOS technology.

As the last element that consumes energy we have the sensors that report the movement of the actuators and help to control them. We will take as reference those studied by Laura Valdez in the FDP "Sensorization of a parallel robot for medical applications".

- The potentiometers: The linear potentiometer has a power of 0.1 to 0.5 W while the wire potentiometer 2W.
- The Lidar sensors: The Adafruit VL53L0X LIDAR sensor has an average consumption value of 20 mW, while the Adafruit VL6180X offers an average consumption value of 1.7 mA. Both can be powered from 3 to 5 V.
- The ultrasound sensor studied has a consumption of 15 mA and 5 V of power supply.
- The Hall effect sensor consumes up to 8 mA and can be supplied with 2.7 to 9 V
- The triangulation laser sensor has a much higher consumption of 150 mA and 5 V power supply.

4.3. Functioning

Once the different components have been considered, their operating times must be evaluated. To do this, a balance must be achieved between the correct performance of the treatment and the operation of the system only for the time necessary.

It is necessary to emphasize, that to be able to estimate of precise form the consumptions of the components, the suitable thing would be to have them physically and to be able to make experimental tests, nevertheless, since the situation does not allow it, they will be analyzed theoretically to give approximate values of batteries.

As mentioned, the operating time of the components is directly related to the development of the treatment. Thus, before carrying out this study for the automation of the system, the movement is

carried out manually on a daily basis based on "clicks" of the actuators, which means a movement of 0.5 mm for each movement. A maximum of two "clicks" per actuator per day are considered, which means a movement of 1 mm.

With the incorporation of the electronics to this system it is intended that the treatment is less aggressive for the user, trying to make the movement of the actuators more progressive thanks to the ability of the motors to provide movement gradually over a longer period of time.

In this way, different scenarios will be proposed based on the actual prescription of a femur elongation provided by Dr. Salcedo for the sensorization TFG. The estimated consumption of the components is the one proposed in the previous section, and we will study which can be the optimal way to carry out the treatment, collect the information, store it and export it to the application with which the specialist works (figs. 29-32).

Page 1

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 30120. El Palmar. Murcia. Spa, Murcia. Spain, Spain, 3...
 0034-968369500, 0034-676584332

Print date: 08/03/2018, 14:21:56
 Case ID: FP POSTQX
 Case Description:
 Patient ID: FEMURPOLITECNICA
 Side: Left
 Bone Type: Femur

Frame ID: F

No	Day	Date-Time	Strut Adjustment in 'CLICKS' (a)						Strut Reference Length (b)					
			RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE	RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE
			1	2	3	4	5	6	1	2	3	4	5	6
0	ju.	POSTOPERATIVE	0	0	0	0	0	0	80	80	80	80	80	80
1	ju.	08/03/2018 09:00	1	1	1	1	1	1	80	80	80	80	80	80
2	vi.	09/03/2018 09:00	2	2	2	2	2	2	79	79	79	79	79	79
3	sá.	10/03/2018 09:00	1	1	2	1	1	1	78	78	78	78	78	78
4	do.	11/03/2018 09:00	2	2	1	2	2	2	77	77	77	77	77	77
5	lu.	12/03/2018 09:00	2	2	2	2	2	2	76	76	76	76	76	76
6	ma.	13/03/2018 09:00	2	2	2	2	2	2	75	75	75	75	75	75
7	mi.	14/03/2018 09:00	2	2	2	2	2	2	74	74	74	74	74	74
8	ju.	15/03/2018 09:00	2	2	2	2	2	2	73	73	73	73	73	73
9	vi.	16/03/2018 09:00	2	1	2	1	2	2	72	73	72	73	72	72
10	sá.	17/03/2018 09:00	2	2	2	2	2	2	71	72	71	72	71	71
11	do.	18/03/2018 09:00	2	2	2	2	2	2	70	71	70	71	70	70
12	lu.	19/03/2018 09:00	2	2	2	2	1	1	69	70	69	70	70	70
13	ma.	20/03/2018 09:00	1	2	2	2	2	2	69	69	68	69	69	69
14	mi.	21/03/2018 09:00	2	2	2	2	2	2	68	68	67	68	68	68
15	ju.	22/03/2018 09:00	2	2	2	1	2	2	67	67	66	67	67	67

Figure 29. Prescription page 1

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 0034-968369500, 0034-676584332

Print date: 08/03/2018, 14:21:56
 Case ID: FP POSTQX
 Case Description:
 Patient ID: FEMURPOLITECNICA
 Side: Left
 Bone Type: Femur

Frame ID: F

No	Day	Date-Time	Strut Adjustment in 'CLICKS' (a)						Strut Reference Length (b)					
			RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE	RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE
			1	2	3	4	5	6	1	2	3	4	5	6
16	vi.	23/03/2018 09:00	2	1	2	2	2	2	66	66	65	66	66	66
17	sá.	24/03/2018 09:00	2	2	2	2	2	2	65	65	64	65	65	65
18	do.	25/03/2018 09:00	2	2	1	2	2	2	64	64	64	64	64	64
19	lu.	26/03/2018 09:00	2	2	2	2	2	2	63	63	63	63	63	63
20	ma.	27/03/2018 09:00	2	2	2	2	2	2	62	62	62	62	62	62
21	mi.	28/03/2018 09:00	2	2	2	2	2	1	61	61	61	61	61	61
22	ju.	29/03/2018 09:00	2	2	2	1	2	2	60	60	60	61	60	60
23	vi.	30/03/2018 09:00	2	2	2	2	1	2	59	59	59	60	59	59
24	sá.	31/03/2018 09:00	1	1	2	2	2	2	58	59	58	59	58	58
25	do.	01/04/2018 09:00	2	2	2	2	2	2	57	58	57	58	57	57
26	lu.	02/04/2018 09:00	2	2	2	2	2	2	56	57	56	57	56	56
27	ma.	03/04/2018 09:00	2	2	2	2	2	2	55	56	55	56	55	55
28	mi.	04/04/2018 09:00	2	2	2	2	2	2	54	55	54	55	54	54
29	ju.	05/04/2018 09:00	2	2	2	2	2	2	53	54	53	54	53	53
30	vi.	06/04/2018 09:00	2	2	2	1	2	2	52	53	52	53	52	52
31	sá.	07/04/2018 09:00	2	2	2	2	2	2	51	52	51	52	51	51

Figure 30. Prescription page 2

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 0034-968369500, 0034-676584332

Print date: 08/03/2018, 14:21:56
 Case ID: FP POSTQX
 Case Description:
 Patient ID: FEMURPOLITECNICA
 Side: Left
 Bone Type: Femur

Frame ID: F

No	Day	Date-Time	Strut Adjustment in 'CLICKS' (a)						Strut Reference Length (b)					
			RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE	RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE
			1	2	3	4	5	6	1	2	3	4	5	6
32	do.	08/04/2018 09:00	2	1	2	2	2	1	50	51	50	51	50	51
33	lu.	09/04/2018 09:00	2	2	2	2	2	2	49	50	49	50	49	50
34	ma.	10/04/2018 09:00	2	2	2	2	2	2	48	49	48	49	48	49
35	mi.	11/04/2018 09:00	2	2	1	2	1	2	47	48	47	48	48	48
36	ju.	12/04/2018 09:00	2	2	2	2	2	2	46	47	46	47	47	47
37	vi.	13/04/2018 09:00	1	2	2	2	2	2	46	46	45	46	46	46
38	sá.	14/04/2018 09:00	2	2	2	1	2	2	45	45	44	46	45	45
39	do.	15/04/2018 09:00	2	2	2	2	2	2	44	44	43	45	44	44
40	lu.	16/04/2018 09:00	2	2	2	2	2	2	43	43	42	44	43	43
41	ma.	17/04/2018 09:00	2	1	2	2	2	2	42	43	41	43	42	42
42	mi.	18/04/2018 09:00	2	2	2	2	2	2	41	42	40	42	41	41
43	ju.	19/04/2018 09:00	2	2	2	2	2	2	40	41	39	41	40	40
44	vi.	20/04/2018 09:00	2	2	2	2	2	1	39	40	38	40	39	39
45	sá.	21/04/2018 09:00	2	2	2	2	2	2	38	39	37	39	38	38
46	do.	22/04/2018 09:00	2	2	2	2	2	2	37	38	36	38	37	37
47	lu.	23/04/2018 09:00	2	2	2	1	2	2	36	37	35	37	36	36

Figure 31. Prescription page 3

Dr. César Salcedo-Cánovas "Virgen de la Arrixaca" Clinic Hospital, Murcia, Spain. Peadiatric Orthopaedic Unit, "Virgen de la Arrixaca" CL... 30120, El Palmar, Murcia, Spai, Murcia, Spain, Spain, 3... 0034-968369500, 0034-676584332			Print date: 08/03/2018, 14:21:56 Case ID: FP POSTQX Case Description: Patient ID: FEMURPOLITECNICA Side: Left Bone Type: Femur				Frame ID: F							
No	Day	Date-Time	Strut Adjustment in 'CLICKS' (a)						Strut Reference Length (b)					
			RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE	RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE
			1	2	3	4	5	6	1	2	3	4	5	6
48	ma.	24/04/2018 09:00	2	2	2	2	2	2	35	36	34	36	35	35
49	mi.	25/04/2018 09:00	2	2	2	2	1	2	34	35	33	35	34	34
50	ju.	26/04/2018 09:00	1	1	1	1	2	1	33	34	33	35	33	34

Figure 32. Prescription page 4

The proposed operating scenarios and why they might be appropriate are set out below:

- Scenario 1. We will try to simulate the operation prior to the automation of the system. For this, we will try to analyze the consumption of the components assuming that the motors perform instantaneously what previously would be a click of the actuator. Each click would be made in a period of approximately 15 seconds, which would have a peak consumption at that time to go to standby during the rest of time. The sensors would check during the movement that the movement is as desired and would store the values in the EEPROM memory. Once a day this data would be passed to the application through the wifi module.
- Scenario 2. The movement of the actuators would be divided over the course of the night, i.e. a maximum movement of 1 millimetre for 8 hours. This will allow the treatment to be carried out in a period of time in which the patient is calmer and so that the load is applied less aggressively, leaving in any case the remaining 16 hours of the day to assimilate the treatment. The sensors will check during operation that the movement is adequate, in addition to two checks during the day to ensure that there are no system failures. The data will be uploaded to the application while being captured by the sensors to improve the patient-specialist feedback.
- Scenario 3. The actuators will perform the movements in three one-hour periods spread over the day. In this way, the aim would be to provide the benefits of a less aggressive movement that is also distributed during the day so that the patient is able to assimilate the treatment. The night period will be left without activity in case the treatment could have negative effects on the patient's sleep. The sensors would act during the periods of movement and take a sample during each rest period to ensure that the whole process is being carried out correctly. The data would be uploaded to the application while being captured by the sensors to improve patient-expert feedback.

It should be noted that, since engine consumption cannot be known in practice, all tests will be carried out assuming that the engines are working at maximum load and efficiency constantly.

Applying the values of current, voltage and power obtained from the component datasheets, the following consumption values are obtained, in Wh, for each component in the proposed scenarios (table 5, 6).

COMPONENT	VOLTAGE [V]	INTENSITY [A]	POWER [W]
Motor DC	6	0,6~1,1	2,16~3,96
Motor nema 17	3,6	1,5/fase	2,95~10,8
Arduino Nano	3,3	0,015	0,0495
Arduino Nano (sleep)	3,3	0,005	0,0165
Arduino UNO Rev 3	5	0,046	0,23
Módulo HC-06	3,3	0,05	0,0165
ESP8266	3	0,225	0,675
ESP32	3	0,225	0,675
EEPROM (read)	5,5	0,007	0,0385
EEPROM (write)	5,5	0,005	0,0275
Wire potentiometer	3~5	0,1	0,5
Sliding potentiometer	3~5	0,4	2
Adafruit VL53L0X	3~5	0,004	0,02
Adafruit VL6180X	3~5	0,0017	0,0051
Ultrasonic sensor	5	0,015	0,075
Hall effect sensor	3	0,008	0,024
Triangulation laser sensor	5	0,15	0,75

Table 5. Electrical data of the components

Hour	COMONENTS Y CONSUMPTION [mWh]																
	Motor (x6)				Microcontroller			Wifi/Bluetooth			Memory						
	Motor DC (min)	Motor DC (max)	Motor nema 17 (min)	Motor nema 17 (max)	Arduino Nano	Arduino UNO Rev 3	Módulo HC-06	ESP8266	ESP32	EEPROM	Wire pot.	Sliding pot.	Adafruit VLS3L0X	Adafruit VL6180X	Ultrasonic sensor	Hall effect sensor	Triangulation laser sensor
1	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
9	54	99	738	270	16,5	230	0,069	2,8	2,8	0,16	12,5	50	0,5	0,1275	1,875	0,6	18,75
10	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
21	54	99	738	270	16,5	230	0,069	2,8	2,8	0,16	12,5	50	0,5	0,1275	1,875	0,6	18,75
22	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
Total consumption	108	198	1476	540	396	5520	0,138	5,6	5,6	0,32	25	100	1	0,255	3,0625	1,2	37,5

Scenario 1

Table 6. Consumption of the components according to the scenario 1

Hour	COMPONENTS Y CONSUMPTION [mW*h]																
	Motor (s6)			Microcontroller		Wifi/Bluetooth			Memory		Sensor (s6)						
	Motor DC (min)	Motor DC (max)	Motor nema 17 (min)	Motor nema 17 (max)	Arduino Nano	Arduino UNO Rev 3	Módulo HC-06	ESP8266	ESP32	EEPROM	Wire pot.	Sliding pot.	Adafruit VL53LOX	Adafruit VL6180X	Ultrasonic sensor	Hall effect sensor	Triangulation laser sensor
1	54	99	73,8	270	49,5	230	16,5	675	675	38,5	500	2000	20	5,1	75	24	750
2	54	99	73,8	270	49,5	230	16,5	675	675	38,5	500	2000	20	5,1	75	24	750
3	54	99	73,8	270	49,5	230	16,5	675	675	38,5	500	2000	20	5,1	75	24	750
4	54	99	73,8	270	49,5	230	16,5	675	675	38,5	500	2000	20	5,1	75	24	750
5	54	99	73,8	270	49,5	230	16,5	675	675	38,5	500	2000	20	5,1	75	24	750
6	54	99	73,8	270	49,5	230	16,5	675	675	38,5	500	2000	20	5,1	75	24	750
7	54	99	73,8	270	49,5	230	16,5	675	675	38,5	500	2000	20	5,1	75	24	750
8	54	99	73,8	270	49,5	230	16,5	675	675	38,5	500	2000	20	5,1	75	24	750
9	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	16,7	230	0,069	2,8	2,8	0,16	12,5	50	0,5	0,1275	1,875	0,6	18,75
15	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	16,7	230	0,069	2,8	2,8	0,16	12,5	50	0,5	0,1275	1,875	0,6	18,75
21	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
Total consumption	432	792	590,4	2160	660,4	5520	132,138	5405,6	5405,6	308,32	4025	16100	161	41,055	603,75	193,2	6037,5

Scenario 2

Table 7. Consumption of the components according to the scenario 2

Hour	COMPONENTS Y CONSUMPTION [mW*h]																
	Motor (M6)			Microcontroller		Wifi/Bluetooth			Memory		Sensor (M6)						
	Motor DC (min)	Motor DC (max)	Motor nema 17 (min)	Motor nema 17 (max)	Arduino Nano	Arduino UNO Rev 3	Módulo HC-06	ESP8266	ESP32	EEPROM	Wire pot.	Sliding pot.	Adafruit VLS3LOX	Adafruit VL6180X	Ultrasonic sensor	Hall effect sensor	Triangulation laser sensor
1	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
9	54	99	73,8	270	49,5	230	16,5	675	675	38,5	500	2000	20	5,1	75	24	750
10	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	16,7	230	0,069	2,8	2,8	0,16	12,5	50	0,5	0,1275	1,875	0,6	18,75
13	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
15	54	99	73,8	270	49,5	230	16,5	675	675	38,5	500	2000	20	5,1	75	24	750
16	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	16,7	230	0,069	2,8	2,8	0,16	12,5	50	0,5	0,1275	1,875	0,6	18,75
20	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
23	54	99	73,8	270	49,5	230	16,5	675	675	38,5	500	2000	20	5,1	75	24	750
24	0	0	0	0	16,5	230	0	0	0	0	0	0	0	0	0	0	0
Total consumption	162	297	221,4	810	495,4	5520	49,638	2030,6	2030,6	115,82	1525	6100	61	15,555	228,75	73,2	2287,5

Table 8. Consumption of the components according to the scenario 3

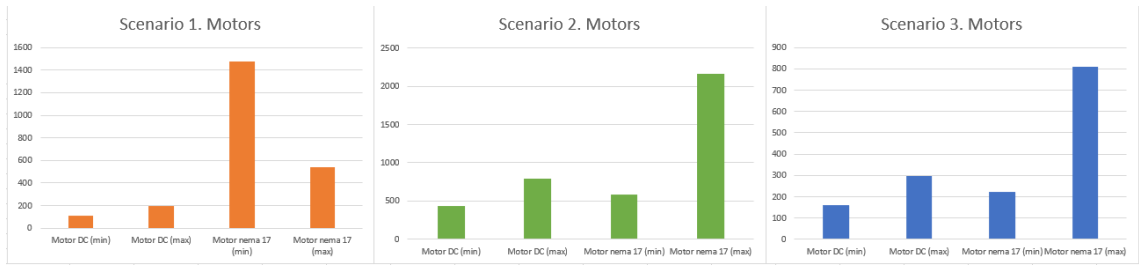


Figure 33. Comparative of engine consumption (mWh)

From the comparison of the engines (fig. 33) we can say that clearly, if a scenario 1 type method were followed, consumption would be substantially lower, however, it would not make sense to automate the system since its benefits would not be applied and it would add complexity in terms of components and substantially increase the cost and weight. From the other two scenarios, the conclusion is obtained that the DC motor is more efficient in all its working range, therefore, if it is desired to benefit from the better control made by the stepper motor it would be fundamental to have a good control of the working points.

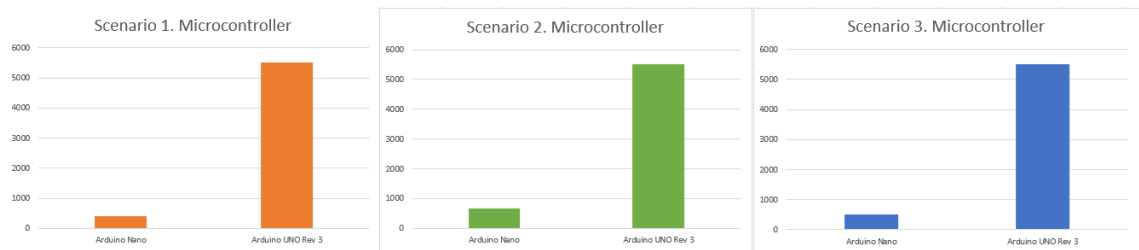


Figure 34. Comparison of microcontroller consumption (mWh)

From the comparison of microcontrollers (fig. 34) a conclusion is reached which, although not related to the work, is also of interest. This is the great development that the technology carries out in relatively short periods of time. We can see how the consumption of the new Arduino model is approximately ten times lower, offering superior performance, so it would be interesting to keep this component as updated as possible in order to improve the performance of the system.

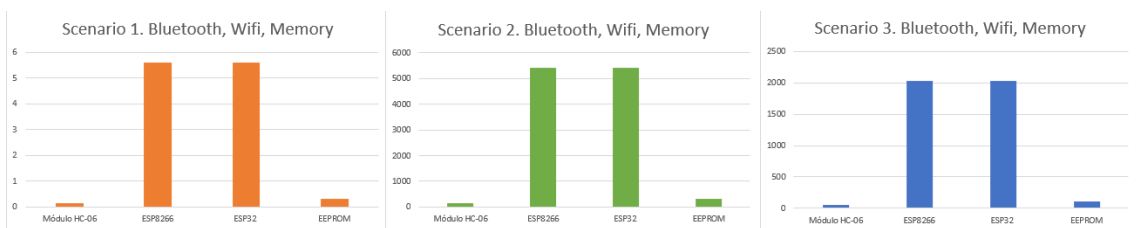


Figure 35. Comparison of Bluetooth, Wifi and memory consumption (mWh)

From the comparison between Bluetooth, Wifi (fig. 35) modules and memory we get the following conclusions:

1. The consumption of the EEPROM memory is negligible in comparison to the rest of the components, so it is interesting to store all the data collected by the sensors in order to take full advantage of the automation of this and improve the parameters on which the specialist works.

- The wifi module consumes much more battery than the bluetooth module, so it is necessary to evaluate how long it is necessary to keep it on. In my opinion, incorporating a wifi module is essential, since with the new market trend of using the IoT (Internet of Things), the robot could be interconnected with other platforms that make it work better. However, it would not be necessary to keep it connected during the whole time of data capture and it would be necessary to choose those moments when it is necessary to consult the information from an external platform either because of the need of the specialist or because it has been programmed that way.

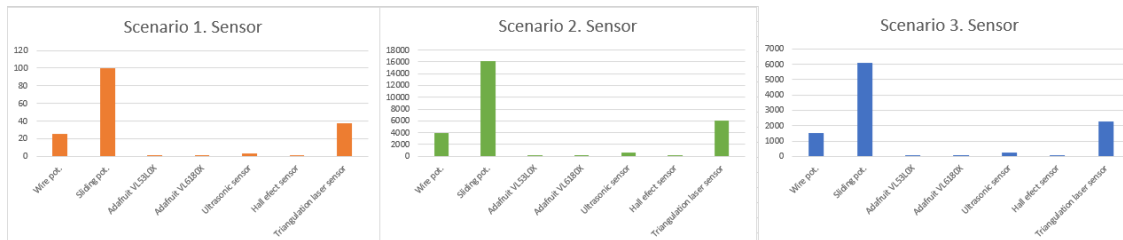


Figure 36. Comparative consumption of Sensors (mWh)

To analyze the data obtained in terms of sensor consumption (fig. 36), we will add the results obtained in the sensorization TFG to give a more rigorous evaluation. The conclusions obtained for each sensor were the following:

- Wire potentiometer: Meets accuracy requirements, however, does not meet the requirements of low volume and easy integration.
- Sliding potentiometer: Meets accuracy requirements except in extreme ranges, which are not relevant to system performance.
- Adafruit VL53L0X sensor: It is highly affected by noise, so it requires data filtering. The main disadvantage found is that it would require an excessively large screen on which to reflect the light beam to achieve acceptable results. Furthermore, it was established that reading this data was not valid for the application.
- Adafruit VL6180X sensor: Like the previous one, it is affected by noise and requires data filtering. It is low in volume and easy to integrate. The main drawback is that it needs another sensor for gradual adjustment.
- Ultrasonic sensor: This sensor was considered unsuitable for the application because it does not achieve accuracies of less than 1 cm.
- Hall effect sensor: It was discarded without testing because it was considered that the magnetic field could not be detected at the distance required by the system.
- Triangulation laser sensor: This sensor was discarded because it was too bulky and the distance for the laser beam to hit the system might not be enough.

In the above-mentioned FDP, it was decided to use the linear type potentiometers because they present reliable values without display delay compared to LIDAR sensors. In addition, they were simpler to install.

To automate the system it would be essential that the sensors worked at the same time as the motors, to allow them to function correctly, maintain patient safety and improve the possibilities of treatment. With this as a starting point, without taking into account the sensors that were discarded because they did not meet the precision requirements, and taking into account that the battery is a highly limiting

factor in the system both in terms of capacity and weight, it seems logical to consider more technologically advanced sensors, such as the LIDAR type, with respect to the potentiometers. These have a consumption ten times lower than the wire potentiometers, and up to forty times lower than the sliders, being necessary only to find the optimal way to adapt them to the robot.

The conclusion based on all the comparisons made regarding consumption is the following:

1. In the area of engines, it should be ensured that they operate at an optimum working point to ensure acceptable consumption.
2. The microcontrollers should be kept up to date because of the improvement in performance.
3. It would be necessary to try to limit the use of Wifi modules to what is necessary due to the increase in consumption. To this end, the bluetooth module could be used as a support since its consumption is very low. The use of the memory should not be limited, since its consumption is very low and the contribution of data to the processing is fundamental.
4. The sensors used should be analysed, as the use of certain sensors that are not very advanced technologically can lead to an unacceptable increase in consumption.

4.4. Battery selection

As it is possible to see, the components that could trigger the system consumption to unacceptable values are the wifi module if used out of control and the potentiometers if it was decided to choose these as sensors for the robot. The motors and the microcontroller are also components with high consumption, however, more content than those mentioned above and bearable by the working times they are required to work.

For the selection of the battery, one is considered capable of providing an autonomy of at least 2 days, since at present it is very difficult for a patient with knowledge of the requirements that the treatment would entail, not to have access to a source of charge in 48 hours, which in extreme cases could even be an external battery and not a connection to the electrical network. In order to be able to supply all the components, a 6-volt battery is required, and a capacity of 700 mAh would be sufficient to supply the requested power.

The battery market, like most fields of technology, has developed a lot in recent years, offering a number of battery designs with different sizes, weights, capacities and prices.

Reviewing the market, it is observed that most of the batteries for similar applications are lithium ion, something that was initially considered convenient. In addition, as it is appreciated that when passing the barrier of the 5 V in batteries these increase slightly their size, weight and benefits, being able to be due to which with the mentioned ones can be loaded typical devices of small electronics like mobile phones, and if the dimensioning is increased, the use would be focused for devices with greater power requirements. Therefore, if would be necessary to use batteries available on the market, could be chosen to place in series two 5 V batteries, abundant and with capacities up to 20000 mAh with contained prices or opt for a single source, which in this case the next step in the market are usually 7.2 or 9 V batteries, also with wide capacity ranges. The weights are usually around 200 gr for the established features with sizes adaptable to the system and prices around 20 euros. It should be noted that for the type of robot being developed, it could be viable to contact battery brands that could offer customized options to the system, as this is an area where small details can make a difference in how a patient develops his life after treatment.

CHAPTER 5

5. HEALTH REGULATIONS AND RISK MANAGEMENT PLAN

In order to limit the possibilities of a product causing damage to people, not fulfilling the function for which it is designed, or not performing to the standard offered, countries have a series of regulations that guarantee safety, efficiency and quality requirements.

Countries where the majority of medical devices are manufactured share a regulatory framework consisting of at least regulatory standards, a government-appointed regulatory body, conformity assessment bodies, a system for classification of devices according to the degree of associated risk, a quality control system, a safety assessment system, a system for authorisation of market access and a system for monitoring compliance of marketed devices with regulations (table 7). This regulatory framework will vary depending on the territory in which it is established, and the tools and requirements shown in the figure are to be found in the major member powers of the WHO (World Health Organization).

COUNTRY/REGION	PRE-MARKET	PLACING ON-MARKET		POST MARKET
	Product control Tools for acknowledging product cleared for the market	Medical device establishment control	Advertising control	Vendor after-sale obligations Examples of common requirements
Australia*	ARTG number	Enterprise Identification (ENTID)	Generally, prohibition of advertisement before a device is cleared to enter the market. Prohibition of any misleading or fraudulent advertisement	1. Problem reporting 2. Implant registration 3. Distribution records 4. Recall procedure 5. Complaint handling
Canada	Device licence	Establishment licence		
European Union	Compliance label (CE mark)	Responsible person registration		
Japan**	Shounin (approval) or Todokede (notification)	Seizo-Gyo (Manufacturer Licence) Yunyu Hanbai-Gyo (Import Licence) Hanbai Todoke (Sales notification)		
United States of America	Approval Letter (PMA) or Marketing Clearance (510k)	Establishment registration		

Table 9. Tools and requirements for medical certification in the major WHO Powers

For this project, we will focus on analysing the requirements for certification in the European Union. In this sense, there are three main regulations for health management, 93/42/ECC for Doctors (DDM), 98/79/EEC for In-Vitro-Diagnosis (IVD) and 90/385/EEC for Active Implants (AID).

Although initially these regulations only covered medical devices, the definition now also includes medical devices. Thus, Regulation (EU) 2017/745 on medical devices, established by the European Parliament and the Council of the European Union on 5 April 2017, in Article 2 first part, provides the following definition for “medical device”:

Any instrument, device, equipment, software, implant, reagent, material or other article intended by the manufacturer to be used for human beings, separately or in combination, for any of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease*
 - diagnosis, follow-up, treatment, relief or compensation of an injury or disability,*
 - investigation, replacement or modification of the anatomy or a physiological or pathological process or state*
 - obtaining information by in vitro examination of samples from the human body, including organ, blood and tissue donations,*
- and which does not exert its principal intended action in or on the human body by pharmacological, immunological or metabolic mechanisms, but to the function of which such mechanisms may contribute.*

Once it is known that it is defined as a medical device, it is necessary to know which are the bodies in charge of regulations in the EU and what would be the objective in terms of procedures for the commercialization of the robot.

The most important role is usually played by the manufacturer, as it is the physical or legal entity in charge of the design, manufacture, packaging and labelling of a medical product for its marketing. Within the European Union, the role of the authorized representative appears, whose function is to annex competent authorities, notified bodies and the manufacturer, provided that the latter is from a country outside the EU. Ultimately, the Notified Body is responsible for checking that the legal criteria are met within the EU country in which it is located. These agents ensure that the devices comply with the protection and risk reduction requirements, manufacture, according to an appropriate route and market surveillance, in order to achieve the CE marking, a process by which it is shown that the product complies with the Directives concerning mandatory legislation on essential requirements within the European Union.

In this case, the role of the engineer is immersed in the functions of the manufacturer, since within the group of people who manufacture the product he will be in charge of managing the technical aspects that refer to the procedure. For this project, we will try to analyze the phases in which the engineer could intervene in order to achieve compliance with the regulations following the standards established in the industry.

5.1. Standardization for CE marking

ISO (International Organization for Standardization) standards are the documents in charge of specifying the requirements that must be used in organizations to guarantee that the products or services offered meet their objective, decreasing errors and increasing productivity. To date, this organization has published around 19500 international standards in different fields, which can be viewed on its website (<http://www.iso.org/>).

This organization is made up of 180 technical committees, and technical activities are decentralized in some 2700 committees, subcommittees and working groups. The working committee that writes the documents related to the system, and therefore to medical robots, is the specific technical committee TC299 for "Robots and Robotic Devices". This committee is made up of 6 working groups, each dealing with a different field. These are:

- Vocabulary and characteristics

- Personal Care Robot Security
- Industrial safety
- Service robots
- Medical Robot Security
- Modularity for service robots.

In terms of regulations applicable to the field of medicine, the IEC (International Electrotechnical Commission) is the organization in charge of carrying out international standards on safety in different technologies applied to medical devices. This commission wrote the IEC 60601 standard, which frames the requirements to which the robot must adapt. It was first published in 1977, and regularly updated and restructured, and is now divided into two parts covering the basic safety and essential performance of all medical equipment, and the requirements for specific groups.

The ISO standards applicable to medical robots, and therefore to the studied system, are ISO 13485 and ISO 14971.

ISO 13485: 2016 specifies the requirements for a quality management system when an entity intends to demonstrate its ability to provide medical devices and related services that will meet applicable regulations and customer requirements at all times. It includes particular requirements for medical devices and excludes some requirements of ISO 9001 that are not appropriate as regulatory requirements.

ISO 14971:2019 covers the terminology, principles and a process for the risk management of medical devices throughout their life cycle, including software as a medical device and in vitro diagnostic medical devices. This standard aims to provide manufacturers with the tools to identify hazards associated with the device, estimate, evaluate and control risks, and monitor the effectiveness of controls.

In this way, with the established considerations, taking into account that according to the definitions the platform is a medical robot, and based mainly on the ISO 14971 standard, the aim will be to develop an adapted risk management plan, in order to comply with the IEC 60601 standard and therefore establish some steps to follow in order to obtain the CE certification for a possible commercialization. To this end, all the steps in the development of the product, from design to manufacture, must be taken into account (fig. 37).

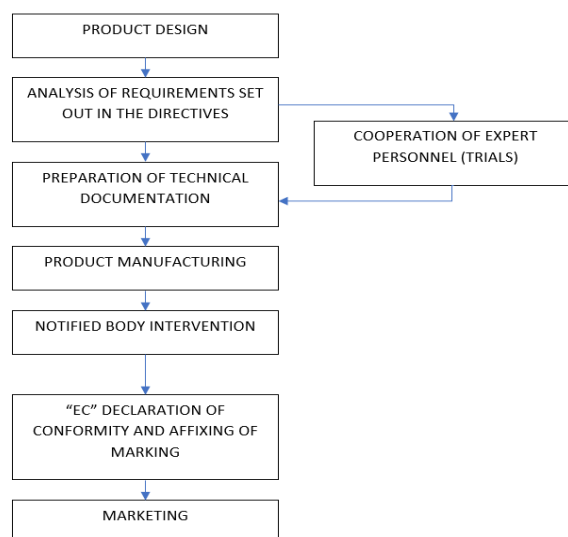


Figure 37. Steps up to the commercialization of a product

5.2. Risk management study

The ISO 14971:2019 (fig. 39) standard, drawn up by the International Organization for Standardization, deals with the processes of managing risks that affect both the patient and the operator, other people or equipment, and the environment, since the activities carried out by any entity can expose them to dangers both to themselves and to third parties. It specifies the process by which the manufacturer of a medical device can identify the hazards associated with it, estimate and evaluate the risks associated with these hazards, control them and monitor the effectiveness of this control. According to this standard, the concept of risk is defined as the combination of the possibility of occurrence of a damage and the consequences of this damage. This does not imply that both must be multiplied to obtain a risk value, as shown in the figure 38.

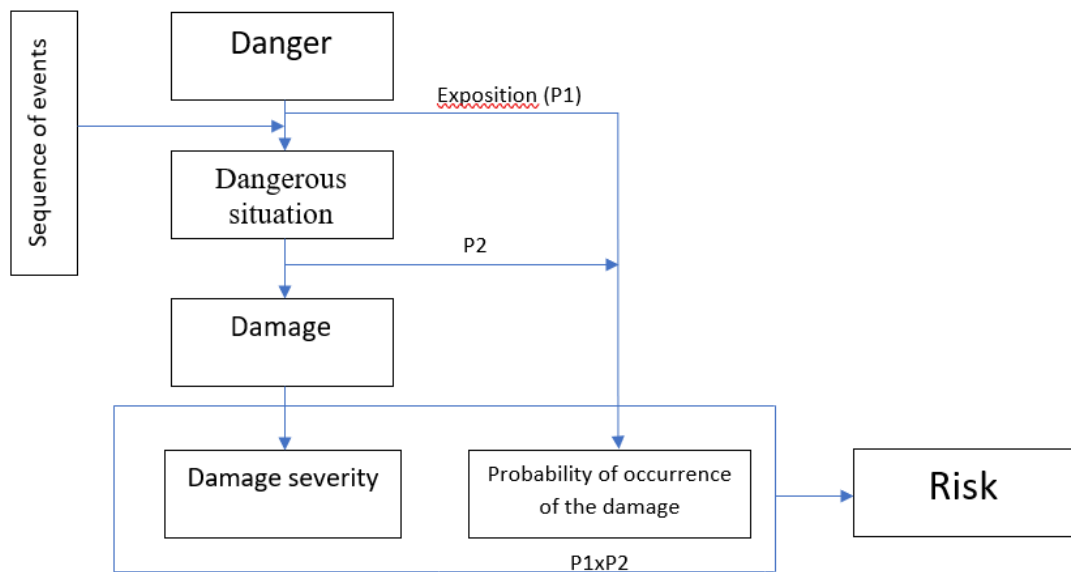


Figure 38. Representation of the relationship between hazard, sequence of events, dangerous situation and damage

Since the perception of a risk is relative and depends on many factors, the aim will be to provide a guide for the whole life of the product from which to qualify and reduce the risks, and ultimately to assess whether it can be affordable to assume a residual risk since the benefits involved are greater than the possible consequences.

The risk management process must establish, document and maintain a process throughout the life cycle to identify associated hazards and consequently correct or control them. According to the regulations, this process must include at least the following elements:

- Risk analysis
- Risk Assessment
- Risk control
- Production and post-production information

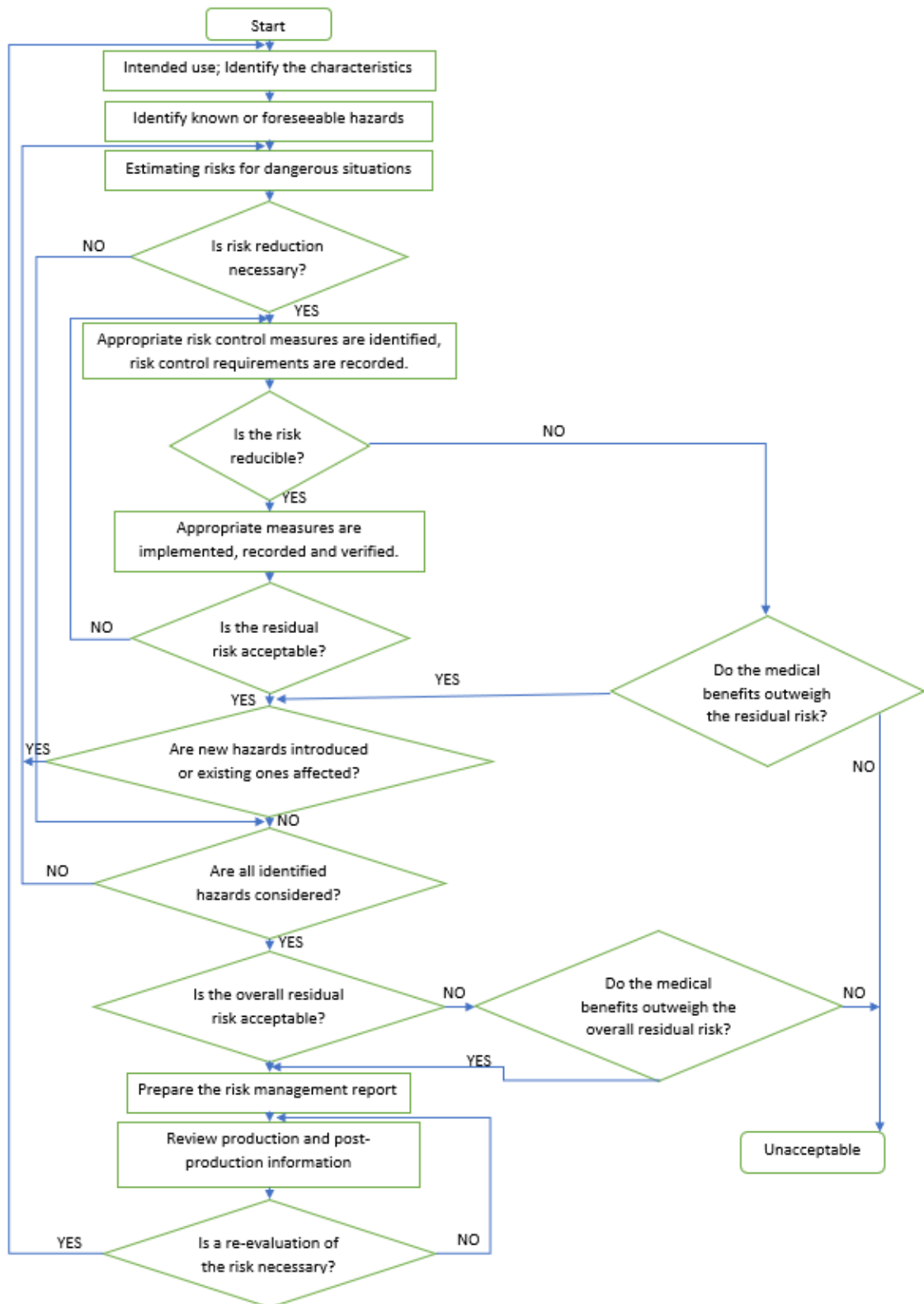


Figure 39. Risk management scheme according to ISO 14971

5.3. Risk management plan

The risk management plan is considered as one more part of the risk management process, which must be supported by the company's management, ensuring that qualified personnel for the task at hand have the necessary resources to manage it. All the processes will be marked in the risk management file.

At least the following points should be included here:

- The scope of risk management activities.
- The assignment of responsibilities and authorities.
- The requirements for the review of risk management activities
- The criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk
- The verification activities.
- The activities related to production and post-production inspection

This plan is fundamental, since it is necessary to mark a route to which to adapt, providing the process with a marked criterion that avoids subjectivities.

For this work, since we are working on a proposal to modify an existing system, on which it has not been possible to work physically due to the situation experienced during the work period by the COVID-19, we will try to give an approximation to the final risk management plan taking into account both the modifications and the indications provided by the manufacturer for the system without automation.

Scope of the risk plan:

The system raised for study is a sanitary robot based on Stewart's hexapod platform. Its application is associated with fracture reduction, limb lengthening and deformation correction, and therefore within the field of traumatology.

As mentioned, the risk management plan will be based on a possible modification of the TL-Hex system in order to provide it with an electronic part capable of automating it. In addition, it will focus on the implementation phase in patients, thus evaluating the risks that it may pose to them.

Assignment of responsibilities and authorities:

Since we are working on a supposed case of improvement, and not on an official project in progress, it is not possible to identify the trained personnel on whom the responsibilities would fall, although it should be noted that it would be convenient for them to have knowledge and experience in dealing with the health product to be verified.

However, this section may include figures such as the board of directors, risk committee with the possibility of external advisors, general management, functional and support areas, specialized risk management area, or internal audits.

Requirements for the review of risk management activities

In accordance with the provisions of the regulations, the management must establish the criteria for the revision of the risk management plan. Ensuring that it is carried out in accordance with the provisions, rectifies any errors and adapts to possible changes and improvements.

Criteria for risk acceptability

According to the regulations, it is the manufacturer who must decide what the criteria are for assessing the risk, however, it does indicate that they must be defined in the risk management plan and in accordance with this maintain a fixed and objective system for the acceptance or disapproval of these. In this case a qualitative analysis will be established with the following classification:

Acceptable	Acceptable risk by providing patient safety information
Undesirable	Acceptable risk in the event which cannot be mitigated or reduced with improvements. Safety information will be provided to the patient
Unacceptable	The risk cannot be accepted

Table 10. Qualitative analysis of risk management

It is considered that the perception of risk often varies from empirically obtained risk estimates. Therefore, the opinions of those involved people should be taken into account, as these also consider social values.

Verification activities:

Before placing the product on the market, the manufacturer must ensure that appropriate control measures have been established and that no aspect of the risk management plan has been neglected. Since in this work an analysis is made on a design proposal, and therefore there is no real system from which to obtain data, and the risk control measures are considerations from which neither the degree of implementation nor the risk reduction can be estimated, no verification actions are considered.

Activities related to production and post-production inspection

Similar to what happens in the control of system models, in the risk management plan it is necessary to establish a flow of information from the production and post-production sections that feed back into the process. With all this information to be recorded in the risk management file, incidents that may arise from the use of the product are analyzed.

In this sense, it is considered appropriate to establish the IAP procedure (Participatory Action Research). This methodology, which is one of the most impressive methodological and theoretical contributions in the field of research, attempts to promote a cycle of reflexive work and action, taking as a reference the dynamics of reality between subject and object.

According to this methodology, a researcher or group of researchers, who have the knowledge and resources to carry out the inspection, employ the community close to the object of research to analyse all the necessary aspects and, therefore, make them participants in the improvements that are made. This is based on the fact that those people who live with the product are the ones who can provide the most information about it. It is worth mentioning that following this approach, different ways of seeing the risks or possible solutions will appear, but for this work, qualified people will be found who will have to use all the information to draw the relevant conclusions.

In this way, a surveillance system will be set up to document incidents arising from the use of the product and to take the necessary corrective measures. For the development and updating of this analysis, the opinions of the patients will be used as the main source, since it will be essential to know both the physical and emotional effects that they develop in order to create a good product. In addition, those risks communicated to the manufacturer or to the health authorities will be used to complement the system.

5.4. Risk assessment

For a correct risk analysis, it is first necessary to identify the product to be evaluated, the people who carry out the evaluation and within which field of application it is focused, since situations may occur in which a product is not used for what it was initially created for. Within the field of application the intended use must be assessed, as well as reasonable misuse, in order to identify and limit the hazards associated with a product both in normal operation and in the event of failure. Finally, for each hazardous situation, the risks must be estimated, and if their elimination is not possible, the possible consequences must be set out in order to manage them in accordance with the risk management plan. Although the standard does not indicate any methodology for risk estimation, it does indicate that it is necessary. This could be done either quantitatively, or qualitatively, choosing the latter as the general method for this project, as no real data are available to make estimates and a reliable qualitative analysis is preferable to an inaccurate quantitative one. Risk estimation should examine the initiating circumstance, the sequence of events that may lead to the hazard, the probability of occurrence, the likelihood that the situation will result in harm and what type of harm may result. Firstly, in order to give the risk management plan better organization and simplify its use, it is considered to classify the hazards according to the nature of their origin. The following classification is proposed:

1. Energy hazards.
2. Biological hazards.
3. Environmental hazards.
4. Hazards arising from human factors and associated with use
5. Hazards associated with design.

The first concept to be considered in the risk assessment is the probability of occurrence. Although the probability is a continuum, the manufacturer may discretize it at different levels according to the expected confidence of the estimates in order to facilitate decision making. This probability estimate should look from the initiating event to the sequence of events that must be triggered for a risk to exist. Each range of the estimate should be defined to assist in the classification of the risk. For probability estimation, the standard offers seven commonly used approaches:

- The use of relevant historical data.
- The prediction of probabilities using analytical or simulation techniques
- The use of experimental data.
- Estimates of reliability
- Production data
- Post-production information
- The use of expert judgement

Following the example set out in the standard, the following ranges are established in terms of the probability of the occurrence of a risk together with its description (table 9).

RISK PROBABILITY LEVEL	DESCRIPTION
Frequent	Occurs with every use of the system
Probably	Occurs at least once per week of system use
Occasional	Occurs at least once per month of system use
Remote	Occurs at least once per year of system use
Unlikely	Occurs less than once per year of system use

Table 11. Semi-quantitative estimate of the probability of occurrence of a risk case

The second concept that must be taken into account is the severity of the potential damage, interpreted as the measure of the consequences of a hazard. For this, there must be defined markers that allow the scope to be discretised into levels that facilitate the analysis, since just like probability, severity is a continuum. For this concept it will be necessary to differentiate between the risks posed to the patient and to the device, since an accident will involve different treatment depending on who suffers it. The following classification is presented in table 10:

RISK SEVERITY LEVEL	DESCRIPTION	
	PATIENT	DEVICE
Critical	Unrecoverable injury	Unserviceable device
Serious	Long-term pain; injury recoverable with medical assistance	Disabled device; recoverable with medical assistance
Moderated	Short-term pain; injury recoverable without medical assistance	Temporary disabling of the device; no technical assistance required to get it working again
Low	Nuisance	Incorrect operation of the device; automatic return to correct operation

Table 12. Qualitative estimation of severity by the occurrence of a risk

Once the conditions for classifying the risks have been established, the manufacturer must establish the treatment to be carried out according to the place of the risks in the classification. The methods for determining acceptable risk included in the standard are the use of applicable standards specifying the requirements which, if implemented, indicate that acceptability has been achieved, comparison of the levels of obvious risk with those of medical devices already in use, or evaluation of data from clinical studies.

Following the recommendation of the standard, the following double entry matrix is created from which risks are classified according to their probability and severity. In this, using the classifications created previously, the acceptability of the risks is traced. Since the manufacturer would be the one

to establish the criteria, in this case they have been established in a personal way following the recommendations of the standard and the search for information (table 11).

		Severity Level			
		Low	Moderated	Serious	Critical
Probability level	Unlikely	Admissible	Admissible	Undesirable	Undesirable
	Remote	Admissible	Admissible	Undesirable	Intolerable
	Occasional	Admissible	Undesirable	Intolerable	Intolerable
	Probably	Undesirable	Undesirable	Intolerable	Intolerable
	Frequent	Undesirable	Intolerable	Intolerable	Intolerable

Table 13. Risk assessment matrix

5.5. Risk control

Once the risks have been identified and assessed, they will be controlled. The fundamental objective of risk control shall be to eliminate or reduce the risk to an acceptable level, according to the criteria defined in the risk management plan and at the discretion of the manufacturer. According to ISO 14971, the steps for risk reduction are as follows:

Analysis of the risk control option:

The manufacturer must analyse the appropriate control measures. To do this, one or more of the following options, whose effectiveness must be verified, must be used in the order of priority set out above.

- Inherent safety by design; The design of the device itself takes into account the risks that may arise and develops the necessary tools for their elimination.
- Protective measures in the product or manufacturing process; Modifications are made that provide safety to the device, such as protection from physical damage or automatic disconnection or blocking systems.
- Safety information; Safety information is included on the device label or in the instructions for use.

Following the previous classifications and risk control options, tables will be created to develop the risk management plan according to the following model (table 12).

HAZARD CLASS					
SITUATION	DANGER	PROBABILITY	SEVERITY	ACCEPTABILITY	RISK CONTROL MEASURE
Danger situation 1	Type of hazard 1	Probability of hazard 1	Severity of hazard 1	Acceptability of danger 1	Control measure for risk 1
Danger situation 2	Type of hazard 2	Probability of hazard 2	Severity of hazard 2	Acceptability of danger 2	Control measure for risk 2
...

Danger situation n	Type of hazard n	Probability of hazard n	Severity of hazard n	Acceptability of danger n	Control measure for risk n
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Table 14. Model table for risk management plan

Once the risk control measures have been considered, the manufacturer should assess whether they can be carried out. If it is not, a risk-benefit analysis of the residual risk should be carried out.

Implementation of the control measures:

The manufacturer should implement the risk control measures, verifying that they are complied with and effective. These checks should be recorded in the risk management file.

Since this project is working on a change model and the product on which to make the assessments has not been developed, the measures that would have to be applied from this point cannot be assessed.

Evaluation of the residual risk:

Once the control measures have been applied, the residual risks must be checked to differentiate between those that are not acceptable and must apply additional control measures and those that are acceptable, on which adapted information must be included in the product documents. The results must also be recorded in the risk management file.

Risk/benefit analysis:

For those residual risks that are not acceptable, the manufacturer will have to perform a risk/benefit assessment, which may result in the medical benefit making it feasible to assume the risk. If the analysis proves to be unfavourable, the manufacturer will be obliged to qualify the risk as unacceptable.

Risks resulting from risk control measures

The manufacturer will also have to check that the risk control measures do not incorporate additional risk situations, and if they do, they must be identified and appropriately addressed in accordance with the risk management plan.

Completeness of risk control:

It will be essential to ensure that all the analyses carried out have been performed in the most exhaustive manner possible, as an error in any phase of the process can trigger problems both in the patient and in the system, and therefore result in responsibilities that will fall on the company and ultimately on the engineer or manager who should have carried out all the checks.

Compliance will be verified by reviewing the risk management file.

5.6. Pre-marketing and after-sales documentation

Before starting the production process, the manufacturer should review that the risk management plan has been properly implemented, that the overall residual risk is acceptable and that adequate means exist to obtain production and post-production information.

Just as important as monitoring and reducing risks during product development is the analysis of the related production and post-production information. This can be used to address additional system failures and include possible improvements developed after the design, thus improving both product quality and patient wellbeing.

Compliance is verified by inspection of the risk management file and other appropriate documents.

5.7. Risk management plan tables

ENERGY HAZARDS					
SITUATION	DANGER	PROBABILITY	SEVERITY	ACCEPTABILITY	RISK CONTROL MEASURE
Overheating of electrical or electronic components	Improper operation of the device	Remote	Moderated	Admissible	· Alarm indicating system malfunction to communicate with assistance · Stopping the device · Ventilation measures · Periodic maintenance - Design with patient/device heat insulation
	Fire	Unlikely	Critical	Undesirable	
	Burns on the patient	Unlikely	Serious	Undesirable	
Internal electrical short circuit	Electrocution	Unlikely	Serious	Undesirable	· Electrical insulation system · Components for short circuit protection · Periodic maintenance
Power supply overvoltage	Damage to the system	Remote	Serious	Undesirable	· Electrical insulation system · Periodic maintenance · Overvoltage protection
	Electrocution	Unlikely	Critical	Undesirable	
High electromagnetic fields	Overvoltage in electrical components	Unlikely	Serious	Undesirable	· Warnings for use under electromagnetic

	Communication interference	Remote	Moderated	Admissible	<ul style="list-style-type: none"> c fields · Electrical insulation system · Automatic data transfer review
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Table 15. Risk Management Plan; Energy Hazards

BIOLOGICAL HAZARDS					
SITUATION	DANGER	PROBABILITY	SEVERITY	ACCEPTABILITY	RISK CONTROL MEASURE
Use of the device by different patients	Infection	Occasional	Moderated	Undesirable	<ul style="list-style-type: none"> · Reuse of electrical and electronic components only · Thorough disinfection after therapy · Marking used/ready-to-use components
Inadequate hygiene when dealing with the device	Infection	Remote	Moderated	Admissible	<ul style="list-style-type: none"> · Manual of hygiene measures in treatment
Allergy to construction materials	Immune response	Remote	Moderated	Admissible	<ul style="list-style-type: none"> · Review of patient's medical history · Use of anti-bacterial materials · Allergen warnings
Foreign substance on treatment area	Physical damage to the patient	Remote	Serious	Undesirable	<ul style="list-style-type: none"> · Manual of treatment of exposed areas · Contacting medical assistance · Protection of treatment areas with measures inherent in the

					design of the device
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Table 16. Risk management plan; Biological hazards

ENVIRONMENTAL HAZARDS					
SITUATION	DANGER	PROBABILITY	SEVERITY	ACCEPTABILITY	RISK CONTROL MEASURE
Polluting product on device	Damage to the device	Occasional	Low	Admissible	<ul style="list-style-type: none"> · Suitable enclosure IP degree of protection · Warnings for use
Liquid spill on electrical system	Damage to the device; Locking	Remote	Serious	Undesirable	<ul style="list-style-type: none"> · Suitable enclosure IP degree of protection · Warnings for use · Automatic failure shutdown system
Dust on electrical components	Loss of system performance	Remote	Moderated	Admissible	<ul style="list-style-type: none"> · Correct operation manual · Periodic maintenance
Excessive environmental humidity	Electrical damage to the system	Occasional	Moderated	Undesirable	<ul style="list-style-type: none"> · Suitable enclosure IP degree of protection · Warnings for use · Fail-safe system
Excessive ambient temperature	Loss of system performance	Remote	Low	Admissible	<ul style="list-style-type: none"> · Warnings for use · Overheat locking system
Electrostatic Discharge	Power line overvoltage; Fault in	Unlikely	Moderated	Admissible	<ul style="list-style-type: none"> · Warnings for use · Electrical insulation

	electrical components				system · Fail-safe system
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Table 17. Risk management plan; Environmental hazards

DANGERS DUE TO HUMAN FACTORS AND ASSOCIATED WITH THE USE					
SITUATION	DANGER	PROBABILITY	SEVERITY	ACCEPTABILITY	RISK CONTROL MEASURE
Device component breakage	System malfunctioning	Remote	Moderated	Admissible	<ul style="list-style-type: none"> · Device locking system · Instructions for use · Contact specialized assistance · Periodic review
	Physical damage to the patient; Injury, clotting, breakage of a bone, pain, etc	Remote	Moderated	Admissible	
Movement of fixation devices	System malfunctioning	Remote	Moderated	Admissible	<ul style="list-style-type: none"> · Periodic review · Warnings for use · Contact for specialized assistance
	Physical damage to the patient	Remote	Serious	Undesirable	
Unexpected physical changes of the patient	Physical damage to the patient	Remote	Serious	Undesirable	<ul style="list-style-type: none"> · Periodic review · Contact for tailored assistance · Warnings for use
Use by non-qualified personnel	System malfunctioning	Remote	Moderated	Admissible	<ul style="list-style-type: none"> · Specialist training · Warnings for use
	Physical damage to the patient	Remote	Serious	Undesirable	
	Damage to the system	Unlikely	Moderated	Admissible	

Poor assembly of the system	Physical damage to the patient; blood and nerve problems, broken bones, swelling, persistent pain, etc	Remote	Serious	Undesirable	<ul style="list-style-type: none"> · Adapted instructions for use · Periodic review · Training for specialists · Performing checklist
	Damage to the system	Remote	Moderated	Admissible	
Low patient interest	Damage to the system	Unlikely	Low	Admissible	<ul style="list-style-type: none"> · Preparatory treatment of the patient · Device prepared with blocking measures and contact with specialist in case of incorrect use · Periodic review
	Physical damage to the patient	Remote	Moderated	Admissible	
Reset device during treatment	Physical damage to the patient	Remote	Serious	Undesirable	<ul style="list-style-type: none"> · Reset indicator alarm · Contact tailored assistance
Interface malfunction	Improperly performed treatment; Physical damage to patient	Unlikely	Moderated	Admissible	<ul style="list-style-type: none"> · Periodic review of the interface · Adapted software design with risk minimization
Poor storage and transport of the device	Damage to the device	Remote	Low	Admissible	<ul style="list-style-type: none"> · Transport of the device with protective measures · Transport and storage plan design

Excessive engine speed	Physical damage to the patient; Bone cannot develop at the same time as movement	Unlikely	Serious	Undesirable	<ul style="list-style-type: none"> · Engine programming with speed limits · Manual device locking system
Reduced engine speed	Physical damage to patient; Bone recomposes before lengthening is performed	Remote	Moderated	Admissible	<ul style="list-style-type: none"> · Reduced Speed Notification System
Engine blocking	Incorrect performance of the treatment	Unlikely	Low	Admissible	<ul style="list-style-type: none"> · Blocking Notification System · Instructions for use · Contact specialized assistance
System does not respond	Incorrect performance of the treatment	Remote	Moderated	Admissible	<ul style="list-style-type: none"> · Instructions for use · Contact specialized assistance · Manual lock button
Inadequate psychological impact	Poorly developed treatment	Unlikely	Serious	Undesirable	<ul style="list-style-type: none"> · Warnings for use · Adapted preparatory treatment · Contact specialized assistance · Periodic review with specialist
Bad measures of the sensors	Incorrect performance of the treatment	Occasional	Moderated	Undesirable	<ul style="list-style-type: none"> · Periodic maintenance · Programming

	Physical damage to the patient	Remote	Moderated	Admissible	with set margins for measurements
Component disconnection	Incorrect performance of the treatment	Remote	Low	Admissible	<ul style="list-style-type: none"> · Automatic locking of the device · Warnings for use · Contact specialized assistance
Incompatibility with other treatment	Physical damage to the patient	Unlikely	Serious	Undesirable	<ul style="list-style-type: none"> · Review of medical history by a specialist · Warnings for use · Periodic review of treatment

Table 18. Risk management plan; Human and use-related hazards

DESIGN HAZARDS					
SITUATION	DANGER	PROBABILITY	SEVERITY	ACCEPTABILITY	RISK CONTROL MEASURE
Cutting or punching parts	Physical damage to the patient	Remote	Moderated	Admissible	<ul style="list-style-type: none"> · Design that avoids these geometries · Post-processing of components · Warnings for use
Incorrectly insulated electrical circuitry	Physical damage to the patient; electrocution	Unlikely	Moderated	Admissible	<ul style="list-style-type: none"> · Appropriate circuitry design · Periodic maintenance · Electrical fault locking system
	Damage to the electrical part of the device	Remote	Moderated	Admissible	
	Poor performance	Unlikely	Moderated	Admissible	

	of the treatment				
Absence of measures in the device so that the patient can stop the operation	Physical damage to the patient	Remote	Serious	Undesirable	<ul style="list-style-type: none"> · Fail-lock button · Alarm in case of failure · Light signal in case of failure
	Damage to the system	Remote	Moderated	Admissible	
Incomplete instructions	Physical damage to the patient	Remote	Moderated	Admissible	<ul style="list-style-type: none"> · Design of the instructions appropriate and adapted to the system · Review and update · Service for queries
	Damage to the system	Remote	Low	Admissible	
Complicated instructions	Damage to the patient; Physical or psychological	Remote	Low	Admissible	<ul style="list-style-type: none"> · Periodic review of the document · Service for queries
Insufficient warnings	Damage to the patient; Physical or psychological	Remote	Low	Admissible	<ul style="list-style-type: none"> · Review and update of warnings · Service for queries
Poor treatment design	Physical damage to the patient	Unlikely	Serious	Admissible	<ul style="list-style-type: none"> · Periodic review of treatment · Possibility of obtaining a second opinion from specialists

Table 19. Risk management plan; Hazards associated with design

CHAPTER 6

6. ACTUATOR CONTROL AND SIMULATION

This chapter proposes a simulation of the control system that would be implemented on the motors that automate the actuators of the hexapod robot with the Simulink software. As previously mentioned, due to the circumstances experienced during the performance of this work, only theoretical tests can be performed, since neither the physical components nor access to the laboratory are available. For this reason, components with similar performance to those selected in previous chapters have been selected for what would have been the practical approach, but for which the manufacturer offers the necessary data to propose the model.

For this analysis, a probable working scenario will be simulated with both actuators. According to these working scenarios, the reference signal for the control would be implemented in the microcontroller, either of speed in case of the DC motor or position in the stepper motor, and through the system electronics, they have to manage to follow the reference to achieve a quarter-turn displacement of the actuator, which would translate into 0.012 mm of linear displacement, in two hours that the treatment lasts. To make the simulation more real, a load is placed on the axis of the rotor that characterizes the opposition of the body to the movement of the actuator.

Although these types of motors exhibit linear behavior over a wide range of input voltages, there are many parameters that may include non-linearities that cannot be predicted in this type of model and would have to be analyzed in the laboratory. These parameters can be of a mechanical type, such as the effect of the load, the noise contributed by the sensors, or thermal variations resulting from the work cycle, or of an electrical type, which can be triggered by the conversion of the analogical-digital signal, or the conditioning of the power part, among others. In order to simulate the system it would be necessary to identify each of the parts that compose it (fig.40), model them in order to parameterize how it would work and finally adapt the design to achieve the best performance.

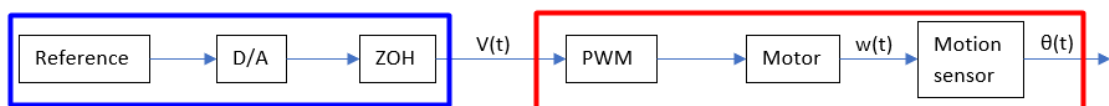


Figure 40. Engine modeling general scheme

This chapter considers the tests based on the assemblies shown previously (Fig. 19, Fig. 20). The motors would have been implemented in the robot making the necessary adaptations to position them so that the robot structure would not have been compromised, the implementation would be simple, and both manual and automatic movement of the actuators would be allowed (fig. 41). Following this operation, the rotation of the motor would drive the screw that transforms into the linear movement of the actuator directly and without the need of gears. Finally, assuming that one turn of the screw

generates a linear movement of 0.5 mm in the actuator, the automated drive could be controlled by controlling the rotation of the motors.



Figure 41. Location of the motor in the actuator

Next, the theoretical modeling of the motors and the control loop that would have to be implemented for each one is proposed. In addition, simulation of system behaviour will be performed using Simulink, which is a MATLAB-based graphical programming environment for modeling, simulating, and analyzing dynamic multidomain systems, providing more detailed knowledge of whether operation is appropriate for the purpose of the project.

6.1. Modeling and simulation of DC engine

Given the system on which the DC motor would work, a closed-loop control system with PID controller is proposed to adapt the operation of the motor (fig. 42). This control method for the DC motor has been widely studied and is commonly used in industry, since it allows the speed and position of the motor to be controlled easily and immediately.

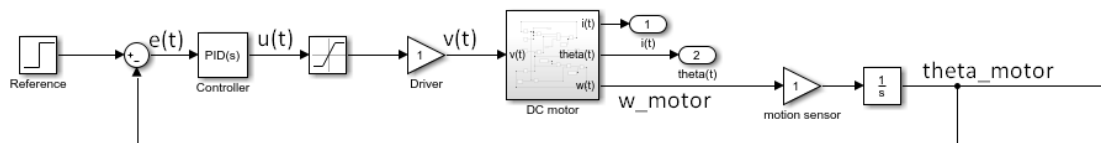


Figure 42. Control loop for the system formed by the DC motor

The modeling of the DC motor is based on its electromechanical scheme (fig.43).

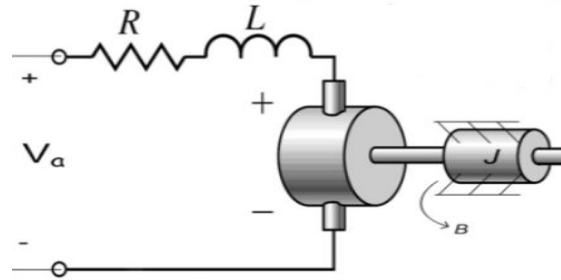


Figure 43. Electromechanical diagram of the DC motor

The first equation is obtained based on the analysis of the electrical part of the circuit mesh:

$$v(t) = Ri(t) + L \frac{di(t)}{dt} + E_a(t)$$

So:

$$L \frac{di(t)}{dt} = v(t) - Ri(t) - E_a(t) \quad (1)$$

Where $v(t)$ is the motor input voltage, $i(t)$ is the input electric current, $E_a(t)$ is the counter electromotive force, R is the terminal resistance and L is the rotor inductance.

The equation for the mechanical section would be as follows:

$$T_m(t) = J \frac{dw(t)}{dt} + Bw(t)$$

So:

$$J \frac{dw(t)}{dt} = T_m(t) - Bw(t) \quad (2)$$

Where J is the motor inertia, $w(t)$ is the motor angular speed, T_m is the motor torque and B is the viscous friction constant.

In DC motors the following relationship exists between the counter electromotive force and angular speed, where K_a is the counter electromotive force constant.

$$E_a(t) = K_a w(t) \quad (3)$$

There is also the following relationship between mechanical torque and electrical current, where K_m is the torque constant.

$$T_m(t) = K_m i(t) \quad (4)$$

These parameters are provided by the manufacturer in the component datasheet. However, some, such as the viscous friction constant, must normally be calculated. According to Monasterio et al. (2020) where the previously stated equations can be analyzed in more detail, and as explained, the constant B can be obtained using both the equation of the mechanical time constant, t_m , and the equation of the no-load motor current.

Using the mechanical time constant equation, the following equation is proposed:

$$B_m = \frac{J}{t_m} - \frac{K_a K_m}{R}$$

By applying the Laplace transform, we would arrive at the system transfer functions that would allow us to obtain the frequency-dependent model.

$$Lsi(s) = v(s) - Ri(s) - E_a(s) \quad (5)$$

$$Jsw(s) = T_m(s) - Bw(s) \quad (6)$$

$$E_a(s) = K_a w(s) \quad (7)$$

$$T_m(s) = K_m i(s) \quad (8)$$

Substituting 7 and 8 in equation 5 results in:

$$v(s) = \frac{(R+Ls)T_m(s)}{K_m} + K_a w(s) \quad (9)$$

Equation 6 gives the angular velocity:

$$w(s) = \frac{T_m(s)}{Js+B} \quad (10)$$

By substituting 10 in 9 and simplifying you get that:

$$v(s) = \frac{(R+Ls)(Js+B)+K_a K_m}{K_m(Js+B)} T_m(s) \quad (11)$$

Therefore the transfer function that relates the motor torque to the input voltage remains:

$$\frac{T_m(s)}{v(s)} = \frac{K_m(Js+B)}{LJs^2+(R+L)Js+RB+K_a K_m} \quad (12)$$

The transfer function that relates the angular velocity to the voltage will be:

$$\frac{w(s)}{v(s)} = \frac{K_m}{LJs^2+(R+L)Js+RB+K_a K_m} \quad (13)$$

By integrating 12, you get the transfer function that relates the position to the voltage:

$$\frac{\theta(s)}{v(s)} = \frac{K_m}{s(LJs^2+(R+L)Js+RB+K_a K_m)} \quad (12)$$

The driver would be modeled as a gain that represents the internal dynamics and therefore shows the variation that the signal would suffer when processed. The motion sensor, either an encoder or a Hall effect sensor, as well as the driver could be modelled as a gain following the same criteria as with the driver. However, no studies have been found that provide a reliable model of these components in order to place them as parts of a control system.

Saturation is implemented to make the system work with the voltage values to which the system would be subjected and the integrator is used to convert the speed output of the encoder to the desired position signal.

Studying each of the components to implement their model and try to analyze them using a theoretical method, it is observed that for the case of mechanical components such as the dc engine, there are many studies that allow to give a fairly accurate approximation if the data of the component is available. However, in the case of electronic components, modelling their behaviour can lead to the appearance of different errors since some factors related to working time could not be taken into account. Fortunately, by having simulation software such as Simulink, tools can be made available that allow you to know how the system works similar to real life based on known system data.

Using Simulink, the DC motor scenario is simulated by driving a load (fig. 44), which would represent the opposition of the patient's body to the movement of the actuator. In this case, an example available on the Matlab platform is used to match the desired system by applying some changes to adapt it to

the type of tests desired. The basis of this example can be implemented by including the command `ee_motor_stepper` in the command screen.

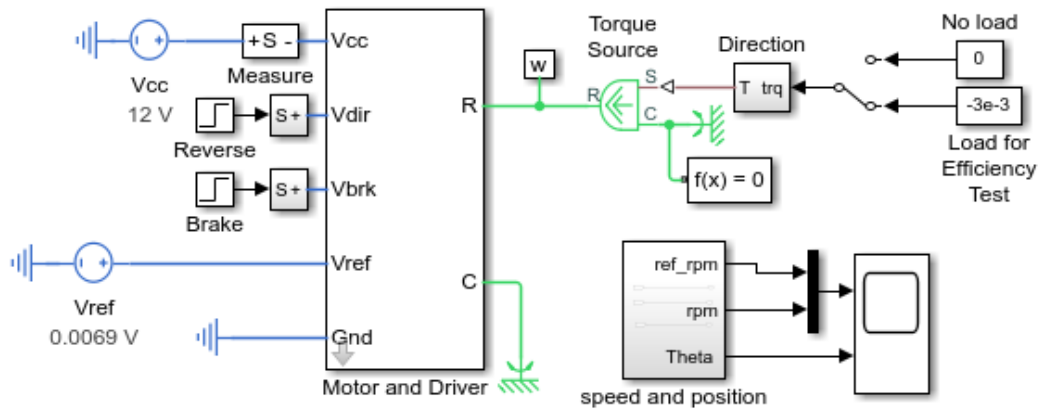


Figure 44. DC motor modeling system with its electrical circuit and load

According to this example, there is a subsystem that characterizes a dc brushless motor and the driver, the necessary power supply, the Vref input that corresponds to the reference marked by the microcontroller, a motion sensor that provides the motion data and a load that acts on the rotor. Since the manufacturer of the DC motor with which the experimental tests were to be carried out did not provide sufficient data to perform the theoretical tests, a similar motor is selected from which the manufacturer does provide the data. In this case, the brushless DC motor with 2 poles from the manufacturer Faulhaber, 12 V nominal voltage and 3056 series (manufacturer's website: <https://www.faulhaber.com/en/products/brushless-dc-motors/>). The parameters are shown in the motor and driver block configuration (fig.50).

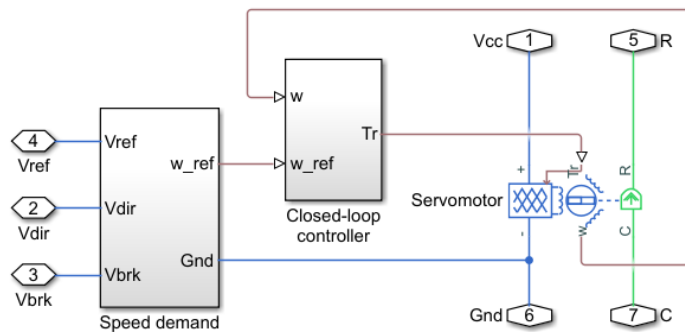


Figure 45. Engine input parameters (sub-system engine and driver)

The signal introduced into the motor (fig. 45) is processed by the driver (fig. 46), which gives the reference signal, direction of rotation and possibility of braking, and the closed-loop controller (fig. 47) which compares the reference with the signal coming from the motor.

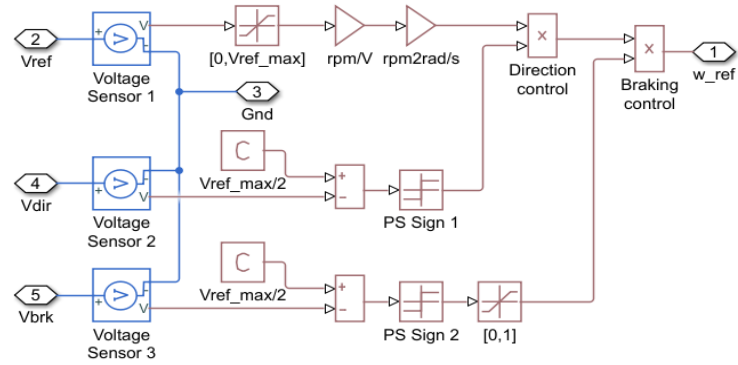


Figure 46. Circuit with driver function (speed demand block)

The driver (Fig. 46) works in such a way that it establishes the speed of the motor according to the input voltage, compared to the direction signal it establishes the direction of rotation, and if necessary it establishes the braking of the motor from the braking voltage signal.

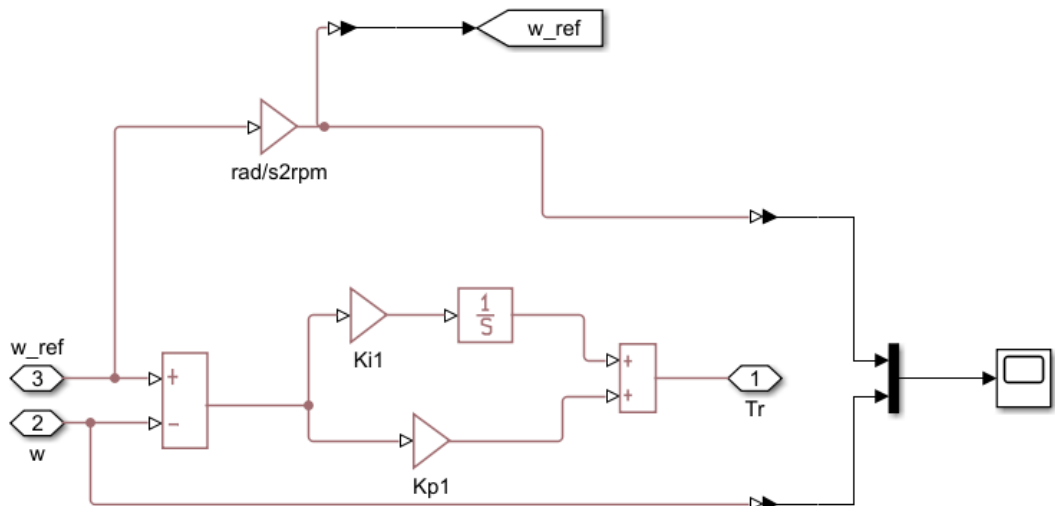


Figure 47. System controller (closed-loop controller block)

The possibility of controlling this type of motor with a PI type controller is considered (fig.47), since $L \ll R$. From this, making experimental tests, the parameters K_i equal to 0.0005 and K_p equal to 0.001 are obtained (fig. 50). With the tests it is seen that adding a derivative part does not improve the stability of the system.

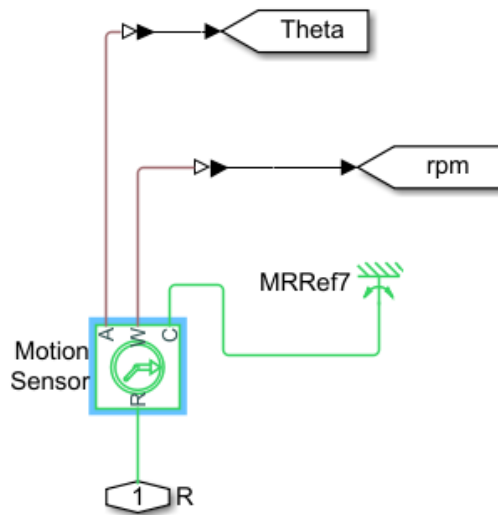


Figure 48. Sensor providing rotor data (w-block)

From the motion sensor (fig.48), the actual speed and position parameters of the motor are obtained from which to set up the control.

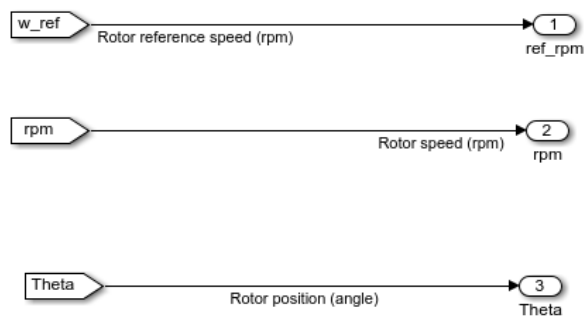


Figure 49. Labels to show the simulation data (speed and position block)

Since the force that the motor has to overcome cannot be obtained experimentally, a load of 30 mNm is put to test. This value is considered acceptable considering that if a manual movement is made on the actuator, the nut moves with the turn provided by the fingers without effort.

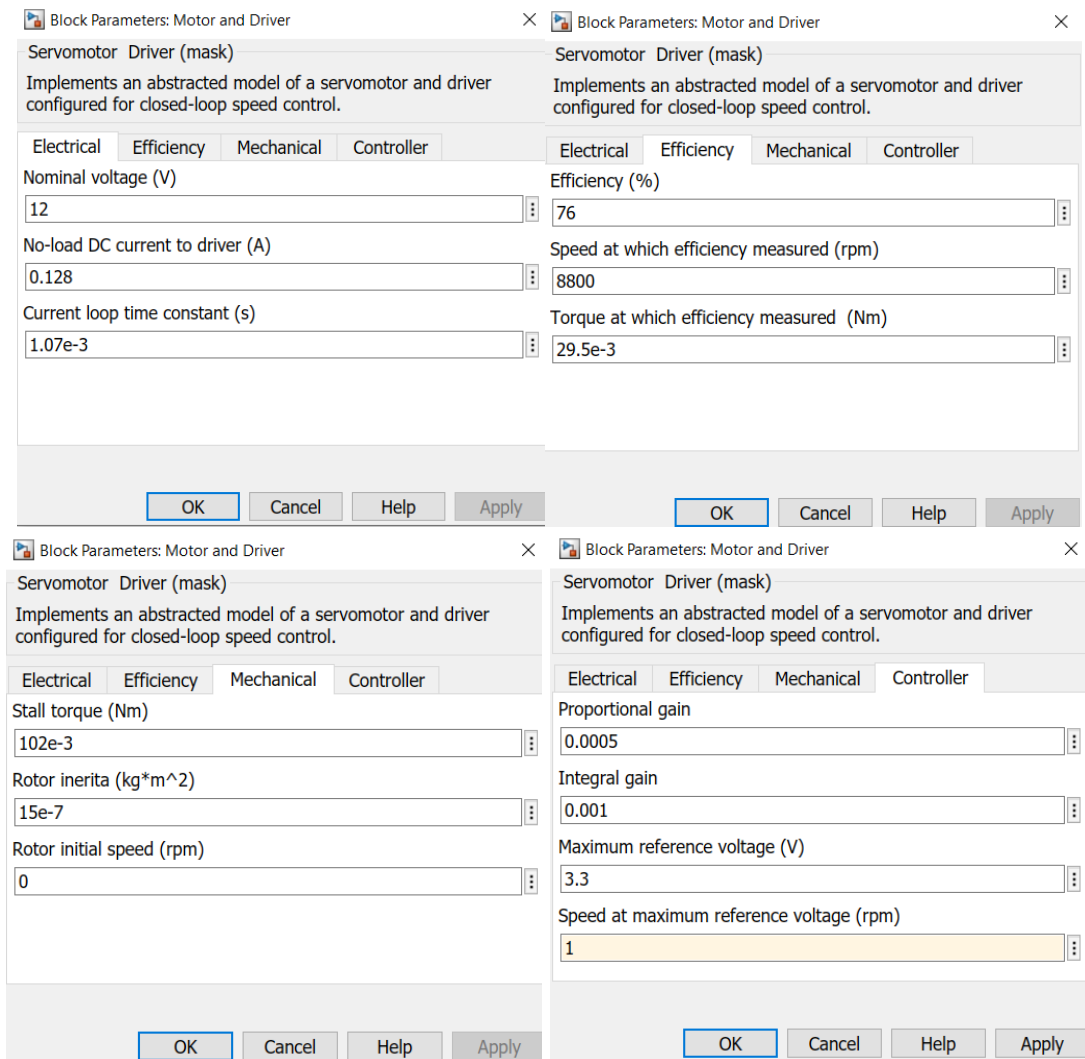


Figure 50. Configuration parameters of the motor and driver subsystem

The simulation (fig. 51) is intended to check if the motor is able to follow the speed marked by the reference, and therefore, would be suitable to be implemented in the robot with sufficient safety guarantees. As can be seen, implementing a PI-type controller makes the motor move to the desired position in the required time. This suggests that this type of motor could be safely integrated into the motor and provide optimal operation.

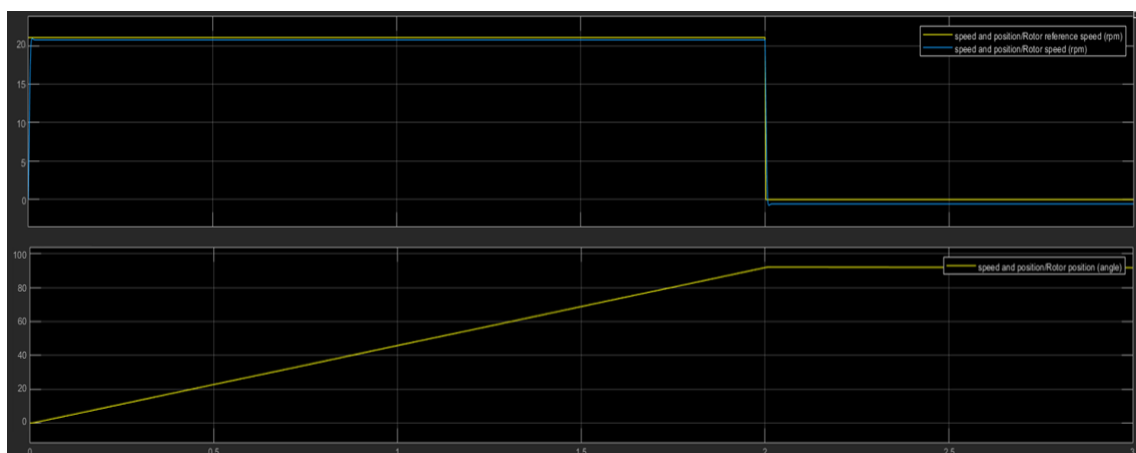


Figure 51. Simulation of DC motor operation.

Even if the simulation shows an adequate behaviour of the system, experimental tests should be raised to verify this simulation, since the fact that the engine has to be a long time providing a stable operation at low speed can generate undesirable errors. In addition, it should be taken into account that during the operation of the system, the six actuator motors would have to operate at the same time, which could lead to incompatibilities that would have to be taken into account both because of the capacity of the controller and because of loading effects on each other. However, it should be noted that these motors provide a higher speed in tracking the setpoint.

6.2. Modeling and simulation of Stepper motor

This section describes the stepper motor in order to simulate and compare it with the DC motor. Although the operating principle of these motors is the same as for dc motors, the way of processing the information is different, since in this case we are dealing with multi-turn motors, in which the position is referred to based on the degrees that the motor is to be rotated relatively, and therefore additional sensors would have to be implemented to control the actual position of the motor. Two signals are sent to the motor, one indicating the direction of rotation and the other a pulse train defining the steps of the motor. The motor steps are the divisions of movement over the 360° of a turn, and therefore, for a motor of 1.8° per step as the one used, an accuracy of 0.0025 mm per step in the linear movement of the actuator could be obtained. The control loop (fig. 52) would be similar to that of the DC motor.

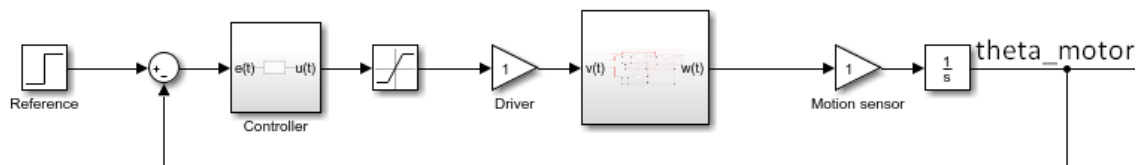


Figure 52. Closed control loop for the stepper motor

Following the method for modeling the DC motor, we start from the distinction between the electrical and mechanical part of the system to obtain the equation that allows us to characterize the stepper motor. In the case of the one used for this analysis, a hybrid stepper motor with two phases is used (fig.53).

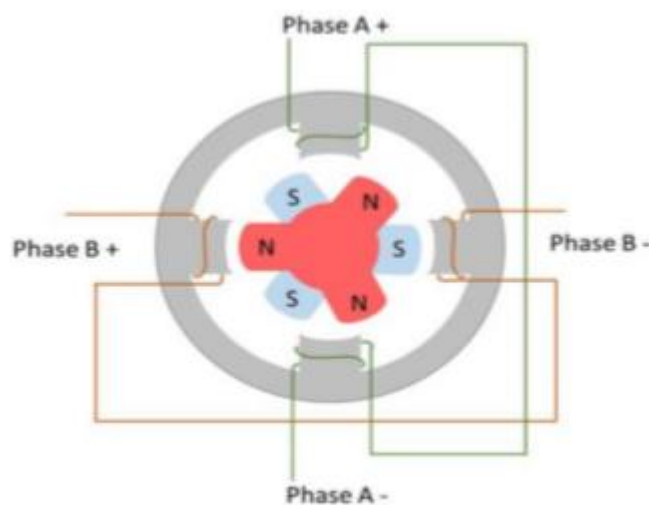


Figure 53. Schematic for step motor with two phases and three teeth

Starting from the electrical part, separate equations must be set up for each phase (fig. 54), although these will be the same since both are modelled as RL circuits with a counter electromotive force (same scheme as for the DC motor). Therefore, equations (1) and (2) are proposed:

$$L_a \frac{di_a(t)}{dt} = v_a(t) - R_a i(t) - E_a(t) \quad (1)$$

$$L_b \frac{di_b(t)}{dt} = v_b(t) - R_b i(t) - E_b(t) \quad (2)$$

Where $v_a(t) = k_m w_m \sin(p\theta_m)$ y $v_b(t) = k_m w_m \cos(p\theta_m)$ are the input voltage to each phase of the motor, $i_a(t)$ and $i_b(t)$ are the electric current circulating in each phase of the stator, $E_a(t)$ y $E_b(t)$ are the counter electromotive force of each phase, $R_a = R_b = R$ is the terminal resistance and $L_a = L_b = L$ is the rotor inductance.

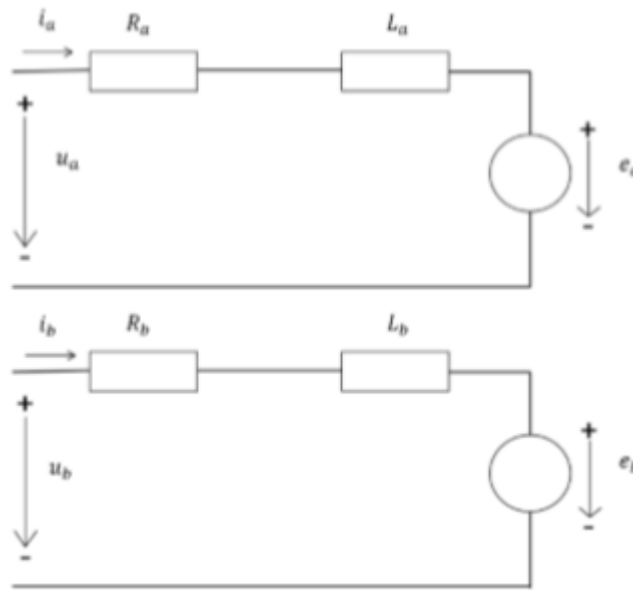


Figure 54. Equivalent circuit of the two phases of the stepper motor

The mechanical part of the system, which would be represented by the motor shaft (fig. 55), poses the following equation:

$$J \frac{dw(t)}{dt} = \tau_{em}(t) - Bw(t) - \tau_{dm}(t) - \tau_l(t) \quad (3)$$

Where $\tau_{em}(t) = k_m(-i_a \sin(p\theta_m) + i_b \cos(p\theta_m))$ is the electromagnetic torque, $\tau_{dm}(t) = T_{dm} \sin(2p\theta_m + \alpha)$ is the applied holding torque, J is the motor inertia, $w(t)$ is the angular speed of the motor, B is the viscous friction constant, which will be obtained according to the expression stated for the DC motor, and α the phase angle of the shaft referred to τ_{dm} , which is the torque of the load. As already mentioned, these parameters can be obtained from the datasheet provided by the motor manufacturer.

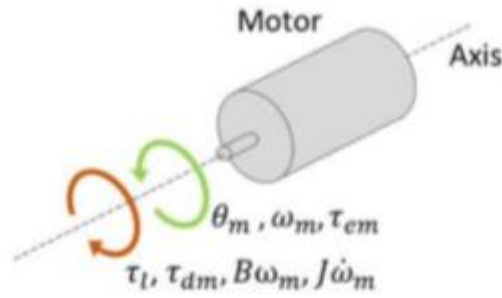


Figure 55. Stepper motor shaft; Mechanical part of the model

At this point, and according to Alkayyall et al. (2018), the FOC (field oriented control) method is proposed to control the position of the hybrid stepper motor. According to this method, the previously posed equations referring to the stator are transformed to the rotor, to control the output torque in a precise way since it is directly connected to the system on which the equations are posed. According to what is exposed in the mentioned document, the equations in the new system would be of the form:

$$L \frac{di_d}{dt} = -Ri_d + pLi_q\omega_m + u_d \quad (4)$$

$$L \frac{di_q}{dt} = -Ri_q - pLi_d\omega_m + u_q - k_m\omega_m \quad (5)$$

As can be seen, from system a and b, we move to system d and q. According to this method, the currents i_d and i_q can be made independent and thus create the linear system given by (6) and (7)

$$L \frac{di_d}{dt} = -Ri_d + u_d^{lin} \quad (6)$$

$$L \frac{di_q}{dt} = -Ri_q + u_q^{lin} \quad (7)$$

To make these variables independent, variables (8) and (9) appear, whose equations are:

$$u_d^{dec} = -Lp\omega_m i_q \quad (8)$$

$$u_q^{dec} = Lp\omega_m i_d + k_m\omega_m \quad (9)$$

Thus, by applying Laplace and according to what was studied in the work mentioned above, the scheme for parameterizing the motor with the independent variables can be proposed (fig. 56).

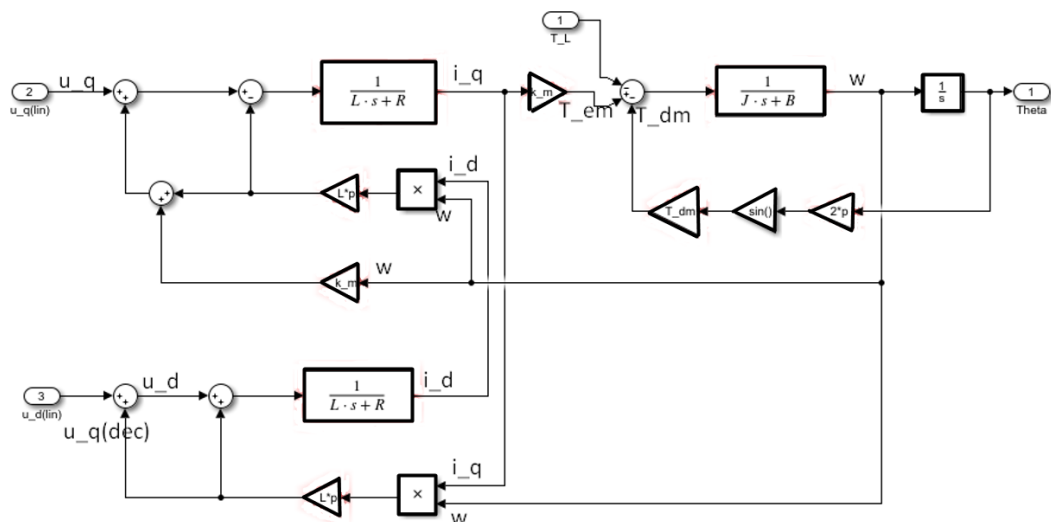


Figure 56. Block diagram modeling the stepper motor

As with the DC motor, a classical control scheme could be proposed, introducing a saturation to work with the actual voltage data, a driver and a motion sensor modelled as a gain representing its internal dynamics, and a controller to reach the desired motor position as a function of the reference. However, Matlab's software, Simulink, will also be used to provide a more accurate simulation of the system based on these criteria.

As shown in the figure, the system proposed consists of a stepper motor configured with the specifications of the manufacturer's datasheet (fig. 60), a driver adapted to the needs of the motor, a position controller (fig. 58), a load that as with the DC motor will simulate the opposition of the patient's body to the robot's drive and a reference input that would simulate the operation of the controller.

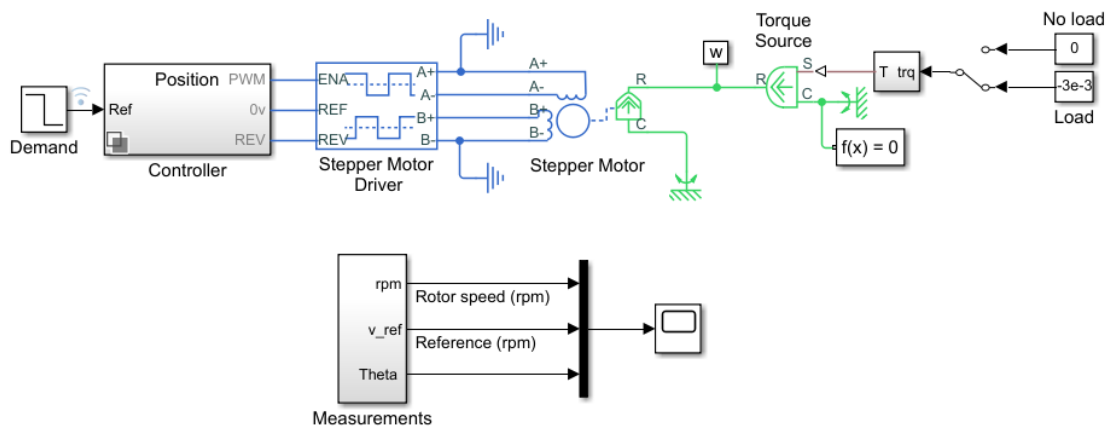


Figure 57. System designed for stepper motor simulation

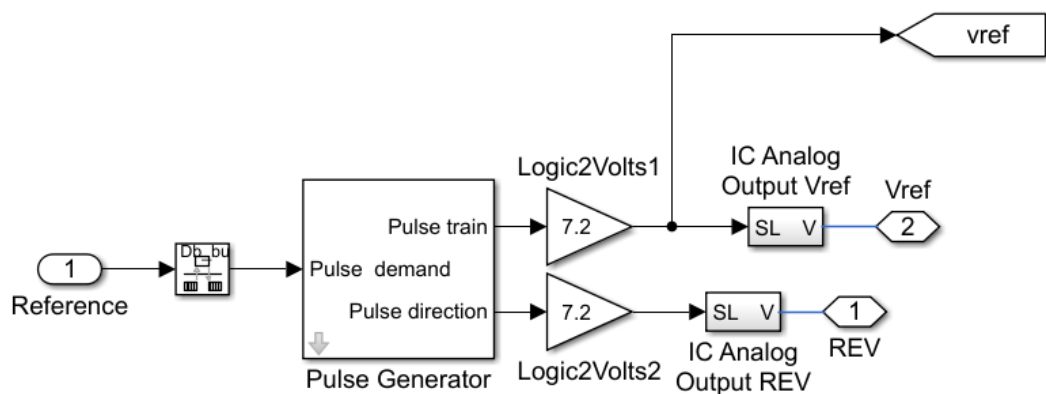


Figure 58. Position controller

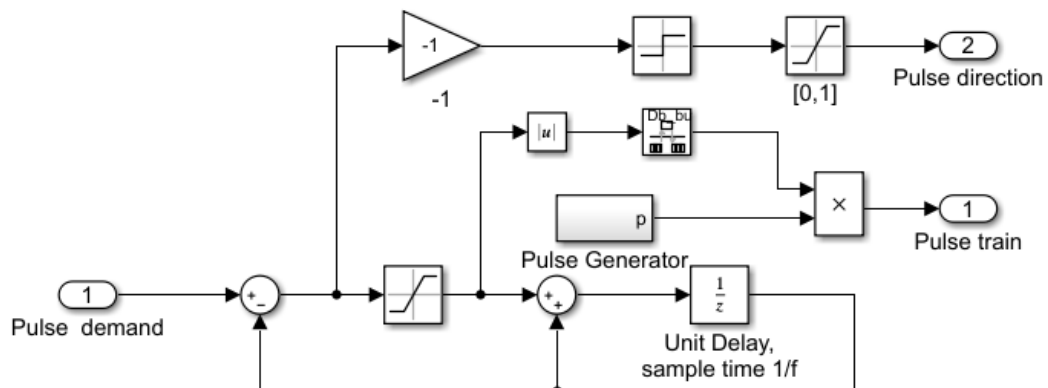


Figure 59. Position controller in pulse generator block

The position controller works in such a way that, depending on the reference entered, a pulse train is generated which is transformed into the movement steps of the motor shaft. Since each motor step involves a 1.8° turn in the actuator, and one turn is equivalent to 0.5 mm in the linear movement of the actuator, high-precision position control is produced.

According to the manufacturer's data, which for this motor are the same as given in the motor proposal, the motor (fig. 60) and the driver (fig. 61) are configured.

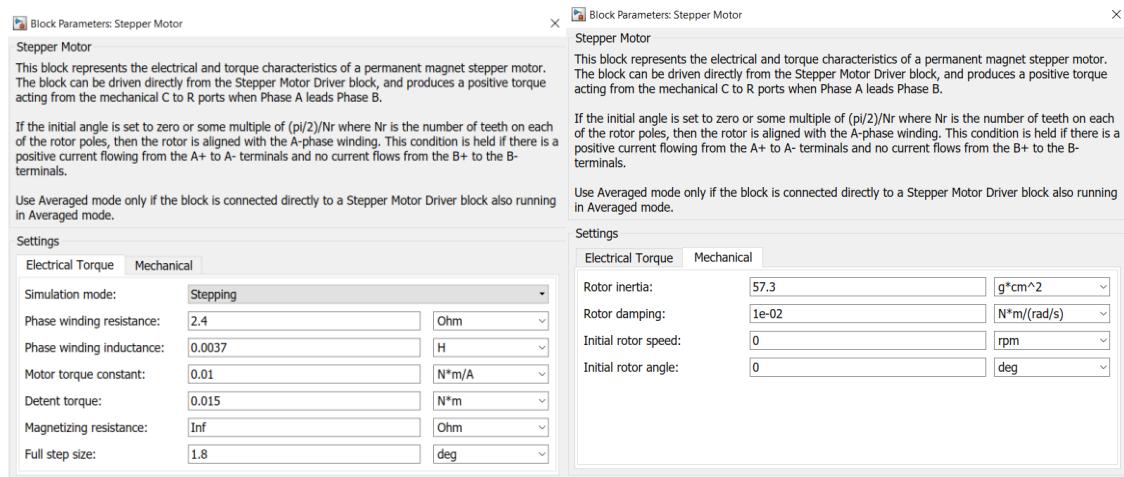


Figure 60. Engine configuration according to the manufacturer's datasheet

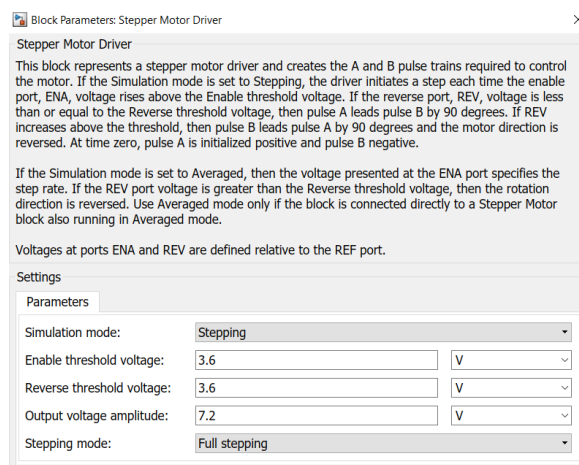


Figure 61. Driver Configuration

Since the simulation scenario calls for a 90° movement of the engine in a period of 2 hours, the controller divides the 50 pulses needed to move the 50 steps in the time period. This leads to a simulation (fig. 62) that adapts to the requirements posed, providing a precision in movement that could not be obtained through manual operation and stability in operation under load. Thus, it can be concluded that this type of motor also offers reliable behavior and could be adapted to the robot.

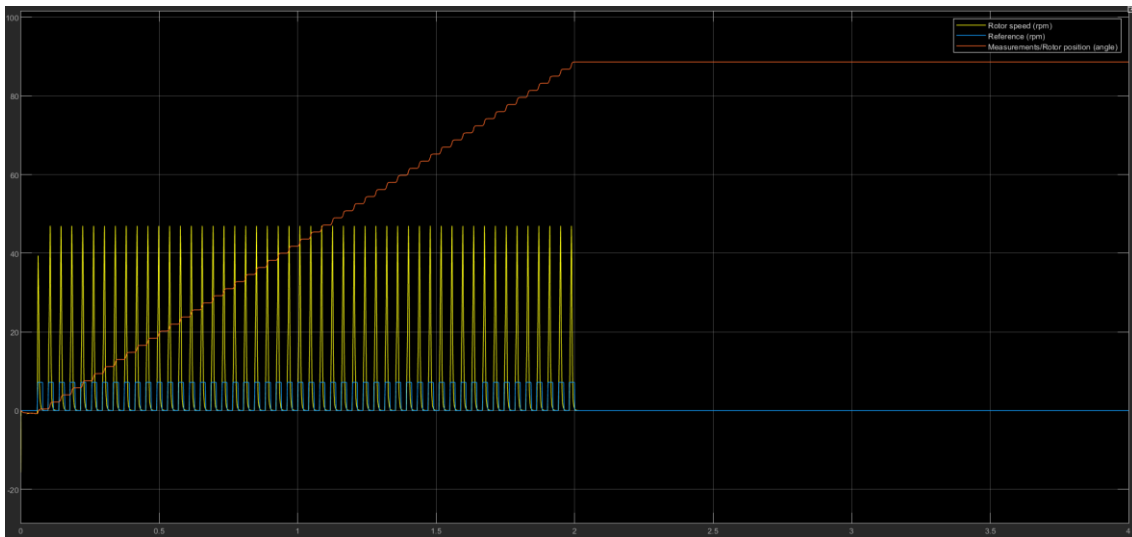


Figure 62. Stepper motor operation simulation

The only phenomenon that could be highlighted is a first pulse made at a slightly lower speed, probably due to the adaptation of the controller to the rotor load, which however does not affect the correct pitch movement. The fact that this motor provides stable turns with high precision followed by a blocking period, instead of continuous operation, may present advantages, since it offers more possibilities for the controller to work with each of the 6 motors while the others are stopped, avoids load variations provided by the drive of the rest of the motors, avoids over-consumption due to the action of different motors simultaneously, and facilitates the change of direction if necessary at any time. In addition, another advantage is that the programming and control of this behaviour is easier.

According to the simulations presented, stepper motors may seem more appropriate for the application. However, although it may seem that these motors behave better for the system requirements, it is essential to check these interpretations in the laboratory, since phenomena such as load variation, friction, vibrations, the use of different motors simultaneously, implementation in the system, or prolonged use may cause the assessment to change.

7. CONCLUSIONS AND FUTURE DEVELOPMENT LINES

The initial objectives of the project were based on the analysis of the parallel robots, in particular the hexapod parallel on which the work is centred, to later analyse possible ways of adapting the robot actuators for automation that do not interfere with the correct operation. Once these ways of adapting the actuators had been established, they would have been assembled and tested in the laboratory in order to validate that the proposals were really implementable in reality.

With the sudden appearance of the COVID-19, the state of alarm and border closures was established in Spain, which affected work in such a way that neither the laboratory could be accessed for testing nor the necessary components were received to be able to work from home. For these reasons, the project was redirected so that work could be done from a theoretical point of view and that it could contribute to future lines of development based on the initial objective. The work developed has been:

- The study of possible actuators for the automatic movement of the robot, which had already been carried out prior to the aforementioned situation.
- The study of the existing regulations for the adaptation of the robot to health specifications.
- The dimensioning and energy analysis of the system.
- Simulation of the systems proposed to automate the robot, with the Simulink software and verification of their possible adaptation.

The conclusions obtained on the basis of the work carried out are:

1. In order to understand the current operation of the hexapod robot on which the project is based and to find the best way to automate it, studies have been carried out on both the existing parallel robots and, in particular, on the TL-Hex robot, to subsequently consider the different possibilities of implementable actuators and select the ones that best suit it. This led to the selection of electric type actuators, and in particular a DC motor and another step by step to perform experimental tests based on the proposed implementation.
2. Analyzing the system, it is concluded that an optimal selection of components is necessary to be able to automate the robot, since if weight, autonomy and adaptability in terms of design are not carefully examined these factors can prevent the project from being planned. For this reason, the different components have been studied from the energy point of view with which the robot could be adapted to evaluate its consumption and work periods, and based on these, to dimension the batteries, and consequently the weight and size of these, verifying that they are adaptable to the requirements of the assembly. For this analysis, different possibilities of components have been proposed, working in such a way that they make up the necessary set to automate the robot, and different work scenarios have been proposed to evaluate their behaviour. Analyzing the results, the feasibility of automating the process in terms of selecting the necessary components is concluded, since as explained in the chapter, it has been proven that there are possibilities that could be incorporated into the system both by design adaptability, and by increasing weight and efficiency, respecting the current proper functioning and adding the benefits of automation.
3. Given that the implementation of robotics in medicine can add a number of factors to be taken into account both in the design and manufacturing process of the system, and in order to

eliminate risks during the use of the robot by the patient, the study is carried out to adapt the robot to health regulations. Initially, a search for information is carried out to classify the standards that govern this type of device. Based on this, the Regulation (EU) 2017/45 on medical devices, the IEC 60601 standard and the ISO standards for standardization 13485 and 14971 are used for information processing. According to these, data to be taken into account for a possible manufacturing of the system are obtained, which refer to dangerous situations that may appear during the activity cycle of the robot, both in its development and operation and that with this study could be avoided from the beginning, the analysis of risks that could be acceptable and others that could not be admitted, and a risk management plan on which to raise the marketing of the product. In addition, the need to create a reference standard for medical robotics, beyond the UNE-EN-ISO 14971 standard for medical devices, is highlighted.

4. Finally, in order to verify that the approaches made in terms of actuator selection and adaptability to the system could be carried out experimentally, a theoretical modeling of each of the selected motors is proposed, and simulations are made with the Simulink software of the complete system as it would be installed in the robot. For the correct characterization of each of the components used, the tools available on the platform are used, which offer a detailed behaviour based on models studied both theoretically and experimentally to offer a simulated behaviour as close as possible to reality. After the experiments carried out, the conclusion is reached that both actuation systems could meet the needs of monitoring the robot's actuation reference according to the treatment proposed, and therefore, the motor selections that had been considered according to the initial considerations for automating the actuators are established as suitable. However, based on the simulations, it is considered that both the operation and the ease of control of the stepper motor make it a better option to adapt it to the system. However, as mentioned previously, these assessments must be tested experimentally to take into account how friction, loads, vibrations or the use of different motors simultaneously would affect the final operation.

As future lines of development, it is considered necessary to continue with the experimental tests for the automation of the system based on the study carried out, since a number of setbacks may arise in the laboratory that cannot be expected by means of simulations, and thus achieve a prototype on which to develop a final product that will allow patients using the TL-Hex robot to benefit from the great advances that the technology can provide to medicine. The possibility of comparing the use of classic actuators such as those proposed with others of recent appearance such as SMAs is also considered, since with the rapid advances that are constantly taking place in the field of engineering, more convenient ways of automating the robot may appear. Furthermore, with this development, society could be shown how much help a greater development of automated robots could provide in this field, as is already happening in other segments of industry.

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