

Universidade do Minho
Escola de Engenharia

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Design and development of an anti-fall cane prototype

março de 2021

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UMinho | 2021

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Dissertação de Mestrado
Mestrado Integrado em Engenharia Biomédica
Biomateriais, Reabilitação e Biomecânica

Trabalho efetuado sob a orientação de:
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fevereiro de 2021

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ACKNOWLEDGMENTS

First of all, I want to thank my mentors, professor Eurico Seabra and professor Cristina Santos for leading the work in the right direction and providing valuable knowledge and experience in each phase of this project. Also, I would like to mention the doctoral student Nuno Ferrete Ribeiro, who was exceptional throughout the entire project development, providing support and advice whenever needed.

I also want to thank ORTHOS XXI and its personnel, for believing in the project and providing the necessary means to innovate and create something new. This project would have been impossible without your support.

Also, to my laboratory colleagues, thank you for the knowledge, advice, good energy, and camaraderie demonstrated even in the hardest of times.

Thank you Maria Vieira for all the patience, support, and love you have shown over the last few years, being present in the most important moments and giving me the strength to make myself better every day. I am genuinely proud of you.

I would also like to express my gratitude towards my friends for all the experiences that we shared, that truly shaped me over the last years and led me down the path that allowed me to be where I am today.

Finally, I thank my parents, for the unconditional support that they always have shown, especially in these last five years. In addition to providing me with the best conditions for my education and success, they also provided me with invaluable knowledge and experiences, that helped me guide my judgment, not only academically, but also throughout my daily-living. Without them, I would be nowhere, and for that, they have my deepest respect.

To all of you, my most sincere thank you.

Rúben Durães

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Resumo

Os eventos relacionados com quedas representam um grave problema de saúde pública, podendo mesmo existir vítimas mortais resultantes destes acidentes. Para além disso, a hospitalização e os custos associados continuam a aumentar. O desenvolvimento de um sistema de deteção de quedas pré-impacto capaz de evitar quedas é essencial para reduzir estes eventos. Já existem alguns avanços em relação a estes sistemas, no entanto, não existe nenhuma solução disponível comercialmente capaz de evitar quedas. Para além disso, o número de utilizadores de bengalas tem aumentado continuamente nas últimas duas décadas. Desta forma, esta tese aborda esta oportunidade de mercado, através do desenvolvimento de uma bengala com um atuador pré-impacto embutido, criando uma bengala anti-queda.

Esta dissertação seguiu um método de design e desenvolvimento de produto, com o principal objetivo de aumentar a usabilidade e sucesso, em geral, do conceito e potencial produto. Numa primeira fase, foram identificadas, categorizadas e classificadas 12 necessidades primárias e 33 necessidades secundárias. Eficácia, confiança, segurança, altura, ergonomia e peso são as mais importantes.

Transformando estas necessidades em termos mensuráveis, um conjunto de especificações alvo foi definido. Usando padrões internacionais e outros recursos úteis, as 12 necessidades primárias foram traduzidas em 18 métricas, cada uma associada a uma unidade e importância especifica.

Para resolver as necessidades do consumidor e especificações do produto, é necessário criar, pontuar e selecionar conceitos. De forma a resolver esta fase complexa, foi desenvolvida uma estrutura funcional para bengala anti-queda. Esta permite a identificação e seleção do subproblema critico, a recuperação do equilíbrio do utilizador. Desta forma, conceitos foram criados e pontuados. O conceito escolhido foi a “rolling cane”, uma bengala com uma plataforma omnidirecional motorizada.

Numa fase final, já com o conceito escolhido, foram utilizadas ferramentas analíticas para encontrar as melhores soluções para as funcionalidades propostas. Cada componente foi dimensionado e proposto. Para além disso, simulações, como testes de carga, separação, e fadiga validaram o protótipo com sucesso. Utilizando o tripé P1, fornecido pela ORTHOS XXI, foi possível fabricar um exosqueleto da bengala anti-queda, que irá incorporar todas as características desenvolvidas analiticamente.

Palavras-Chave: Bengala Anti-Queda, Necessidades do Consumior, ISO, Especificações, Simulações.

ABSTRACT

Fall-related events represent a major public health problem, where death is among the consequences of these accidents. Also, hospitalization and associated costs keep rising. Thus, the development of a pre-impact fall detection system capable of fall avoidance is essential to reduce or even eliminate fall events. Some advances have been made regarding these systems, but there is no commercially available solution capable of avoiding the fall. Also, the number of cane users has been growing steadily for the last two decades. Therefore, this thesis aims to address this market opportunity, by developing a cane with a built-in pre-impact actuator, creating an anti-fall cane.

This dissertation followed a product design and development method, with the main objective of increasing the usability, acceptability, and chances of success, in general, of the concept and potential product. In the first stage, a total of 12 primary needs and 33 secondary needs were identified, categorized, and classified, in terms of relative importance. Effectiveness, reliability, safety, height, ergonomy, and weight were the most important needs.

Transforming these needs into measurable terms, a set of target specifications was set. These take the input of the consumer and guide the remainder of the development effort. Using international standards, and other useful resources, the 12 primary needs were translated to 18 metrics, each with a specific unit, and associated importance and value.

To tackle the needs and meet the specifications, concepts need to be created, scored, and selected. To better address this complex problem, a functional structure for the anti-fall cane was developed. This allowed the identification and selection of the critical subproblem, the balance recovery of the user. Thus, concepts were generated and scored. The selected concept was the rolling cane, a powered omnidirectional wheel platform.

Finally, with the final concept selected, analytical tools were deployed to encounter the best solutions for the proposed features. Every component was dimensioned and proposed. Furthermore, simulations, such as load, separation, and fatigue tests successfully validated the prototype. Also, using the P1 tripod, offered by ORTHOS XXI, it was possible to fabricate an exoskeleton of the anti-fall cane, which will incorporate all the features developed analytically.

KEYWORDS: ANTI-FALL CANE, CONSUMER NEED, ISO, SPECIFICATIONS, SIMULATIONS.

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LIST OF ACRONYMS AND ABBREVIATIONS

3D	3 Dimensional
ACC	Accuracy
ACCM	Accelerometer
ADL	Activity of Daily Living
AD	Assistive Device
AI	Artificial Intelligence
APS	Assistive Product Specification
ARIMA	Autoregressive Integrated Moving Average
AT	Assistive Technology
BBS	Berg Balance Scale
BW	Body Weight
BiRD Lab	Biomedical Robotic Devices Laboratory
CAC	Conventional Admittance Control
CCI	Contradiction Indices
CMEMS	Centre of MicroElectroMechanical Systems
CNs	Consumer Needs
COG	Centre of Gravity
COM	Centre of Mass
COP	Centre of Pressure
COP-FD	Centre of Pressure – Fall Detection
DOF	Degrees Of Freedom
DSA	Dynamic Supporting Area
EMS	Elderly Mobility Scale
FD	Fall Detection
FDS	Fall Detection System
FES	Fear Efficacy Scale
FES-I	Fear Efficacy Scale - International
FN	False Negative

FP	Fall Prediction
FPT	False Positives
FPS	Fall Prediction Systems
FRIDs	Fall-Risk Increasing Drugs
FoF	Fear of Falling
FoG	Freezing of Gait
FoS	Factor of Safety
GATE	Global Cooperation on Assistive Technology
GPS	Global Positioning System
GYRO	Gyroscope
HRCS	Human-Robot Coordination Stability
IEMG	Imaging Electromyography
IMU	Inertial Measurement Unit
LDA	Linear Discriminant Analysis
LM-FD	Leg Motion - Fall Detection
LRF	Laser Range Finder
MAGN	Magnetometer
MDS	Movement Disorder Society
MEMS	MicroElectroMechanical Systems
MSD	Musculoskeletal Disorder
N/A	Not Available
NHIS	National Health Interview Survey
OA	Osteoarthritis
PD	Parkinson's Disease
PNP	Peripheral Neuropathy
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RF	Radio Frequency
SE	Sensitivity
SP	Specificity
SVM	Support-Vector Machine

TF	Triangle Feature
TN	True Negatives
TP	True Positives
UPDRS	Unified Parkison's Disease Rating Scale
USA	United States of America
VA	Vertical Angles
WHO	World Health Organisation
ZMP	Zero Moment Point
rpm	rotations per minute
sEMG	surface Electromyography

1. INTRODUCTION

This dissertation presents the work developed in the scope of the fifth year of the Integrated Master's in Biomedical Engineering during the academic years of 2019/20.

This dissertation was developed at Biomedical Robotic Devices Laboratory (BiRD LAB) from the Centre of MicroElectroMechanical Systems (CMEMs), at the University of Minho, Braga, Portugal, and at ORTHOS XXI, a company based in Guimarães, Portugal. This dissertation addresses the design and development of an anti-fall cane prototype, capable of detecting and avoiding fall events. This dissertation adopts a product design methodology, intending to obtain a consumer-focused device.

1.1. Motivation

Falls are defined as inadvertently coming to contact with the ground, floor, or other lower level, and are considered a predominant factor in causing unintentional injuries [1]. Falls are directly related to age and frailty level. Statistics confirm that 28-35% of adults aged 65 and older fall at least once a year increasing to 32-42% after the age of 70 [1,2]. These are high fall rates and they represent a major public health problem because falls often require medical attention and are associated with function disabilities, morbidity, premature institutionalization, even death. Also, a post-fall psychological trauma, which includes a loss of confidence, confusion, depression, auto restrictions to activities, social withdrawal, and fear of falling, fundamentally increasing the adults dependence [1,3,4].

These facts taken together with a world population getting progressively older [5], it is found not only a social problem but an economic one as well. In the year 2000, in the United States of America (USA), the health care system spent $19 billion on the direct medical costs of fall-related injuries [6]. In the year 2012, it rose to $616.5 million for fatal and $30.3 billion for non-fatal injuries, and rose again to $637.5 million and $31.3 billion, respectively, in 2015 [7]. In Europe, the combined costs for hip fractures alone were estimated at €24.4 billion, in the year 2000, with expectations to double in the year 2050 due to the aging population [8].

This is an ever-increasing worry and interest in the scientific community since the implementation of successful fall prevention and fall detection technologies and policies can reduce the monetary costs and physical/psychological damages that a fall victim suffers. Environmental interventions, personal care/support, and Assistive Technology (AT) devices can be used throughout the lifespan, in various occupational roles, and at various stages of the disease, of the user [9].

The main focus of this dissertation will be on the AT devices, also known as Assistive Devices (ADs). The WHO Global Cooperation on Assistive Technology (GATE) defines an assistive product as "any product (including devices, equipment, instruments, and software), either specially designed and produced or generally available, whose primary purpose is to maintain or improve an individual functioning and independence and thereby promote their wellbeing" [10]. These devices are used by people with functional disabilities as an alternative way of performing actions, tasks, and activities [11]. Their importance is already recognized since they offer to the user an increase in independence, allowing greater activity levels even if the individual has some degree of difficulty performing Activities of Daily Living (ADL) [12]. One study found that the use of these technologies is simultaneously associated with improved performance and satisfaction of the user when performing ADL and a reduction of the burden of the caregivers responsible and the surrounding community [13]. The use of ADs is increasing as well, in 1985 in the USA there were 6000 available products while in 2005 there were 29000 [14].

This kind of technology includes mobility devices, where the cane is included. Canes are recommended to compensate for balance, coordination, strength and to decrease the risk for falls [15]. They increase the base of support [16], decrease weight bearing on lower extremities, and provide extra sensory and proprioceptive feedback regarding body position and changes in the walking surface [3], [17]. Canes are associated with a psychological effect, giving the user a greater feeling of safety and confidence, resulting in better activity levels [17]. Enabling users to walk safely can also lead to physiological benefits. A physically active lifestyle is associated with a decreased risk for a variety of diseases and health conditions [18], such as prevention of osteoporosis and cardiorespiratory complications, improved renal function, and enhanced circulatory system [16]. Some users report additional benefits of canes such as a means to self-defense, to proclaim frailty, and the capacity to maintain their occupational skills [3,16].

Following the previously presented trends, there is evidence that cane use has been growing over the past few decades [15]. Results from the 1980 and 1990 National Health Interview Survey (NHIS) found a 26% increase (2878 sampled users in 1980 to 3626 in 1990) in the use of canes [11]. Between 1994 and 1997 the NHIS estimated that 14% of the USA adults aged 65 and older used a mobility device and that 40% of those aged 85 and older used a cane, representing by far the most used mobility device with 4.8 million American users [19]. In 2011, the Health and Retirement Study analysed a nationally representative sample (n=35,338,000) of adults aged 65 and older in the USA, with results showing that the most commonly used mobility device was a cane with 16.4% of the total population (5,788,000 users) [15].

However, despite all the mentioned benefits, there is clear evidence that the abandonment and disuse of canes is a problem yet to be successfully addressed. Most of the falls at home occur with the absence of the walking-aid device and, consequently, those users suffer from more severe injuries [16]. The abandonment of such devices among the geriatric community occurs mainly due to forgetfulness, inaccessibility, feeling of oldness, the thought of no need, inappropriate device prescription, lack of user education, or use of not prescribed devices [16,20].

1.2. Problem statement and scope

As previously explored, there is an ever-increasing problem with falls. Also, the market for ADs, canes included has been growing steadily over the years. Furthermore, clinical and biomechanical analysis of canes confirms that these ADs improve the quality of life of the user. However, they are also associated with the attentional and neuromotor demands, destabilizing biomechanics effects, interference with limb movement during balance recovery, upper-limb loading, strength, metabolic and physiologic demands [16]. As the use of mobility aids is associated with balance impairment, functional decline, and falling risk, it's easy to attribute all the blame regarding these negative factors to the user and not the product itself. Despite this being true, a closer look reveals more of this complex problem.

One major problem associated with incorrect cane use and design is incorrect cane height, which even small maladjustments can alter gait patterns, posture, and the angle at which forces are applied to the device, increasing the chances the cane tip can slip or tip over [16,21]. Other factors, such as the inability to use the device in the correct hand, improper leaning posture, and wrong use of the device in general, are all possible causes of falls while using canes [21]. A study found that, from a sample of 333 subjects, one-third of them experienced some type of problem associated with its use or design [22].

These results suggest that more research is needed to improve the design of walking aids, specifically canes, and more information is needed about the precedents of fall events, to understand the fall risk factors and develop specific and effective fall prevention devices.

Therefore, there is a clear path towards the development of a real-time fall prevention system built-in a cane device. By taking the problems already identified, this dissertation will follow a methodology linked with product design and development. The main objective is the development of a consumer-oriented device. By taking the end-user into account since the initial phases of the product development, usability and acceptability should be improved when compared to the classic cane concept. Also, with the inclusion of up-to-date technology, and the creation of an innovative solution for a major problem, the anti-fall cane aims to be a competitive product.

1.3. Goals and research questions

The main goal of this master's thesis is the design and development of a cane-type robot prototype. To accomplish this main goal, it is necessary to understand what the users want and need, as well as, several aspects of consumer-driven product design.

Thereby, with this thesis, it is necessary to achieve the following goals:

- Goal 1: The first goal consists of a survey and interpretive study of important information related to falls. The objective is to understand what are the risk factors for falls and what consequences they have, as well as the existing mechanisms that can tackle this problem;
- Goal 2: The second goal is an extensive analysis of studies, techniques, and devices that are already developed, and, if possible, implemented into canes. Therefore, it will be possible to gather information about the characteristics of these systems, such as the technology used, the fall parameters used during the detection, what is the classification criteria, and the associated performance. With this data, it is possible to create a mission statement for the anti-fall cane.
- Goal 3: The third goal aims to find what the consumer wants when buying and using a cane. This sets the foundation for the remaining work developed during this thesis, setting the characteristics that the product should have and the attention and focus that each one should extract from the team;
- Goal 4: This goal consists of transforming the needs previously identified into measurable values, possible to use in an engineering context. This guides what the eventually selected concept needs to achieve to be successful. This list of values will be considered a target, which will later be taken into account during the validation of the prototype;
- Goal 5: The fifth goal is to create, score and select a concept, taking into account all the information that was gathered, up to this moment. Functional decomposition of the anti-fall cane needs to be performed, to reveal the main focus of this dissertation, the development of a concept capable of avoiding falls. The creation and selection process should be performed by the team, using a creative and iterative process;
- Goal 6: This goal is related to the creation of a prototype that includes the chosen concept. Therefore, all the necessary strategies and components will be created and dimensioned using Computer-Aided Design (CAD) and other techniques, to maximize the possibilities of

success of the said prototype. Also, this will be important to reduce the monetary cost involved in the prototyping process;

- Goal 7: The last goal aims to prove and test both the analytical and the physical prototype, using the previously identified specifications. This will be important to determine if the selected concept is one that is capable of tackling the needs and specifications determined throughout this dissertation, and, ultimately, if the said concept is the best candidate to further investigation and development.

The following Research Questions (RQ) are expected to be answered in this thesis:

- RQ1: What a consumer wants and needs when looking to buy and use a cane-related device? This RQ is addressed in Chapters 3;
- RQ2: What are the measurable target specifications associated with the consumer needs, that can be translated into real and observable parameters? This RQ is addressed in Chapter 4;
- RQ3: What is the functional structure of the anti-fall cane, essential to generate and select a winning concept? This RQ is addressed in Chapter 5;
- RQ4: Is the selected concept a valid candidate for further research and development? This RQ is addressed in Chapter 6.

1.4. Contribution to knowledge

The main contributions of this work are:

- The initial design and development of a new anti-fall cane, capable of detecting and avoiding falls and their related negative consequences;
- A consumer-centreed concept, backed by extensive literature research. This also allows for future developments without the need to perform said research, since the consumer needs are listed universally;
- A tool that summarizes all the idealized features for the anti-fall cane, summarized in a functional structure of the anti-fall cane, also constructed universally. This allows the inclusion of future concepts and features, without the need to construct another functional structure;

1.5. Publications

From work produced throughout these academic years, it was possible to publish one conference paper.

Conference Paper

- N. F. Ribeiro, R. Durães, Rafael N. Ferreira, E. Seabra and C. P. Santos, "Product Design and Mechanical Validation of a Cane-Type Robot for Fall Prevention", 21st IEEE International Conference on Autonomous Robot Systems and Competitions (ICARSC2021), Santa Maria da Feira, Portugal, 28-29 April 2021. **[SUBMITTED]**

1.6. Thesis outline

This dissertation is organized as follows. An introduction related to falls, their consequences, and risk factors is available in Chapter 2. Also, it is included a state-of-the-art regarding the available approaches related to falls, what systems and devices are used to detected and prevent those events, and a market and patent research, with special attention to cane devices.

In Chapter 3 it is presented the mission statement for the work developed during this thesis. Also, it is developed a list of consumer needs and their importance, considering the scientific literature, and that users have when they are looking to buy and use a cane-related device.

Chapter 4 addresses the transformation of the previously identified consumer needs into a set of target specifications, which will guide the engineering process of the anti-fall cane. Also, these specifications are ranked, which is derived from the previously determined relative importance of the consumer needs.

The process that leads to concept creation and selection, described in Chapter 5. In this chapter, the functional decomposition of the anti-fall cane is done. Also, the generation, scoring, and selection of sketches for the anti-fall cane concept are performed, resulting in the chosen "rolling cane" concept, which is further explored in this thesis.

In Chapter 6, the prototyping of the anti-fall cane is described. After selecting the concept, a set of analytical tools are used to choose the necessary components for the creation of a functional prototype. This process includes the dimensioning of the DC motors and other key components. To maximize the validation process, analytical static simulations are performed, against the product specifications. Also, with the help of ORTHOS XXI, a physical exoskeleton of the anti-fall cane is produced.

The conclusions and proposals of future work are written in Chapter 7.

2. CANES AND FALL-RELATED SYSTEMS: STATE-OF-THE-ART

The universe surrounding fall events is one of ever-increasing worry, either for patients that suffer from physical/psychological consequences or for the scientific community and governments, that have a health and an economic problem at hand that needs an effective solution. Considering the information about cane usage and its effectiveness, it was decided to improve and adapt the concept of the most used assistive device for fall prevention purposes. To increase the odds of success for such a prototype, extensive literature research was performed to identify risk factors that lead to falls, allowing a profound perception about fall events; and to identify fall-related systems, their utility for fall prevention or mitigation, as well as their features, which can be taken into account for the anti-fall cane. Also, a market research and a patent review were conducted to find more solutions and achieve a more comprehensive search.

2.1. Risk factors for falls

To implement effective fall prevention programs, it is necessary to understand the risk factors for falls as the majority of them do not result from a single cause, but rather from multiple interactions between predisposing/intrinsic and situational/extrinsic risk factors [6,23,24]. Inside the predisposing risk factors for falls are the individual characteristics that impair stability and may cause them to fall easier, and in the situational risk factors are all the other factors that are present at the time of the fall or acted towards it. It is important to study the people and the surrounding environment to design efficient fall prevention systems. As stated before, falls are complex events, there could be more than one risk factor involved.

2.1.1. Psychological changes and social values

The first factor comprehends culture and traditions. Results show resistance by the elderly towards the adoption and implementation of recommendations, for example, the use of assistive devices, since a fall carries a stigma, a social value, and meaning widely associated with aging, diminishing of competencies, and independence. The acquisition of these values can be very dangerous. They change the perspective of a fall to an inevitable episode and natural of aging, inducing a retraction in the active search for help and decision making towards preventive actions, ultimately increasing the risk of future falls [1,3,25,26].

Fall-related psychological concerns include concepts such as, but not limited to, Fear of Falling (FoF) [27]. Up to 83% of community-dwelling older people experience some fall-related psychological issue

[28], which includes FoF, which in turn has been heavily associated with higher risk and rate of falls [4,24,29]. Tinetti et al. [30] developed a fall risk index, the Fear Efficacy Scale (FES) as an instrument to measure FoF, which evolved further into the Falls Efficacy Scale - International (FES-I) [31]. Psychological disorders, such as depression, often present in subjects that fall, are frequently associated with FoF [32,33]. Depression causes sleeping problems, like insomnia [34], poor appetite and weight loss [35–37], deficits in attention, processing speed, and physical activity, all factors related to higher fall frequency [32,38,39].

2.1.2. Polypharmacy and FRIDs

Drug use among the older community has been increasing in the past decades [40,41], and polypharmacy, the consumption of multiple medications, originates drug-drug and/or drug-disease interactions associated with falls among older people. Studies have determined that taking four or more drugs, no matter the type, significantly increases the risk of falls [23,24,42].

Nonetheless, certain medications can be associated with falls independently of other drug use. Medication prescribed to cure depression can enhance the symptoms described before. Antidepressants and antipsychotics are commonly prescribed to older adults and their use is associated with falls, caused mainly through interactions between the drug and the central nervous system [32,43].

The Swedish National Board of Health and Welfare created a list of Fall-Risk Increasing Drugs (FRIDs) and signaled other medications that cause or worsen conditions indirectly related to an increase in falls (e.g. orthostatic hypotension) [42,44], further proving that medication intake is a serious risk factor for falls.

2.1.3. Physical changes and medical status

As said before, a fall shouldn't be accepted as a normal part of getting older, as it is caused by several risk factors that can affect a person of any age. However, as age progresses, the chances of a fall event increase, as stated before during the motivation. Aging brings physical and cognitive changes that contribute to the increase in fall risk, including sensory, musculoskeletal, neurological, and metabolic changes [45].

Inside the sensory department, the most common factors associated with an increase in fall risk are balance impairments [46–48], vision changes [49–52], hearing loss [53,54], and peripheral neuropathy (PNP) [55,56]. These changes affect the somatosensory system, and as the input and process of stimuli are reduced, the probability of postural errors increases and the control of the body orientation

is reduced, leading to higher fall frequency [57,58]. The presence of a single sensory impairment increased the odds of difficulty with falls by 61%, however, an even bigger problem appears when these factors act together, as when two or more sensory impairments are present there is a 5.02 fold increase in odds of reporting difficulty with falls [59]. Another study results, shown in Fig. 1, indicate the same trend as persons with more sensory impairments had more falls during the same period [50].

Musculoskeletal Disorders (MSDs) and diseases are the leading contributors to disability worldwide, and they are prevalent across the life-course [60]. The main conditions linked with a higher fall risk affect:

- the joints, such as rheumatoid arthritis [61,62], and osteoarthritis (OA), where odds of falling increased with an increasing number of lower-extremity symptomatic OA joints, up to 85% higher;
- bones, mainly through osteoporosis, results show a 22% increase in falls during the same period [63];

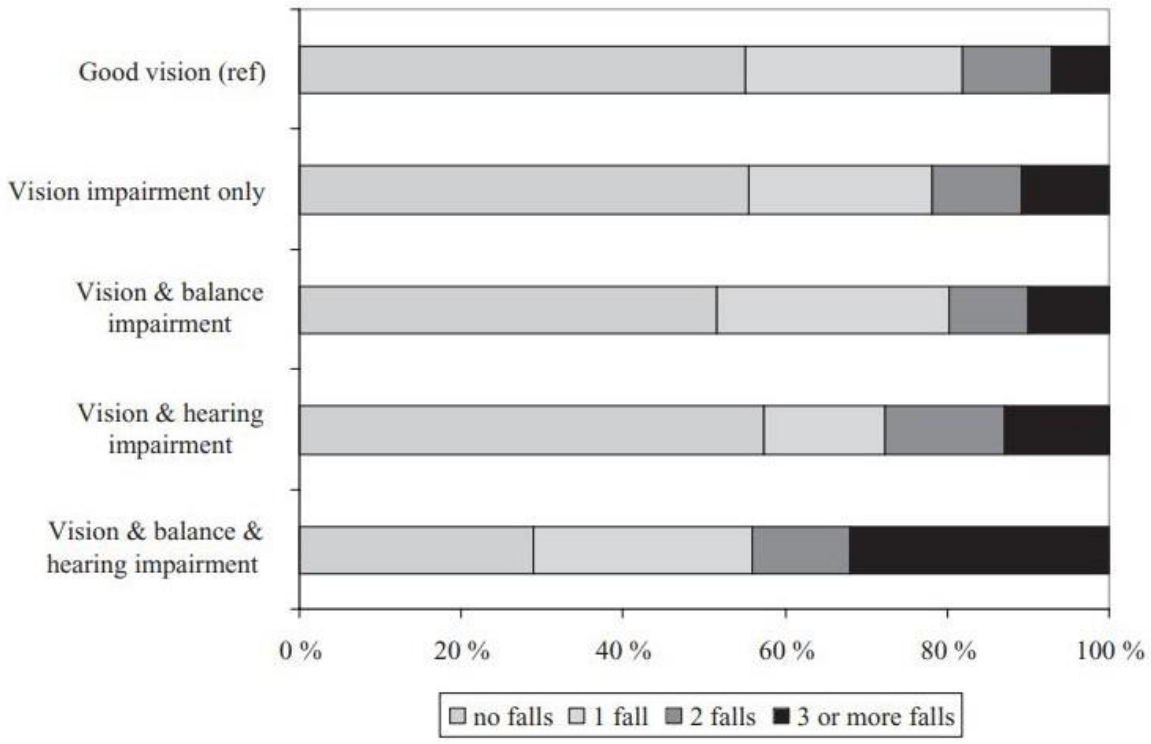


Figure 1: Percentages of persons with 0, 1, 2, and recurrent falls, taken from [50].

- muscles, through sarcopenia, defined as the loss of muscle mass and strength that occurs with advancing age, an analysis of 22 studies revealed that 20 of them showed a significantly higher risk of falls for sarcopenic individuals when compared to non-sarcopenic ones [64];
- multiple body areas, through inflammatory diseases, and general pain [65,66].

These disorders in the musculoskeletal system can lead to impaired mobility, dexterity, and functional ability, provoking impaired gait to a degree where ADLs become difficult and then impossible to carry out [23,45,60]. Afrin et. al. [67] found that the risk of fall increases as the number of Musculoskeletal Disorders (MSDs) increases, the results are shown in Fig. 2.

Neurological disorders and their consequences are currently estimated to affect as many as a billion people worldwide, found in geographical regions [68]. With a demographical transition from a young to an aging population, neurological disorders such as Parkinson's Disease (PD) have been increasing. With the intent to study the lifetime risk of dementia, stroke, and parkinsonism, a study followed 12102 individuals for 26 years, with results showing one in two women and one in three men will develop dementia, stroke, or parkinsonism during their life [69]. Coincidently, these are all neurological disorders associated with higher fall rates [70–72], the results are presented in Fig. 3. Conditions such as PNP and generalized pain were referenced before, special emphasis was given to strokes and PD, as they have the highest fall incidence.

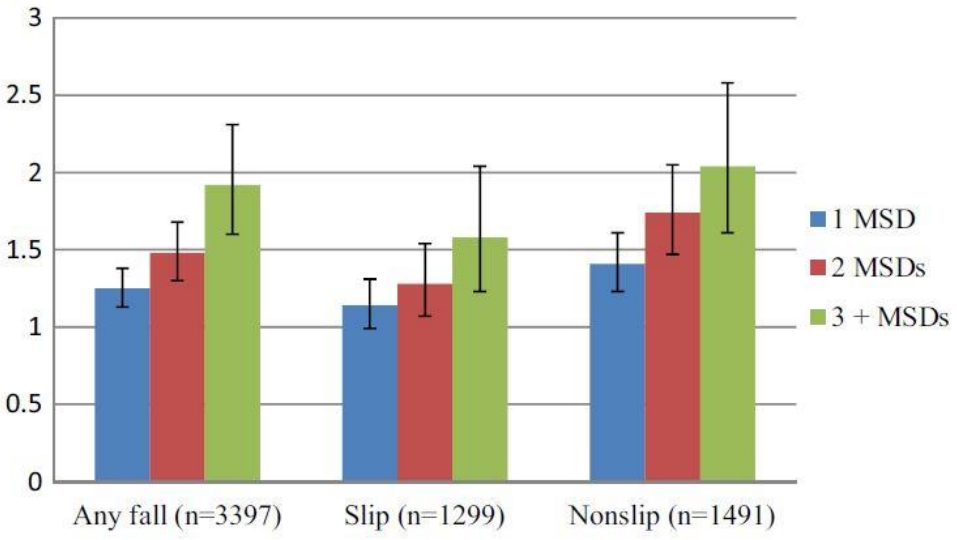


Figure 2: Fall risks related to the number of MSDs [67].

Parkinson's disease is a chronic progressive neurodegenerative disorder characterized by the presence of motor symptomatology such as postural/balance instability and Freezing of Gait (FoG), which, together with other non-motor symptoms [68], result in an average of 60.5% one time fallers and 39% recurrent fallers, with recurrent fallers reporting an average of 21 falls per year [73]. These are high numbers, explained, mainly, by FoG. The definition of FoG is "a brief, episodic absence or a marked reduction of forward progression of the feet despite the intention to walk" [74], and lasts between a couple of seconds and, on rare occasions, several minutes [75]. The FoG patients present significant gait disorders such as knee-trembling, reduced stride amplitude, impaired gait coordination, and increased variability of step timing [74,76], which lead to severe reductions in the patients' independence and mobility, significantly impairing their quality of life.

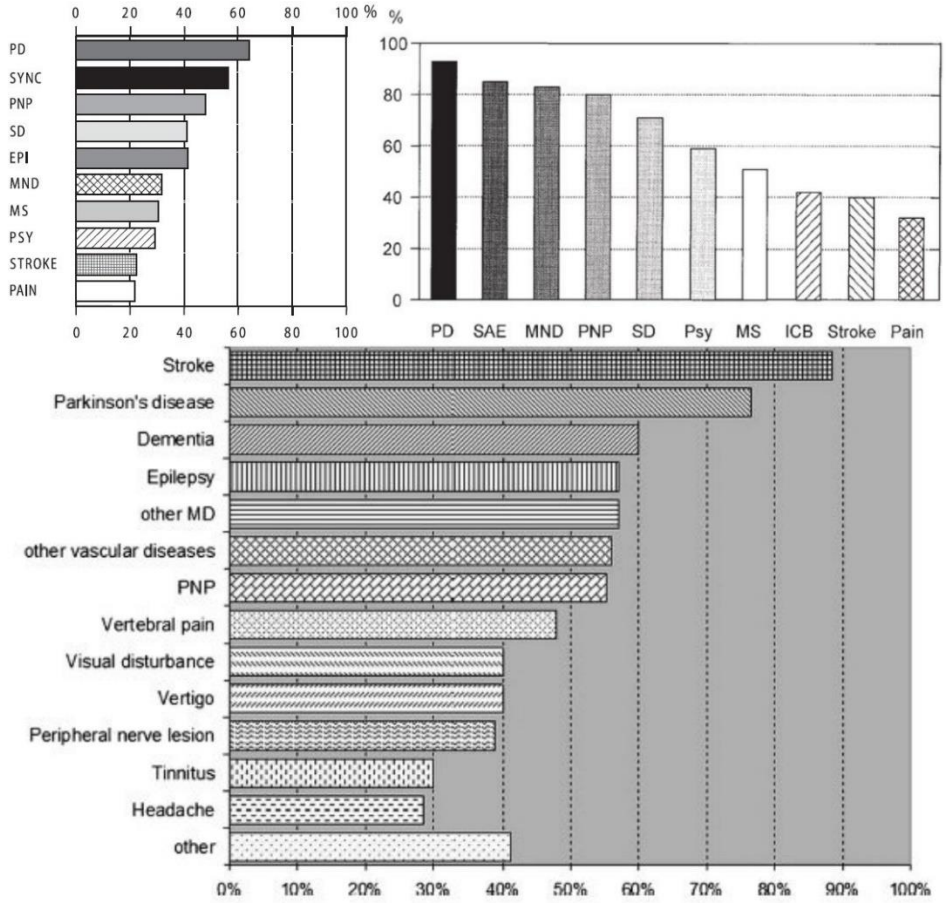


Figure 3: On the top left are displayed the ten neurological diagnoses with the highest frequency of falls [70], on the top right ten neurological diagnoses with the highest disease-specific prevalence of gait disorders [71], and the bottom shows a one-year fall incidence in the most common neurological disorders [72].
(*PD* Parkinson's disease; *SYNC* syncope; *PNP* polyneuropathy; *SD* spinal disorders; *MND* motor neuron disease; *MS* multiple sclerosis; *EPIL* epilepsy; *SAE* subcortical arteriosclerotic encephalopathy; *PSY* psychogenic gait disorders; *ICB* intracerebral bleeding).

Stroke can be defined as a sudden neurological deficit owing to localized brain ischemia, attributed to focal occlusion of the cerebral blood vessel, or hemorrhage, which results in the rupture of a blood vessel [68]. Studies have reported that between 14% and 65% of people with stroke fall at least once during hospitalization and that between 37% and 73% fall during the first six months after leaving the hospital [77], making falls the number one medical complication after a stroke [78]. The deficits that lead to such high rates are dependent on the patient and stroke event (type and severity of stroke), but impaired mobility, reduced balance, hemineglect, and cognitive impairment have been identified as consequences of stroke, all identified as risk factors for falls [77,79,80].

As for metabolic changes, the main mechanism affecting fall risk is metabolic syndrome, defined by the American Heart Association and the National Heart, Lung, and Blood Institute as a constellation of interrelated risk factors that appear to directly promote the development of cardiovascular conditions [81], such as insulin resistance, obesity, and hypertension [82]. Liao et. al. [83] associated the metabolic syndrome with higher fall risk, with a 2.5-fold higher prevalence of this condition found in the group who fell. The prevalence of the disease also increases with age, up to 55% in persons aged 65 years, and over [83]. An older study conducted by Pendergast et. al. [84] analysed energetic, cardiovascular, and muscle function alterations, and successfully linked a progressive decrease in metabolic capacities, present in advancing age, with a higher risk of falls, injury, and institutionalization. Furthermore, metabolic syndrome has been associated with higher cognitive impairment in a stroke-free population, previously identified as a risk factor for falls [85].

A common trend among these studies is that age represents a risk factor for falls, which goes accordingly to the WHO global report on falls, which found an exponential increase in fatal fall rates with age for both sexes, with the highest being at the age of 85 years and over [1]. Results can be seen in Fig. 4.

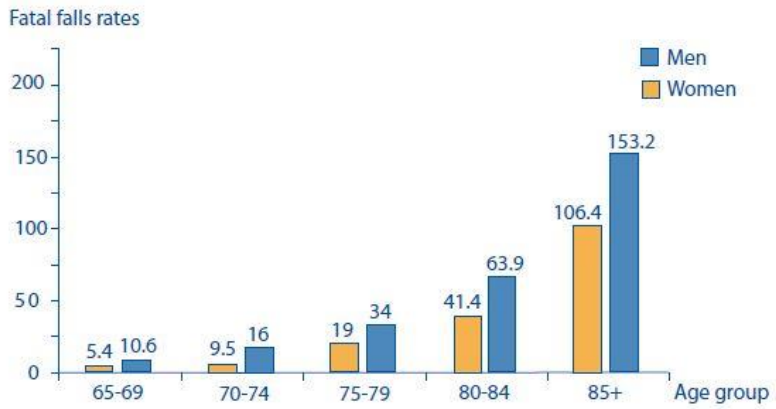


Figure 4: Fatal fall rates by age and sex group, in the U.S.A. in 2001 [1].

A second trend is that while mortality rates from falls are higher among men, women are at greater risk of falling, and, thus, have higher fall rates. This goes accordingly to studies that specifically investigated the influence of gender in falls [86,87]. Also, the WHO global report on falls acknowledges this trend as well, by stating that the fatal rates of women are lower, despite more occurrences of falls among them [1].

2.1.4. Situational risk factors

Situational, or environmental, risk factors include the interaction between the previous individual's intrinsic conditions and the surrounding environment, these factors are not themselves the cause of falls – rather, the interaction between other factors and their exposure to the situational ones [1]. The impact of situational risk factors on falls varies between 20% and 50% of fall events [23]. There are many situational risk factors, those with a larger prevalence in falls are:

- poor building environment/design, including, for example, narrow steps, slippery/uneven surfaces, poor lighting, and looser rugs [1,23,88];
- footwear style, namely how accustomed the individual was to wear the particular style of footwear at the time of the fall [23,89]. Kelsey et. al. [90] results show that at the time of in-home falls, 51.9% of people were barefoot, wearing socks without shoes, or wearing slippers, all common footwear styles among older people;
- non-use/non-access or inappropriate walking aids/assistive devices [1,20,23].

This last situational risk was further investigated because, apart from being one of the biggest situational risk factors, it directly includes this dissertation theme. When these devices are prescribed, their non-use results in higher fall rates. A study conducted by Luz et al. [20] found that 75% of correspondents who fell were not using their device at the time of fall despite stating that canes help prevent falls. Another study was realized by Cruz et al. [91], confirming that elderly users of assistive devices fall more when they are not using the walking aid, as 84.2% of the participants were not using ADs at the time of the fall. As for why the patients were not using the walking aids, both studies reveal that patients do not feel the need to use them, undervaluing the relevance of cane use to their safety, and some associate the non-use to social stigma, previously reported.

2.2. A review of fall-related systems

There has been an increase in interest by the scientific community regarding fall events and the environment surrounding them. A natural and important reaction to an interdimensional problem. Part of this interest is being redirected to the development of fall-related technologies, namely Fall Detection (FD) and Fall Prediction (FP) systems, as these are seen as effective tools to reduce all the negative consequences of a fall event. Despite both aiming to reduce, or even eliminate, the consequences of a fall, there are some significant and important differences between them.

Fall Prediction Systems (FPS) are used to alert the user before the occurrence of a fall, precluding the emotional consequences of that incident. This prediction consists of an estimation/assessment of the fall risk [92]. Fall Detection Systems (FDS) can be divided into two main categories: post-impact and pre-impact. Technology-based on post-impact fall detection can detect a fall after the impact [93], signaling the fall to professionals and surrounding people [94], reducing the time between the accident and the correct/professional medical care that the individual might need. However, the fall still happens and the subject can suffer all the consequences that were described earlier.

On the other hand, pre-impact fall detection refers to techniques that allow falls to be detected before the body hits against the ground, providing protection or avoiding the fall altogether [95]. Hemmatpour et al. [96] highlight the real-time fall prevention systems. In these cases, data are collected from sensors and then processed, determining the risk of a fall in real-time. If a fall can be detected in its earliest stage, more efficient impact reduction or even anti-fall systems, based on external walking aids [96], can be implemented [97], thus tackling the main problem presented earlier. Given the above-mentioned reasons, pre-impact fall detection is considered superior to post-impact fall detection [95].

2.2.1. Review strategy

To understand the pre-impact FDS, an extensive literature review was conducted based on three databases: Web of Science, IEEE, and Scopus. A keyword iteration table was created for each database, considering the number of articles found, to have the best search terms for a successful review. The chosen keyword combinations were “Pre-impact fall detection”, “Pre-impact fall detection”, and “(“Abstract”: Pre-fall detection) OR (“Abstract”: Anti-fall system)” for Web of Science, Scopus, and IEEE Xplore, respectively. A total of 353 results were found using the previous keyword combinations. The review of these articles was conducted based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flowchart [98].

After including 22 records obtained through cross-reference, removing 86 duplicates, and 199 articles based on the title and abstract, leaving 90 full-text articles assessed for eligibility. After the analysis, another 35 full-text articles were found not relevant to the work in question, leaving 55 articles included in the final review. Figure 5 illustrates a PRISMA flow diagram of the entire study selection process.

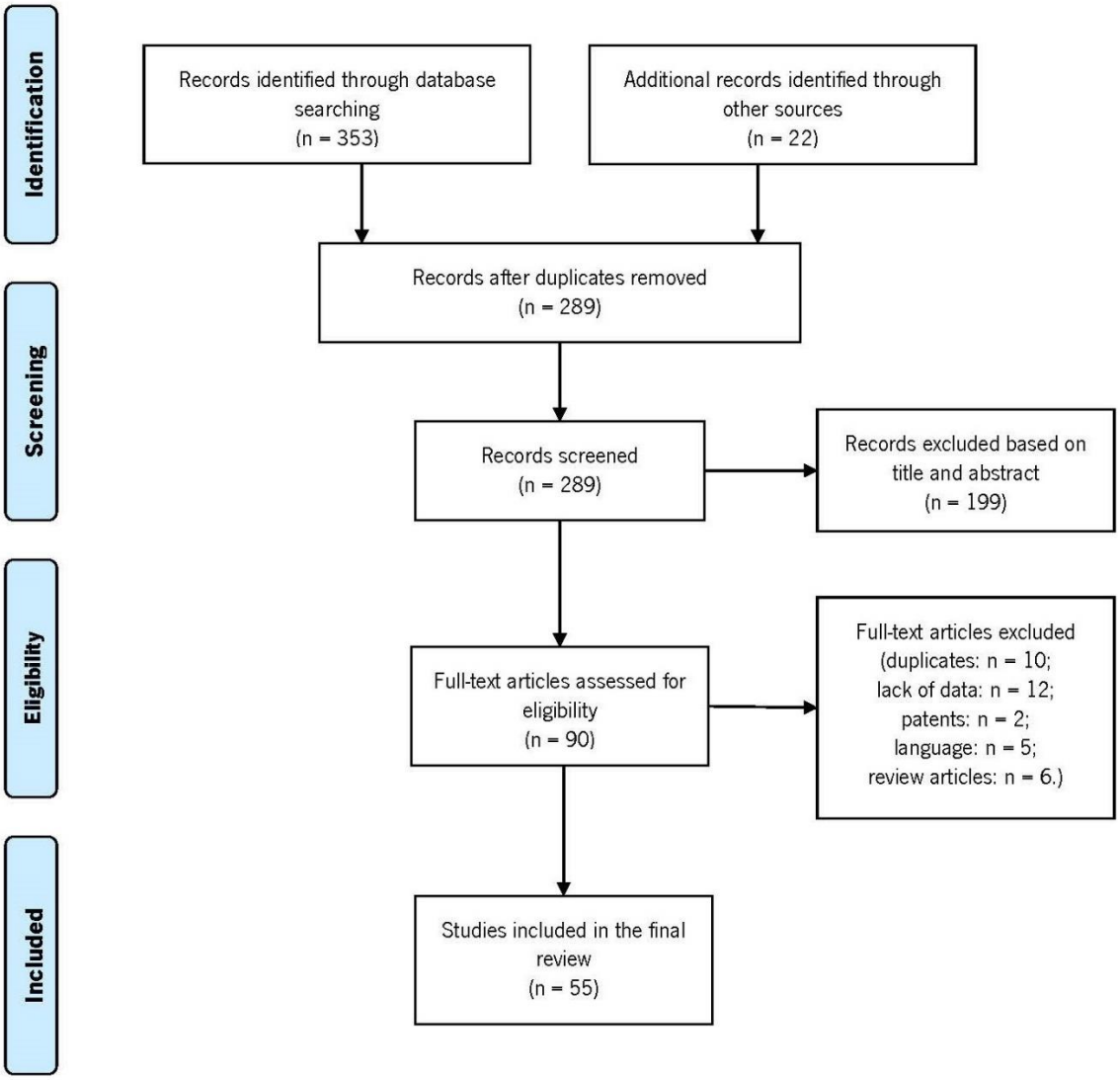


Figure 5: PRISMA flowchart for the literature review on pre-impact FDS.

2.2.2. Review arrangement

After the review of the included articles, it was found that the structure of all the pre-impact FDS is very similar. They have the objective to differentiate between fall events and ADLs. However, this can be difficult as some ADLs (e.g., sitting down) can produce results identical to falls [94]. All the studies that were included in the final review tested the respective FDS with falls performed/simulated by young subjects, this is one limitation of the available research and it is a transversal one because of the difficulty and danger of gathering data from elderly falls. The data are recorded and then processed, using a fall detection technique that is capable of distinguishing falls and ADLs.

The performance of the said technique is expressed in statistical measures, the most common being specificity (SP) and sensitivity (SE) [94]. Generally, there are four possible outcomes in an FDS. True Positives (TP): number of falls that occur and are correctly detected. True Negatives (TN): number of ADLs that are correctly detected as ADLs. False Positives (FPT): number of ADLs that are incorrectly detected as fall events. False Negatives (FN): number of falls that is incorrectly detected as a non-fall event [99]. Sensitivity measures the proportion of actual positives that are correctly identified as such (e.g., classify a fall as a fall), while specificity measures the proportion of actual negatives that are correctly identified as such (e.g., classify an ADL as ADL) [100]. Equations 2.1 and 2.2 for these terms are shown below [101].

$$SE = \frac{TP}{TP + FN} \times 100 \tag{2.1}$$

$$SP = \frac{TN}{TN + FPT} \times 100 \tag{2.2}$$

Since this work is focused on pre-impact FDS, the lead time was considered an equally important parameter regarding the performance of the fall detection techniques. The lead time (T_{lead}) comprises the time between the detection (T_{detect}) of the fall and the fall impact (T_{impact}), and accounts for the time protective measures to be activated to protect the fall victims from fall impacts thus, the longer the lead time is, the better the pre-impact fall detection performance is. The lead time can be obtained through eq. 2.3 [102,103]:

$$T_{lead} = T_{impact} - T_{detect} \tag{2.3}$$

After reviewing the pre-impact literature, fall detection methods were categorized into four types: vídeo-based systems/context-aware systems, wearable devices, pre-impact FDS that implement effective

fall impact reduction/protection systems, and canes with implemented fall-related systems. In each section, a representative example is further explained, and the results are summarized using a table.

2.2.3. Context-aware systems

Video-based/context-aware systems rely on motion capture systems (usually high-speed cameras) and reflective markers placed at strategic anatomical zones. These markers are tracked by the motion capture system, providing information about the body kinematic and the fall parameters, giving the necessary data for accurate classification of the fall event. That is the main advantage of these systems [94,104]. However, privacy issues with recording personal video and a limitation of space in the application of video-based systems make them practically impossible to implement in real-life applications [94,95,105]. Results are summarized in table 1.

Li *et al.* [106] use a Microsoft Kinect sensor, a lower cost context-aware technology, and a modified Zero Moment Point (ZMP) criterion to detect a fall. ZMP is defined as a point on the ground where the net moment of the inertial and gravity forces has no component along the axes parallel to the ground [107]. Defining a Dynamic Supporting Area (DSA) that contains the projection of both feet and the area between the two feet, it is hypothesized that the ZMP should be within the DAS and the person will lose balance if that is not verified. Using the Kinect sensor 2.0 to create a skeletal model with 3D coordinates of 25 joints on the human body, it was achieved a lead time of 867.9 ms, the highest among all the studies analysed, and a sensitivity of 100%. However, the specificity was only 81.3%, indicating that some ADLs were identified as falls.

Table 1: Context-aware fall-related systems

Article	Technology	Fall indicators	Classification Method	Performance	Lead Time
Nyan et al. [108]	Six cameras, seven reflective markers	3-D positional data (sagittal and lateral tilt angle of the body segments	The threshold of angle data between thigh and torso	N/A	700 ms
Hu and Qu [109]	Eight cameras, twenty-six reflective markers	Head vertical velocity, upper arm vertical velocity, trunk	Statistical – Autoregressive Integrated Moving Average (ARIMA)	SE= 88.5-94.7%, SP= 92.9-99.2%	200-300 ms

Table 1: Context-aware fall-related systems

Article	Technology	Fall indicators	Classification Method	Performance	Lead Time
	(twelve segment body model)	vertical velocity, shank frontal velocity, head frontal angular velocity	model, based on historical movement data		
Martelli et al. [110]	Six cameras, thirty-nine reflective markers	Linear acceleration from all body segments	Machine learning algorithm	SE= 92.7%, SP= 98%, ACC= 95.4%	351 ms
Wu [111]	Three cameras, three reflective markers (posterior side of the trunk)	Horizontal and vertical trunk velocity	The threshold of the trunk velocity	N/A	300-400 ms
Liu and Lockhart [112]	Optical motion analysis system (Qualysis), Inertial Measurement Unit (IMU) attached to the trunk, 3D Accelerometer (ACCM) attached to the thigh	Trunk sagittal angle and trunk angular velocity	Individual Threshold	SE= 100%, SP= 95.65%	255 ms (detection time)
Otanasap and Boonbrahm [113]	Triple Microsoft Kinect (vision-based motion sensor)	Head positional velocity and Centre Of Gravity (COG)	Dynamic Threshold of the fall indicators	SE= 97%, SP= 100%, Accuracy (ACC) = 96.2%	521.64 ms
Li et al. [106]	Microsoft Kinect sensor 2.0	Motion information (location, speed and acceleration) of a skeletal model with 3D	Modified ZMP	SE = 100%, SP = 81.3%, ACC = 91.7%	867.9 ms

Table 1: Context-aware fall-related systems

Article	Technology	Fall indicators	Classification Method	Performance	Lead Time
		coordinates of 25 joints of the human body			
Tao and Yun [114]	Multiple Microsoft Kinect cameras making a 3D human model with 25 joints	COG, line of gravity, and base of support	Recurrent Neural Networks (Long Short-Term Memory)	ACC = 91.7%	333 ms

2.2.4. Wearable devices

The majority of existing pre-impact fall detection systems are wearable devices. They can be defined as miniature sensor-based devices that are worn by the user [94]. Wearable Micro-Electro-Mechanical Systems (MEMS), such as ACCMs and gyroscopes have become much smaller, light-weight, and low-cost through advances made in this area [115]. They capture human movement discreetly and allow these measurements to be monitored over an extended space and time. At the same time, they are easier to implement and do not require additional infrastructure installation, overcoming the limitations of the context-aware systems previously presented, offering a much more suitable solution for pre-impact fall detection [95].

However, these systems are not perfect and present some limitations. First, people under fall detection policies will be required to wear the sensors all the time, this could result in low user compliance and low device usage. Second, data stability is lower when compared to context-aware systems, resulting in lower performance and lead time. Third, some fall detection indicators cannot be measured directly by the sensors, for example, variables associated with body segment velocity are obtained through the integration of acceleration signals that come from ACCMs, inducing some unavoidable errors from the procedure [94,116].

Nyan *et al.* [97] present the implementation of a wearable pre-impact fall detection prototype, using inertial sensors, e.g., 3D ACCMs and GYROs. The approach is based on the angular movements of the thigh and torso segments during falls, it is hypothesized that the thigh segment normally does not exceed a certain threshold angle to the side and forward directions in ADLs. This allowed the creation of

multiple threshold values between thigh orientation, torso segment orientation, body segment orientation, and template, resulting in a lead time of 700 ms, one of the highest values among wearable technology, and a specificity of 100%. However, the sensitivity was 95.2% (40/42), since two front falls were not detected.

Leone *et al.* [117] used four wireless surface electromyography (sEMG) probes that monitor the lower limb muscle behaviour, in particular, the Gastrocnemius Lateralis and Tibilias Anterior muscles of the right and left legs. This hardware system associated with a machine learning scheme that includes a Markov Random Field (MRF) based Fisher-Markov selector and a Linear Discriminant Analysis (LDA) classifier allowed an average lead time of 775 ms, the highest among wearable devices. However, the performance is not ideal, with a sensitivity of 89.1% and a specificity of 87.1%. This type of approach is recent in the field of pre-impact fall detection and these results show that electromyography analysis is very promising for the development of a fast and efficient machine learning-based system for pre-impact fall detection. Results are summarized in table 2.

Table 2: Wearable devices related to pre-impact FDS

Article	Technology	Fall Indicators	Classification Method	Performance	Lead Time
Bourke et al. [118]	3D ACCM attached to the chest	Vertical velocity of the trunk	The threshold of the trunk velocity	SE= 100%, SP=100%	150 - 750 ms, Mean= 323 ms
Nyan et al. [97]	3D ACCM and 3D GYRO attached to the chest, 3D ACCM and 2D GYRO, attached to the thigh	The orientation of the torso and thigh segments	Multiple thresholds	SE = 95.2%, SP=100%	700 ms
Shan and Yuan [103]	3D ACCM attached to the waist	Waist acceleration	Machine learning algorithm, Support-Vector Machine (SVM) classifier	SE= 100%, SP= 100%	182 - 228 ms, Mean= 204 ms

Table 2: Wearable devices related to pre-impact FDS

Article	Technology	Fall Indicators	Classification Method	Performance	Lead Time
Liang et al. [119]	Four MTx human motion trackers	Acceleration, vertical velocity, and rate of turn	The threshold of the waist acceleration	SE N/A, SP= 100%	500 ms
Zhao et al. [120]	9-axial IMU attached to the trunk	Acceleration and angular velocity of the trunk	The threshold of the acceleration and angular velocity of the trunk	N/A	257 – 329 ms
Ah net al. [121]	3D ACCM and 3D GYRO attached to the waist	Acceleration, angular velocity, and vertical angle of the waist	The threshold of the acceleration and angular features	SE= 100%, SP=100%	530 ms
Liang et al. [122]	Nine IMUs attached to the left instep, right instep, right shank, left shank, thigh, waist, waist side, and chest	Acceleration, angular velocity, and magnetic field of the body segments	Multiple thresholds	N/A	495 – 764 ms
Aziz et al. [123]	3D ACCM and 3D GYRO attached to the waist	Acceleration, velocity, and angular velocity of the waist	Machine learning algorithm, SVM classifier	SE= 93.5 – 100%, SP=85.6 – 99.7%	63 – 188 ms
Lopez-Yunez et al. [124]	Two 3D ACCM attached to the abdómen and left side of the waist	Gravitational acceleration, body acceleration, tilt angle, and orientation	The threshold of the previous fall indicators	90 – 100% Efficiency	N/A

Table 2: Wearable devices related to pre-impact FDS

Article	Technology	Fall Indicators	Classification Method	Performance	Lead Time
Lee et al. [102]	9-axial IMU attached to the waist	Vertical velocity of the trunk	The threshold of the trunk velocity	SE = 84 – 97.4 %, SP = 85.5 – 99.4%	184 – 231 ms
Leone et al. [125]	Four EMG sensors placed in the lower limbs	Electromyography patterns of the lower limbs	Contradiction Indices (CCI) and IEMG Threshold	SE = 82.8%, SP = 77.9%	N/A
Wu et al. [126]	3D ACCM and 3D GYRO attached to the waist and thigh	Angle and angular velocity of the thigh	A hierarchical classifier based on Fisher discriminant analysis	SE = 95.5%, SP = 97.3%	376 – 404 ms
Otanasap [99]	MetaTracker (tracking platform that includes light, pressure, humidity, motion sensors, and a 3D ACCM) attached to the chest	Velocity and acceleration of the chest position	Dynamic Threshold Model of the previous fall indicators	SE = 99.48%, SP = 95.31%	365.12 ms
Aziz et al. [127]	3D ACCM attached bilaterally on the ankles and thighs, and at the waist, sternum, and head	Acceleration of the body at the position of the sensors	Machine learning algorithm, SVM classifier	SE = 96%, SP = 96%	N/A
Rathi et al. [128]	Motion sensors ADXL345 and MPU6050	Body acceleration, gravitational	Machine learning	SE = 100%, SP = 98.7%	175 – 250 ms

Table 2: Wearable devices related to pre-impact FDS

Article	Technology	Fall Indicators	Classification Method	Performance	Lead Time
	attached to the waist area	acceleration, and orientation	algorithm, SVM classifier		
Leone et al. [117]	Four Wireless sEMG probes attached to the lower limb muscles	sEMG signals of the lower limb muscles	Machine learning algorithm, Fisher-Markov selector, LDA classifier	SE = 89.1%, SP = 87.1%	775 ms
Xi et al. [129]	Four sEMG electrodes attached to the muscles of the left lower limb	Electrical potentials generated by muscle activity	Machine learning algorithm	SE = 98.7%, SP = 98.59%	Calculation time = 65.586 ms
Liang et al. [130]	IMU attached to the waist	Acceleration and angular velocity from the waist	SVM classifier	SE = 97.22%, SP = 93.75%, ACC = 94.91%	N/A
Er and Ang [131]	IMUs attached to the chest, both tighs, and shanks	Multiple combinations of acceleration, orientation, quaternion, and gyroscope signals	CHMM detector	SE = 90%, PR = 92%	450 ms
Rescio et al. [132]	Four sEMG sensors attached to the Gastrocnemius and Tibilias muscles	Lower limb muscle activity	Machine learning algorithm, MRF based Fisher-Markov selector, CCI, and IEMG	SE = 91.3%, SP = 89.5%	770 ms
Xiao et al. [133]	Nine sEMG sensors attached	Lower limb sEMG signals	Machine learning	SE = 93.71%, SP = 92.67%	202.4 ms

Table 2: Wearable devices related to pre-impact FDS

Article	Technology	Fall Indicators	Classification Method	Performance	Lead Time
	to the tibialis anterior, gastrocnemius, vastus medialis, and biceps femoris		algorithm, SVM classifier,		
Ahn et al. [134]	Custom-made IMU attached to the middle of the left and right anterior superior iliac spines	Acceleration and angular velocity of the trunk	The threshold of acceleration, angular velocity, and trunk inclination, Vertical Angles (VA) algorithm vs Triangle Feature (TF) algorithm	VA algorithm: SE = 100%, SP = 78.3%, ACC = 86.9% TF algorithm: SE = 100%, SP = 83.9%, ACC = 90.3%	VA algorithm: 401 ms TF algorithm: 427 ms
Mezzina et al. [135]	Ten EMG electrodes attached to the lower limbs and thirteen EEG sites all along the scalp	Physiological signals of the muscular and cortical activity	Dynamic threshold approach (muscular score and cortical Dynamics Change Detector)	SE = 93.33%, SP = 99.82%	403.16 ms
Bourke and Lyons [136]	Bi-axial GYRO sensor mounted on the trunk	Pitch and roll angular velocities	The threshold of the angular velocity and trunk-angle	SE = 99.2%, SP = 100%	N/A
Wu and Xue [137]	Integrated 3D ACCM and 3D	Acceleration and angular rate of the COG	The threshold of the magnitude	SE = 100%, SP = 100%	70 – 375 ms

Table 2: Wearable devices related to pre-impact FDS

Article	Technology	Fall Indicators	Classification Method	Performance	Lead Time
	GYRO attached near the COG		of inertial frame vertical velocity		
Bourke et al. [138]	Tri-axial ACCM located at the anterior aspect of the trunk, at the sternum and, at the anterior of the thigh at the midpoint of the femur	Trunk and thigh longitudinal, anterior/posterior, and medial-lateral ACCM readings	The threshold of the acceleration of the trunk and thigh	SE not specified, SP = 67.08 – 100%	N/A
Liu and Lockhart [139]	IMU placed close to the sternum	Sagittal trunk angular kinematics	Threshold of the trunk angular velocity and trunk angle	SE = 100%, SP = 95.65%	255 ms
Tong et al. [140]	Tri-axial ACCM attached to the upper trunk	Acceleration from the upper trunk	Machine learning algorithm	SE = 100%, SP = 88.75%	200 – 400 ms
Nyan et al. [141]	Three 3D GYRO attached to sternum, waist, and underarm	Angular rate of sternum, waist, and underarm	Multiple thresholds for angular rate	SE = 100%, SP = 92.5 – 97.5%	98 – 220 ms
Sabatini et al. [93]	BIMU, an integrated device with a 3D ACCM, 3-axis GYRO, and a barometric altimeter attached to the right anterior iliac spine	Vertical velocity of the waist	The threshold of the trunk velocity	SE = 80%, SP = 100%	40 – 300 ms Mean = 157 ms

Table 2: Wearable devices related to pre-impact FDS

Article	Technology	Fall Indicators	Classification Method	Performance	Lead Time
Wu and Xue [142]	Single IMU inserted in a bag attached to the waist	Acceleration and vertical velocity of the COG	The threshold of the inertial frame vertical velocity	117 simulated falls, 3 false alarms	70 – 375 ms
Wu et al. [101]	3D ACCM and 3D GYRO attached to the left wrist, right arm, waist, left shank, right thigh, and front head	Acceleration and angle velocity of the body sensor position	Statistical (ARIMA model based on historical movement data)	SE = 94.8%, SP = 95.2%	N/A
Zhen et al. [143]	3D ACCM, GYRO, and MAGN attached to the waist, and a smartphone application	Acceleration and angle rate of the waist	Machine learning algorithm, SVM classifier	SE = 99%, SP = 96.5%	268 ms

2.2.5. Fall impact reduction/protection systems based on pre-impact FDS

The main objective of pre-impact fall detection is protecting the user since early detection allows the activation of on-demand fall protection systems. All the systems found throughout the literature review consist of inflatable airbag devices that are worn by the user, that rely on other devices, and an algorithm to detect the pre-impact phase of the fall. The main objective with these airbags is to protect (mainly) hips from fracture, one of the most common injuries originated from falls, although the positioning of the device can influence the protection effectiveness. Results are summarized in table 3.

Shi et al. [144] present a mobile human airbag system designed for fall protection for the elderly hips. The data is collected by a Micro IMU (μIMU) that consists of 3D MEMS ACCM, 3D GYRO, a Bluetooth module, and a microcontroller unit. Using an SVM classifier, it is possible to detect falls and trigger the inflation of the airbag on the appropriate hip. Results show that the SVM algorithm obtained a 100% ACC and the airbag inflation process took less than 333 ms, allowing for a real-time fall and non-fall

classification and the deployment of the airbag when fall events occurred, providing a functional protection system.

Table 3: Fall impact reduction/protection systems based on pre-impact FDS

Article	Technology	Fall Indicators	Classification Method	Performance	Lead Time
Yao et al. [145]	Early fall alarm, protection airbag system, remote monitoring platform, and a guardian's cellphone	Acceleration, velocity, and orientation	The threshold of the acceleration and pitch angle	N/A	380 ms (inflation time of the protection airbag system)
Thella et al. [146]	Three ACCM attached to the sternum and waist, mini airbag system	Acceleration of the body segments	Machine learning algorithm, SVM classifier	N/A	150 ms
Zhong et al. [147]	IMU attached to the waist, Vicon recording system, four reflective markers placed around the waist, and a protection airbag system	Vertical acceleration of the body segments	The threshold of the vertical velocity and displacement profile	SE = 93.6%, SP = 95.6%	363 ms
Ahn et al. [148]	Custom made IMU, belt-type spring trigger airbag system	Acceleration, angular velocity, and vertical angle	The threshold of the previous fall indicators	SE = 100%, SP = 100%	401.9 ms
Tamura et al. [149]	3D ACCM and GYRO, wearable airbag system	Acceleration and angular velocity	A threshold of the acceleration and angular velocity	ACC = 93%	197.4 ms, with an inflation time of 121 ms

Table 3: Fall impact reduction/protection systems based on pre-impact FDS

Article	Technology	Fall Indicators	Classification Method	Performance	Lead Time
Shi et al. [144]	μIMU (3D MEMS ACCM and GYRO), a smart mechanical airbag deployment system	3D angular rates and accelerations	Machine learning, SVM classifier	ACC = 100%	333 ms (inflation time of the airbag system)
Sivaranjani et al. [150]	3D ACCM and single-axis GYRO, portable inflatable jacket	Acceleration and angular velocity	The threshold of the acceleration and angular velocity	High SE, SP, and ACC	N/A

2.2.6. Canes with implemented fall-related systems

A big part of the results analysed had built-in wheels, defying the classic cane concept. These wheels allow the implementation of the pre-impact FDS, as well as, an actuator system capable of preventing the fall event, eliminating the physical consequences of a fall. This is a big advantage because all the classic canes had built-in or embedded technology that was capable of detecting the fall but had no system in place to reduce or eliminate the fall event.

Yan and Huang [151] developed a cane-type robot based on an omnidirectional platform designed for pre-impact fall detection and prevention. The system has a ball joint, torque sensors for four directions, and two Laser Range Finders (LRFs). The torque sensors allow the system to gather data for the magnitude and direction of the resultant force and the LRFs measure the distance between the user's legs and the cane, and it keeps track of possible obstacles in the way. With these indicators, a stability region for the robot and another stability region for the user is created, creating the Human-Robot Coordination Stability (HRCS). A fall is detected when the user is out of the HCRS and the fall is prevented by adjusting the ball-joint angle and omnidirectional platform position. While it is not specified in the text, this operation mode hints at the use of powered actuators.

There were several studies identified during the literature review that culminated in the latest paper elaborated by Di et al. [152]. The first one by Huang et al. [153] presents a prototype of an omnidirectional cane that later evolved into a second prototype with a vision system component [154]. However, as seen in Di. et al. [155–157] and Fukuda et al. [158], this component was abandoned for a

third prototype version that presents the first pre-impact FDS and actuator. Later, Di et al. [159,160] refined the classification method to a ZMP estimation, and again to the Centre Of Pressure (COP) stability theory [161], which coincides with the reported study in table 4. Di et al. [152] developed an intelligent walking-aid cane robot based on the Centre of Pressure - Fall Detection (COP-FD) and Leg Motion Fall Detection (LM-FD). The detection is possible thanks to the data gathered by a six-axis torque sensor and a wearable in-shoe load sensor. The actuator is based on moving the cane and main shaft in the opposite direction of the detected fall. Results are summarized in table 4.

Table 4: Canes with implemented fall-related systems

Article	Technology	Fall Indicators	Classification Method	Performance	Lead Time
Almeida et al. [162]	Gyration MG1101 MicroGyro, Atmel EB63 microprocessor	Angular velocity of the cane	Angular velocity threshold	N/A	N/A
Yan and Huang [151]	Cane based on an omnidirectional platform, torque sensors for four directions, two LRFs.	Magnitude and direction of the resultant force, angle, and velocity of the user	The threshold of the HRCS	N/A	N/A
Wakita et al. [163]	Cane based on an omnidirectional platform, two LRFs, a tilt angle sensor, and a six-axis force sensor.	Slop angle of the cane, the distance between the user and the cane, magnitude, and direction of the resultant force	Intention Based Motion Control, Conventional Admittance Control (CAC), and thresholds the force signals	N/A	N/A
Di et al. [152]	Cane based on an omnidirectional platform, six-axis torque sensor, an LRF, FlexiForce sensor	Position of the cane, resultant reaction forces	COP-FD and LM-FD methods	N/A	300 ms

Table 4: Canes with implemented fall-related systems

Article	Technology	Fall Indicators	Classification Method	Performance	Lead Time
Lam and Fujimoto [164]	One motorized omnidirectional wheel, balance control sensor, GYRO, and ACCM	Velocity, angle, and force applied to the cane	Lie algebra method	N/A	N/A
Chen et al. [165]	Three-axis acceleration sensor, embedded GPS	Acceleration of the cane	Finite State Machine (FSM) method applied to one sensor	ACC = 84%	N/A
Lan et al. [166]	Three-axis ACCM and gyroscope, two pressure sensors, Bluetooth unit	Angular rate of the cane, grip, and vertical force	Subsequence matching	N/A	N/A
Lachtar and Val [167]	Three-axis ACCM and magnetometer	Acceleration of the cane	Multistage threshold framework	N/A	N/A

2.3. Market research

After understanding the literature behind FDS, a market research was conducted to find the products related to FDS already being distributed to the community. The analysis of the research was arranged to emulate the one made on the literature review where video-based, ambient-sensing and context-aware systems appear first, wearable devices next, and smart canes last.

2.3.1. Context-aware systems commercially available

One of the products previously referred to in the scientific articles about video-based FDS was the Microsoft Kinect, now Microsoft Azure Kinect. Azure Kinect offers a developer kit, Azure Kinect DK, with advanced Artificial Intelligence (AI) that provides sophisticated computer vision. Kinect contains a depth sensor, spatial microphone array with a video camera, and an orientation sensor as an all-in-one small device with multiple modes, options, and software development kits [168]. This specific product enables

Ocuvera, the only computer vision-based fall prevention solution available on the market. The company uses machine learning algorithms and Kinect sensors to predict patients' intent to exit the bed. This allows the prevention of dangerous fall situations before they occur with a warning of 60-180 seconds.

Regarding the privacy issue about the video-based systems, Ocuvera claims the depth images aren't able to detect any personally identifiable data (age, gender, skin tone, facial structure) [169]. An example of an Ocuvera installation is represented in Fig. 6.



Figure 6: Ocuvera room system hardware [169].

Another company based on this type of technology is SafelyYou [170], however, the product only works for post-fall detection. Azure Kinect is only available in China and the USA for 399$, Ocuvera, and SafelyYou do not specify prices, the client needs to contact the company to determine the best way to integrate the service in the existing workflow.

In the ambient-sensing/context-aware systems, Vayyar offers a 4D imaging sensor that can monitor people's location, movement, height, posture, and vital signs wirelessly, camera-free, and in real-time, using advanced Radio Frequency (RF) technology [171]. Using this product, Walabot HOME was created, a product that automatically detects falls and notifies the set emergency contact [172]. Emerald [173] and Xandar Kardian [174] are other companies that use radio signals to analyze motion, and SafeinHome [175] uses wireless sensors to acquire information

As exciting as the RF technology can be, none of these products can predict a fall, they all relate to post-fall events. Furthermore, there is no information about pricing available online, all the companies need to be contacted before the acquisition of the product.

2.3.2. Wearable devices commercially available

Regarding wearable devices, these come in various forms and devices, and as they are wearable, they can be taken with the user wherever it goes, overcoming the inherent flaw (space dependent) of the previous technology. None the less, Philips Lifeline developed the HomeSafe with AutoAlert, a medical alert system that relies on a wearable device that can be used as a pendant capable of detecting falls, as long as the user is in range of the in-home communicator [176]. The HomeSafe removes the main advantage of wearable devices by establishing a maximum range of use. This is a big flaw, there are several medical alert systems available on the market, but they all possess the same flaws, either they do not have fall detection and rely on the push of a button to signal an accident, or they have wearables with limited range, which is not ideal. Furthermore, Philips Lifeline and other companies established a payment method that is based on installation fees and monthly/annual fees, which can make the acquisition of the product unattractive to the consumer.

One particular wearable device seems to be very popular among fall detection, watches. Apple developed the Apple Watch Series 5, a watch that uses ACCM and GYRO sensors and a custom algorithm, that is capable of detecting falls and connect the user to emergency services automatically if needed [177]. Very similar to the Apple Watch is the Wellnest Wearable [178] and the UnaliWear Kanega LTE [179], both watches capable of detecting falls. However, these products only detect the fall after it has occurred, not avoiding potential injuries. There is no information about the price of the Wellnest Wearable, the Apple Watch can be acquired for €459 and the Kanega LTE for $769.40, as it offers dedicated emergency assistance. These watches are represented in Fig. 7.

To protect the user from a fall, companies developed pads to protect hips from fracture, the most common type of injury after a fall event. Products like Fall-Safe Hip Protectors [180], Impact Active Hip Protectors [181], and Posey Hipsters [182] are all examples of simple hip protection pads. Taking this concept to the next level, companies developed wearable airbags capable of detecting falls and deploying at the right moment to avoid hip damage. Helite Hip'Safe is a wearable airbag that does exactly that, through a complex algorithm that analyzes the motion, Helite claims a lead time of 200 ms and a inflation time of 80 ms.



Figure 7: Watches with FD systems. 1:Apple Watch Series 5 [177]; 2: UnaliWear Kanega LTE [180]; 3: Wellnest Wearable [178].

The 2 hip airbags reduce the impact forces by 85% and are reusable [183]. Similar products are founded in the Tango Belt [184], which claims an inflation time of less than 30 ms, and Hip-Hope [185]. Helite Hip'Safe can be purchased for €649, there is no information about pricing for the other products, and it is represented in Fig.8.

Another interesting product is the Parade Connect shoes. In case of loss of balance and contact with the ground in a sudden and prolonged way, the shoes detect the fall and can alert the user's relatives with precise GPS information. The onboard device is invisible, autonomous, it does not require other devices and runs on a battery [186]. Another similar product comes from another French company, Group ERAM E-Vone, a similarly connected shoe [187]. Once again, both products do not protect the user or detect the pre-fall, dealing only with the post-fall issue. Parade Connect shoes can be bought for 179€, there is no information about E-Vone price.



Figure 8: Helite Hip'Safe uninflated as seen on top, and Helite Hip'Safe inflated on the bottom [183].

2.3.3. Canes commercially available related to FDS

Speaking now about canes, as it was mentioned before, they are the most popular mobility device. They come in various forms, different handles, bases and tips, luxury canes made with expensive and rare materials, others made from cheaper materials like aluminium and wood, some with lanterns, magnets to pick up items, and alarms. To narrow down the cane market research and to maintain the information relevant to the work in question, only canes with built-in fall-related systems were considered.

The first cane is the iStand SmartCane, a device manufactured by WhatBox, Inc., that offers a fall detection system embedded in the device and a GPS module that makes the cane trackable in real-time for as many persons as the users want. That is possible because the iStand has a mobile application and a Bluetooth module that allows pairing between the cane and the mobile phone. The alerts are sent through the user's existing social media network, like Facebook and Nextdoor, or text messages in the event of fall detection, lost cane, and even low battery. In terms of design, the cane is equipped with a flexible shaft for joint comfort, anti-trip stand-alone base, and an extra-long ergonomic handle. The SmartCane can be purchased for $149 with no subscription and no monthly fees, it is only available in the USA [188]. This device is represented in Fig. 9.

The second product comes from France, the Smart Dring Cane is a connected cane with built-in GPS, ACCM, and GYRO sensors. The DRING service is based on AI algorithms, which allows the cane to know the activity and the habits of the user, making it not only possible to signal unusual activity to the caregivers, but also provide adaptation of the device to the individual users.

The cane has a fall sensor built into the cane that triggers a pre-alert BIP if the cane falls, which can be canceled by putting the cane in a vertical position. However, if the cane falls by itself, there is no pre-alert. In case of a real fall, the relatives of the user are notified and a confirmation is sent to the cane. The device is easy to use, there is no need to install mobile applications, since the alarm system is 100% integrated into the cane, and the device is active permanently with a battery that lasts several weeks. The Smart Dring Cane can be purchased for 129€ [189]. The Smart Dring Cane is represented in Fig. 10.

The market research was resumed in Fig. 11 where it was divided into two big categories, post-impact, and pre-impact fall detection. A total of 17 products were analysed, 12 were categorized as post-impact fall detection, and 5 as pre-impact fall detection. To do a market research final analysis, every price available was converted to Euros (€), using the conversion rate of 1 United States Dollar = 0.91 Euro. Only products with prices available online were included in this reflection and they were summarized in Fig. 12.

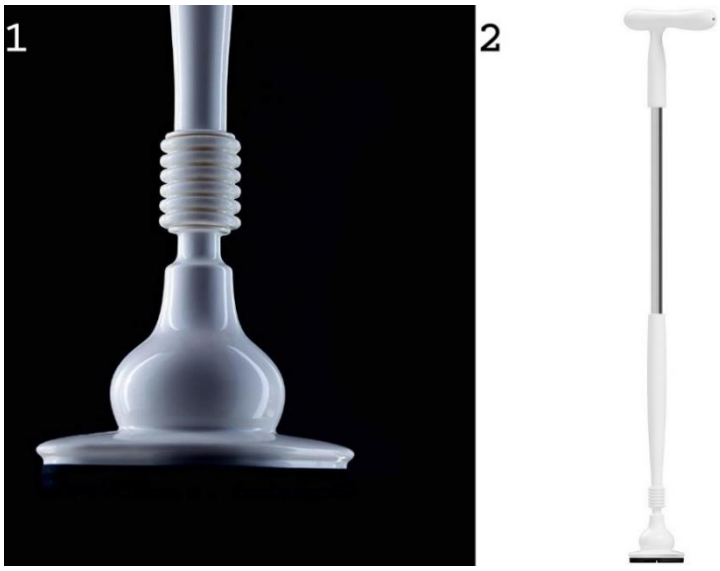


Figure 9: iStand SmartCane [188]. 1: The flexible shaft and anti-trip stand-alone base; 2: Design and complete features of the iStand SmartCane.

Using a bubble dispersion chart, it is easy to see in which direction the market has grown and evolved. The right side of the chart represents all the available products related to post-fall detection systems, a total of 5, and the left side the ones related to pre-impact fall detection, a total of 2.

The Microsoft Azure Kinect was included in the pre-impact fall detection tab because of its potential as a product for the fall detection/prediction problem. However, it is only a camera that does not offer fall prediction or detection to the user, it is not a finished product in this context. Therefore, only Helit Hip'Safe can detect a fall before it happens, claiming a lead-time of 200ms, and it is the second most expensive product on this final review, behind the UnaliWear Kanega LTE.



Figure 10: Smart Dring Cane with an integrated FDS [189].

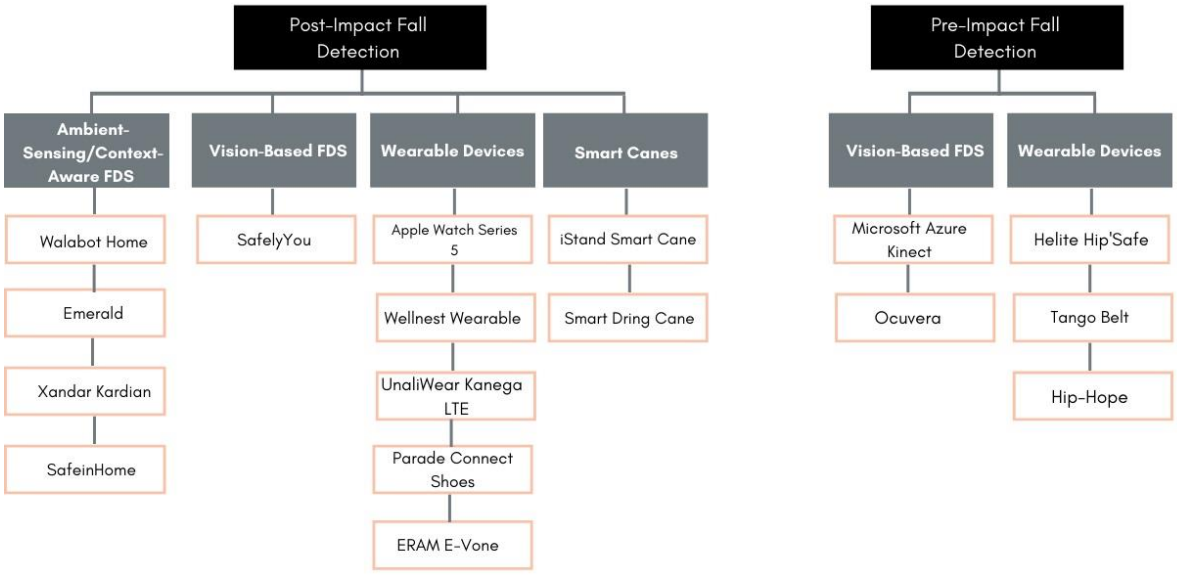


Figure 11: Market research summary.

Another important point is that both cane devices are the cheapest products available in the entire array of products, however, they only work with post-impact fall detection. Both Fig. 11 and 12 show the market trend, a very focused market regarding post-impact fall detection with more products and more variety when compared to the pre-impact fall detection. There is a clear market opportunity for a pre-impact fall detection cane device.

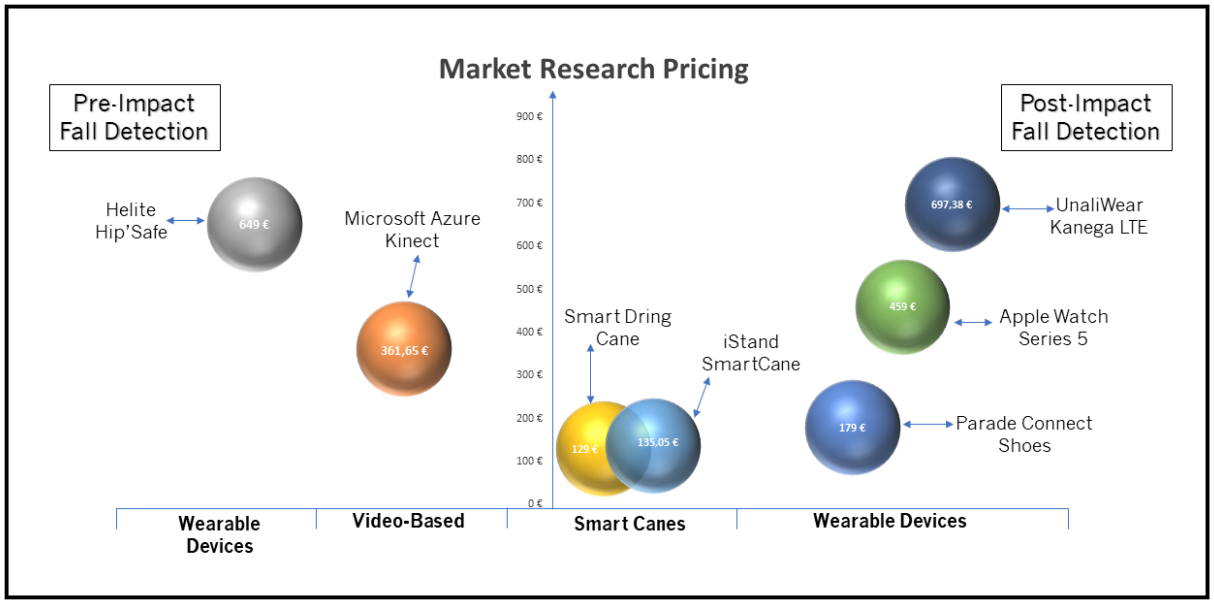


Figure 12: Market research pricing represented using a bubble dispersion chart.

2.4. Patent review

On November 04th, 2019, an advanced patent search on international patents was performed on Espacenet [190], which gives free access to over 120 million patent documents. The search was conducted using "(Cane OR "Walking Stick") AND ("Fall" OR "Near Fall" OR "Fall Detection" OR "Fall Prediction" OR "Fall Prevention" OR "Falling")" as a keyword combination. On the same day, another patent search was conducted on the United States Patent and Trademark Office [191], the keywords used were "ABST/(Cane OR "Walking Stick") AND ("Fall" OR "Near Fall" OR "Fall Detection" OR "Fall Prediction" OR "Fall Prevention" OR "Falling") OR TTL/(Cane OR "Walking Stick") AND ("Fall" OR "Near Fall" OR "Fall Detection" OR "Fall Prediction" OR "Fall Prevention" OR "Falling")". Compared to the literature review, the keyword combination was much more complex, because of the immense number of available patents and search results, and the need to restrict them. Furthermore, this keyword combination was previously tested by Mouta et al. [192].

On Espacenet, 446 patents were found, and on the United States Patent and Trademark Office, 404 results were found, giving a total of 850 potential patents of interest. The review of the results was conducted based on a PRISMA flowchart [98], shown in Fig. 13.

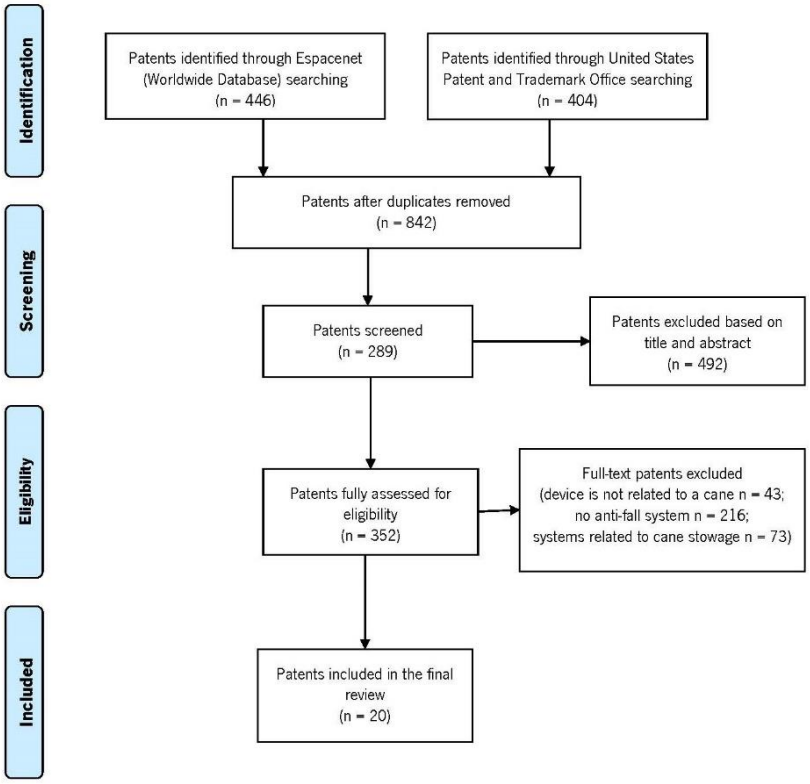


Figure 13: PRISMA flowchart for the patent review.

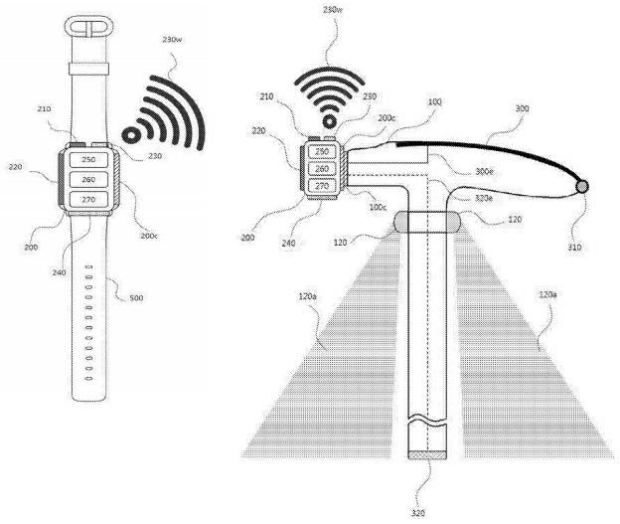


Figure 14: Intelligent Walking Assistive Apparatus For Visual Impairment Aged and Feeble Person – KR20160144193 [193].

From all the 850 potential patents, 20 were included in the final review based on abstract, description, and drawings. From the final group, 9 patents were related to post-fall systems. Figure 14 shows an intelligent cane that can be used by the elderly, based on a detachable intelligent control module and a wearable device with a wireless mobile communication module, that is capable of guiding the elderly through a safe route when walking, and rapidly notify a guardian when an accident occurs [193].

However, this intelligent cane does not only comprise a post-fall mechanism as well as a wearable device, which is not ideal, since it relies on the use of wearable technology and does not have a fall prevention actuator. Another example is shown in Fig. 15, this time a quad-wheel and quad-legged cane with adjustable handle, retractable wheels, a rigid support structure that overhangs the wheels, providing fail-safe braking [194]. In this case, there is no need to use external devices but there is no fall detection/prevention system either, all the fall prevention claims are based on the retractable wheels, that allow the formation of a 4 point BOS, increasing the support in all directions.

From the 10 remaining patents, 3 were selected based on whether it has fall detection/prevention systems and whether it has only built-in technology into the cane. The results were summarized in table 5. The anti-falling walking stick for an old person comprises a walking stick shell, a supporting unit, a three-dimensional axial accelerated speed monitor, and a central analysing unit. When the user loses balance and is about to fall, or during the fall, a supportive leg can pop up automatically, successfully supporting the user, avoid the fall, and possible injuries. The fall event can occur in different directions, the central analysing unit analyzes the received data and determines the direction of the fall. With this information, the two branches closest to the fall are deployed [195].

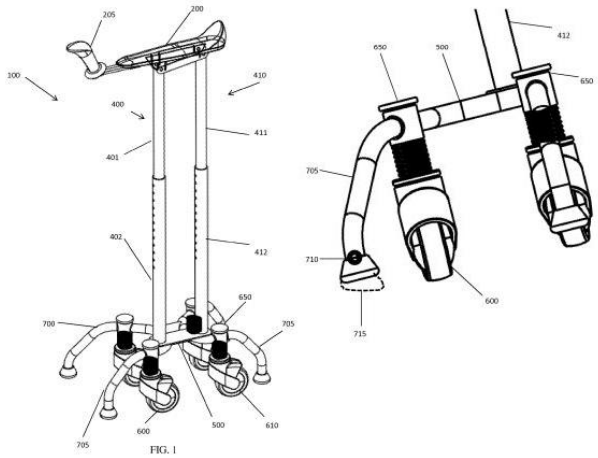


Figure 15: Wheeled Support Cane - US20140261594 A1 [194].

The second patent refers to an omni-wheeled base cane that simulates the user's gait, thus, it moves alongside the pedestrian. Through the ZMP, it can determine a pre-fall state moving the cane in the opposite direction of the fall to avoid it and possible injuries [196].

Finally, the robotic cane device includes a grip handle, a motorized omnidirectional wheel, a balance control sensor, and a controller module. Acquiring and computing the data received through the sensors, the robotic cane attempts to remain in an upright position, to avoid the fall. Furthermore, if the grip force value exceeds the threshold value, the system provides an opposite force regarding the user weight projection [197].

Table 5: Selected patents with fall detection/prevention systems built into the cane

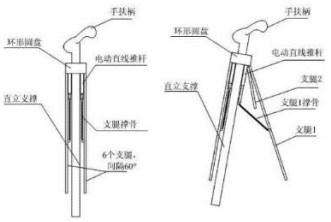
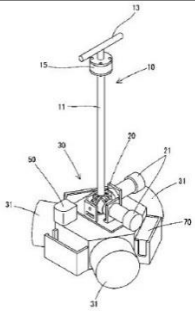
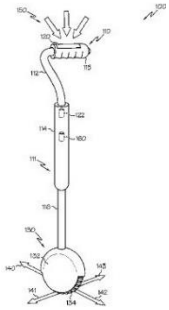
Name	Mosaics
Anti-falling walking stick for an old person [195]	
Walking supporting device and fall prevention method using the same [196]	

Table 5: Selected patents with fall detection/prevention systems built into the cane

Name	Mosaics
Robotic cane devices [197]	

2.5. Discussion

After extensive and comprehensive literature research, it can be concluded that a clear market opportunity for an anti-fall cane is available. There are no commercially available canes with built-in pre-impact fall detection systems. This direction is intensified by looking at all the trends that confirm more and more patients continue to suffer from falls [1,2], as well as, the rising number of cane users [11,15].

Results show, as well, that most systems dedicated to pre-impact FD are wearable systems, which have some advantages, but simultaneously, some glaring faults related to lower user compliance and device usage. For example, after the Hip'Safe airbags are deployed, they need to be repacked and the CO_2 cartridge replaced. This represents additional time and monetary costs to the user, possibly decreasing the efficacy of the device. Also, the available information about canes with such systems is not complete, there is no mechanical validation of the devices. Furthermore, data regarding performance is not available, only Di et al. [152] reported 300 ms of lead-time, and Chen et al. [165] reported an ACC of 84%, disclosing information about these parameters.

Therefore, the main objective is to perform the first advances towards a user-focused device, capable of reducing or even eliminate the usability and acceptability issues. Using a real-time fall prevention system, based on data gathered by a sensory unit, processed by a Central Processing Unit (CPU), and an actuator capable of preventing a probable fall, this platform will be exploited to prove the functionally of the concept, and, ultimately, reduce fall-rates.

3. Mission Statement and Consumer Needs

As previously discussed, an opportunity for an anti-fall cane was identified, and a technology and market assessment were conducted. With these inputs, it is possible to create a project mission statement, which indicates the target market for the product, business goals, and key assumptions [198].

Also in this chapter, the Consumer Needs (CNs) for the anti-fall cane are identified. For this dissertation, the word *consumer* is defined as the individual that represents the end-user for the anti-fall cane. They are important to judge the actual usefulness of the device [199]. The process of identifying CNs is an integral part of future product development phases like the definition of product specifications and concept generation/selection. For the present work, the definition adopted for *need* is an attribute of a potential product that is desired by the customer. Other common terms used in the literature and industrial practice include *want*, *customer attributes,* and *customer requirements* [200]. One important detail regarding needs is that they are largely independent of any particular product developed, they are not specific to the concept that is selected in further phases, allowing for their identification without knowing how they will be addressed [200].

3.1. Mission statement contextualization

It is important to understand the project's relevancy and what possible place it could have in the market. The problem is clear, high rates of falls can lead to serious injuries in the elder community. However, they are not exclusive to this age group or community, as previously seen in the risk factors for falls.

To understand what device a patient needs, it is detrimental that the patient is analysed individually according to his specific context, namely, what disease and/or other risk factors affect daily living. To contextualize some environments where the anti-fall cane could be used, research was conducted to find mobility assessment tools related to the most common risk factor for falls, advanced age, and the main diseases previously identified as a risk factor for falls, namely, Parkinson's disease and stroke. Examples of these tools are present in Appendix I.

3.1.1. Elderly Mobility Scale

The Elderly Mobility Scale (EMS) is a 20 point assessment tool for the assessment of frail subjects, mostly used in a hospital setting or daycare facilities. The main purpose of this scale is to provide an assessment of mobility, considering locomotion, balance, and key position changes helping in the

prediction of the individual fall risk [201,202]. This is possible through the use of seven functional activities including bed mobility, transfers, and bodily reaction to perturbation [203].

The EMS is significantly more likely to detect an improvement in mobility than either the Barthel Index or Functional Ambulation Category and the magnitude of said detection is significantly greater using this assessment tool [202]. Furthermore, there is has been an association between lower EMS scores and higher fall rates [204], making it an adequate tool to use in this case.

In the EMS, gait is assessed based on the type of assistance required to walk. The subject achieves maximum points if they walk safely with no aid or 1 stick. When a frame, rollator, 2 sticks, or crutches are used the score reduces. These scores are comprised of the following ranges:

- Scores under 10 – generally these patients are dependent on mobility maneuvers; require help with basic ADL, such as transfers, toileting, and dressing;
- Scores between 10 – 13 – generally these patients are borderline in terms of safe mobility and independence in ADL i.e. they require some help with some mobility maneuvers;
- Scores over 14 – Generally these patients can perform mobility maneuvers alone and safely and are independent in basic ADL.

Looking at the description of the scores, the anti-fall cane is most likely slotted into the 10-13 range. However, these are general interpretations of these scores, other factors must be taken into account, for example, cognition, that may impact general mobility. The EMS scale is shown in table 16.

3.1.2. Unified Parkison's Disease Rating Scale and the Hohen and Yahr Scale

The Unified Parkison's Disease Rating Scale (UPDRS) [205] has been the most widely used comprehensive assessment of Parkison's disease. In 2008, the Movement Disorder Society (MDS) sponsored a revised version of this scale, creating the MDS-UPDRS [206], the recommended scale for the overall assessment of PD by the National Institute of Neurological Disorders and Stroke [207].

This revised version was developed to be a comprehensive clinical rating scale covering motor and nonmotor elements of Parkison's disease, and it is divided into four parts: part 1, Nonmotor Experiences of Daily Living; part 2, Motor Experiences of Daily Living; part 3, Motor Examination; part 4, Complications of Therapy [208].

In part 3, there is an item corresponding to the Hoehn and Yahr stage, which is a scale in on itself. The Hoehn and Yahr Staging Scale of Parkinson's Disease (HY scale), developed by Hoehn and

Yahr in 1967 [209], is a standard clinical measure of the progressions of Parkison's disease designed to measure the signs and symptoms associated with a functional impairment such as postural instability, rigidity, and tremor [210]. As with the UPDRS, the HY scale received a modified version in the 1990s, which can be seen in Appendix I [211].

A cross-sectional study found that this scale was one of the best independent variables associated with predicting falls, with 77% sensitivity and 71% specificity [212], and Cheng et al. also found a correlation between higher Hoehn and Yahr stage and higher fall risk [213].

Studies show that Parkison's disease patients that use or need canes are between Hoehn and Yahr stages number 2 and 4 [214–218], however, PD is extremely complex and every individual should be examined first by professionals before the prescription of any device. The MDS-UPDRS is shown in table 17, and the modified HY scale in table 18.

3.1.3. Berg Balance Scale

The Berg Balance Scale (BBS), developed by Berg et al. in 1989 [219], is used to determine a patient's ability to safely balance during a series of predetermined tasks, and it is been associated with patients with acute stroke [220–222].

The scale consists of 14 items requiring subjects to maintain positions or complete movement tasks of varying levels of difficulty. Items receive a score of 0-4 based on the ability to meet the specific time and distance requirements of the test. A score of zero represents an inability to complete the item and a score of 4 represents the ability to complete the task independently [220]. A score of 56 indicates functional balance, and a score lower than 45 indicates an individual with a greater risk of fall, while cane users have scores between 44 and 50 [223].

Some thresholds of the BBS can be determined, however, as both scales previously presented, their use in gait-aid prescription is limited, as all clients are individual ones [224]. The BBS is shown in table 19.

3.1.4. Mission statement

The data obtained with all the previous research results point towards a potential product and an available market opportunity. This information is formalized as a mission statement, which lays out the broad constraints and objectives for the project, specifying the direction to go in but not specifying a precise destination or a particular way to proceed.

Table 6: Mission statement for the anti-fall cane

Mission Statement: Anti-Fall Cane	
Product Description	• A cane, with a built-in real-time fall prevention strategy
Benefit Proposition	• Prevents falls and avoids injuries related to those events altogether.
Primary Market	• Consumers with balance impairments.
Secondary Markets	• Institutionalized elders; • Rehabilitation patients.
Assumptions	• Handheld; • Built-in FDS and actuator; • No wearables; • Rechargeable battery technology.
Stakeholders	• Consumers; • Companies with a presence in the market (e.g. Dring, iStand, ORTHOS XXI).

The benefit proposition is related to the real-time fall prevention strategy, it is the ability to prevent the fall and avoid the related negative consequences. Therefore, the primary market for this device will be consumers with balance impairments. As previously identified, fall events are provoked by many different risk factors, and by setting a broad primary market, it is possible to include every consumer that might need some type of balance assistance.

The secondary markets are institutionalized elders and rehabilitation patients. Falls are not exclusive to the older community, however, age was identified as a big prominent risk factor, and a clear link was established between aging and higher fall rates. Furthermore, the institutionalized and rehabilitation parameters were chosen to set the starting phase of the anti-fall cane as a market product. This would allow the team to better study the product performance before developing other features for real-world applications.

The assumptions for the anti-fall cane are a handheld device that does not need wearable technology, with a built-in real-time fall prevention strategy. If needed, the cane should have a rechargeable battery. The handheld assumption is determined by the nature of the cane as an AD, it is a product that is held by one hand. The second assumption is no wearables, and it is the result of all the associated problems that were identified during the literature review. As a result, the anti-fall cane should have a real-time fall prevention strategy fully incorporated into the device. Lastly, if the final concept needs a power source, the anti-fall cane should have a rechargeable battery, capable of storing power for a considerate amount of time.

Finally, the stakeholders, the groups of people that are affected by the product's success or failure, for the anti-fall cane are the end-users and the companies with a presence in the market, that

might be interested in such a device. The mission statement for the anti-fall cane is summarized in table 6.

3.2. Consumer needs contextualization

The transition between the planning phase, explored so far, to the development phase is done by establishing the CNs. Being conscious of these needs is very important for the development and success of the project. To improve the effectiveness of AT, like canes, and the satisfaction of the users, it is important to understand why technology users accept or reject a device [225]. Premature device abandonment is costly both in monetary terms and outcome achievement. [226].

Mobility devices are the ones that are most abandoned [227], a study reported an average rate of abandonment of 66% for canes [228]. It is also wasteful when a device does not enhance the person's quality of life, even if it is used [229]. Opportunities are lost when such decisions are directed poorly at the needs of the consumer [226]. Assistive products work better when they are matched to the needs and goals of the user [10,225,226], solutions should be developed involving consumers and knowledge, personal needs, goals, values, and environment [225]. Historically, end-users have been missing in AT development [10], and in the case of the elder consumers, that is no different, because society, in general, has a negative opinion of older person's ability and interest in new technology [26].

A product offer benefits when they satisfy needs, therefore, it is possible to deduce that satisfying needs is a necessary condition for product success [10]. However, developing a new product can be a risk because satisfying needs is still important on a new product, and one can argue that the team can only be sure of whether the customer needs have been identified successfully after the first prototype [200].

3.3. Primary and Secondary consumer needs

3.3.1. Search strategy

While the process of identifying customer needs is not an exact science, the data obtained is always useful, even if it does not allow for the identification of every need. Thus, a modified method for gathering the customer needs was followed, to lower the inherent risk of developing a new product [200].

Instead of conducting interviews, focus groups, or other methods to gather data from users, it was conducted a literature search for typical uses, likes, dislikes, and suggested improvements associated with canes, and needs users have regarding AT. By analysing various studies, it was possible to avoid problems like the monetary cost associated with focus groups, the time consumed with interviews, and the innovative factor on the project, while simultaneously acquiring a bigger point of view on the matter, a result of the bigger number of opinions taken account.

3.3.2. Primary and secondary consumer needs

Addressing the primary and secondary needs, a short definition of each one was made. Affordability represents the extent to which the purchase, maintenance, and/or repair of the cane causes financial problems to the user [226,230]. A recent study demonstrates that cost is the most common reason for unmet needs regarding mobility devices, such as canes [231].

If the cane is easy to set up and use that means the user can assemble the product quickly, or it already comes assembled within an adequate package, learns how to correctly use the device faster, or with less training required [232]. At the same time, the device can be transported and operated in different locations. It responds accordingly to the user's input and it is compatible with other devices [226].

To maximize physical comfort, the cane needs to have the correct height, its handle to be ergonomic, and it has to be light. The device cannot cause any physical pain to the user. Cane height and its proper adjustment are detrimental to avoid improper postures and even further risk of falls [21]. The handle should be personalized to accommodate different hands with different conditions, such as arthritis, using different shapes, sizes, and textures [229,233]. Furthermore, the device should be light to facilitate its use throughout the user's daily routine and to avoid possible injuries [232]. On the same note, the device cannot cause any physical harm to the user, such as injuries or infections, the cane needs to be safe to use, simultaneously offering support to the user [22,26,226].

Considering the device usage, the cane needs to be easily obtained through versatile, yet simple processes, e.g., physical and online stores [234,235]. However, there are still personal factors potentially affecting the use of the cane. The view on a mobility device, such as a cane, needs to evolve to something of greater meaning, with a more positive connotation [26]. Reduce social stigma can start in the design process, through the development of more stylish and fashionable devices [236], compatible with the

user personality and lifestyle, increasing overall the psychological comfort when using the device in public, or in private [226].

Finally, the cane needs to be effective, durable, and reliable. The use of the anti-fall cane will improve the consumer living situation, through enhanced functional capabilities and/or independence, by preventing the fall and its related injuries, and meeting the user's needs for such a device [226,237]. In terms of durability, the device needs to be operable for a proposed extended period of time, its life expectancy, and if possible surpass it [225,235]. However, while in that period, the cane needs to operate on a reliable form, with repeatable use resulting in predictable outcomes [225,226].

In table 7, the customer needs for a cane have been organized into a hierarchical list, consisting of primary needs, the most general ones, and secondary needs, the ones that express needs in more detail, resulting in 12 primary needs and 33 secondary needs. This table summarizes all the needs gathered from the literature, some may not be technologically possible and some contradictory between them, however, this step only registers them [200].

Table 7: Primary and secondary needs for canes, extracted from the literature

Primary Needs	Secondary Needs
The cane is affordable [226,230–232,234,238–240].	The cane is cheap; The cane has no hidden costs; The cane is maintenance-free; The cane is covered by financing programs; The cane possesses a cost-free warranty.
The cane is easy to set up and use [22,226,237–239].	The cane has a user-friendly interface; The cane automatically turns on; The cane operates independently of other devices; The cane is already assembled; The cane can be learned with ease; The cane is easily transported; The cane is equally easy to use in the right or left hands.
The cane has the correct height [21,22,229,241,242].	The cane height is adjustable; The cane comes with the correct height.

Table 7: Primary and secondary needs for canes, extracted from the literature

Primary Needs	Secondary Needs
The handle of the cane is ergonomic [22,26,226,229,232,233,237,239,243].	The cane handle is adjustable to the hand; The cane handle has the correct size and shape accordingly to the user; The cane handle has a pleasing texture.
The cane is safe to use [3,226,229,236,237].	The cane provokes no physical reactions; The cane can be used everywhere; The cane has an anti-slip tip.
The cane is light [16,22,232,237,238].	The cane weight does not provoke fatigue.
The cane is stylish [3,17,22,26,226,228,232,236,242,243].	The cane design is compatible with the consumer's ideals; The cane is customizable.
The cane offers support [22,26,242].	The cane supports a percentage of the body weight; The cane helps the user to walk.
The cane can be easily obtained [20,225,228,232,234,235].	The cane can be bought everywhere; The process to buy the cane is simple.
The cane is effective [26], [225], [226], [237]	The cane prevents a fall; The cane meets the consumer's needs.
The cane is durable [225,235,237]	The cane is durable without expensive maintenance; The cane lasts it is expected life; The cane lasts longer than the expected life.
The cane is reliable [225,226].	The cane is breakdown free; The cane does not need any special conditions to properly function; The cane remains dependable under repeated use; The cane suffers no damage if not properly operated.

3.4. The hierarchy among consumer needs

The next step is to establish relative importance to the different needs, which allows correct trade-offs and resource usage along with the design of the cane. This process is usually performed in two ways: relying on the team members and their experience with the problem and the consumers, or, further question the end-users to obtain their importance assessment [200]. The first option is cheaper and faster, however, more inaccurate than the latter. Considering the present work, this relative importance was determined by the ORTHOS XXI, the author, and the authors' advisors educated assessment of the needs. This prioritization is expressed on a numerical scale from 1 to 5, where 5 represents the maximum importance and 1 the least.

This dissertation aims to prove a concept and obtain a functional prototype. For that reason, needs like the style of the cane and access to the public have been overshadowed, in terms of relative importance, by the more functional needs related to cane height, weight, comfort, and safety, which got the maximum relative importance of 5. Table 8 lays out the hierarchy of CNs.

Table 8: Relative importance between consumer needs, where 5 represents maximum importance and 1 the least.

Number		Need	Importance
1	The cane	is affordable	3
2	The cane	is easy to set up and use	2
3	The cane	has the correct height	5
4	The handle	of the cane is ergonomic	5
5	The cane	is safe to use	5
6	The cane	is light	5
7	The cane	is stylish	1
8	The cane	offers support	4
9	The cane	can be easily obtained	1
10	The cane	is effective	5
11	The cane	is durable	3
12	The cane	is reliable	5

3.5. Discussion

Identifying CNs sets a group of factors that need to be taken into account for the rest of the project. Furthermore, knowing what a customer wants in a product, and developing the product with those needs in mind can increase the chance of success of the said product.

The method to identify CNs can be considered non-optimal, however, due to the many restrictions related to in-person interviews and meetings, a compromise was made, and a literature-based search was conducted. Even though this analysis is not as complex when compared to the systematic literature review, a great effort was performed to gather as much information as possible. Through a cross-reference and exploration of other questionnaires about this topic, the probability of a faulty identification of CNs is reduced.

After the information was filtered and interpreted, the author and advisors attributed maximum importance to the height, ergonomy, safety, weight, effectiveness, and reliability of the anti-fall cane. The main objective of the anti-fall cane is to eliminate the negative consequences of fall events. Therefore, the product needs to be safe and comfortable to use, it is impossible to develop a device that can harm users that might be in a frail state already. To guarantee the success of such a device, it needs to be effective and reliable, and to ensure those two, the height and weight of the anti-fall cane are parameters that always need to be taken into account.

This type of identification process allowed a broader point of view, with needs like the style being among the most common primary needs. This is an interesting statistic because it can be related to a previously reported risk factor, associated with social values and stigma associated with assistive devices. These results show that users give a lot of importance to the sense of fashion of the product, and they can potentially reject the product based just “on looks”.

However, as stated before, the style of the product is not a priority at the moment. Other needs like the price of the cane did not receive more relative importance because of the project phase. Developing a prototype is going to be costly, as all the components are going to be experimental and bought as one-offs.

However, all needs have to be taken into account because the final product will encompass all of them. As the anti-fall cane moves to deeper stages of development, this relative importance hierarchy should be revisited to better reflect the status of the device. To further establish a universal development system for the anti-fall cane, the consumer needs are transformed into product specifications, which will guide the remaining phases for this dissertation.

4. Anti-Fall Cane Target Specifications

As important as the CNs are, they do not provide much guidance about how to design and engineer the anti-fall cane. For that reason, a set of product specifications is set, which tells what the product has to do, through precise and measurable terms. They do not specify how to resolve the customer needs, but they represent what will be attempted to satisfy the needs identified in the last chapter.

It is important to set some definitions and terms to avoid confusion. As it was said before, product specifications, sometimes called *product requirements* or *engineering characteristics*, is a set of individual specifications that describe what the product has to do. A *specification* consists of a *metric* and a *value*, which can be in several forms, like a number, a range, or an inequality, which is always accompanied by the correct unit [244].

The product specifications are being set early in the development process with the objective of design and engineer the anti-fall cane to meet those specifications. However, there is no knowledge of what constraints the product technology will place on the project itself, some specifications will not be possible to meet, others will be met or exceeded, depending on the selected product concept. They are preliminary specifications, representing hopes, aspirations, and goals for a possible product compatible with the market. They are defined right after the CNs, before the knowledge of what difficulties will appear in further phases [244].

4.1. Approaching the anti-fall cane metrics

To set target specifications, an approach proposed by Ulrich and Eppinger [244] was followed, and it consists of the preparation of a list of metrics, the collection of competitive benchmarking, the definition of target values for each metric, and a final reflection of the results obtained. The relationship between CNs and metrics is the key to the entire concept of product specifications. To create the list of metrics, it is necessary to look again at the list of needs and determine what precise and measurable property of the cane is associated with the need.

To conduct the competitive benchmarking, e-mails were sent to Dring Smartcane (contact@dring.io) and iStand SmartCane (mazy@whatboxinc.com), as they were the only smartcanes available in the market. These e-mails exposed the desire to meet within the possibility of both parties, to better discuss parameters related to the algorithms, hardware used, materials, dimensions, and validation performed before shipping. This would be important because the available online information is vague, e.g., the Dring Smartcane uses a “fall sensor” and “quality materials”. These claims can be true, however, they do not disclosure, e.g., the performance of the said sensor and the algorithm used. Unfortunately, no response was given. The other option would be to buy both products and perform the necessary data

collection. However, that is not possible for this dissertations' work. Therefore, the benchmark information was collected using international standards and the consultation with ORTHOS XXI.

The third step is the definition of target values for each metric. In addition to the relation between the needs and metrics, it is necessary to establish the units of measurement and an importance rating for each metric. The importance of metrics reflects the importance of the associated needs. When a metric is linked with a single need, the importance level of the need becomes the importance level of the metric, otherwise, the importance is determined by the nature of the relationship between both metrics and needs [244].

4.2. Exploring the anti-fall cane metrics

All information regarding the relationship between customer needs and metrics, with the respective relative importance, units, and value range associated with them is summarized in table 11. Some metrics can be considered less difficult to obtain than others, such as the total mass of the cane, in kilograms (kg). However, some metrics cannot be translated into numbers or conventional units. This happens with every metric that is translated to tests such as metrics no. 7, 8, 9, 10, 13, 16, and 17, where the only possible result is to pass or fail that same test. The metric no. 12, associated with beauty, fashion, and style of the device which cannot be quantified, as it is considered a subjective (Subj.) parameter, that can be evaluated, for example, by a panel of consumers. Lastly, metric no. 14, associated with the ease of acquiring the product, is best translated into a list of possible ways to obtain the anti-fall cane.

4.2.1. Cane price and complexity level

The price of the cane was transformed into the cane manufacturing cost, leaving the possibility for a profit margin when the product reaches the customers. Looking at the previously presented market research pricing, the Dring and iStand canes are priced at 129€ and 136€, respectively. Furthermore, the only market available product with an implemented pre-impact FDS is the Helite Hip'Safe, available at 649€. Therefore, it is fair to determine a price range of 150 € to 650 €. The presence of built-in fall-related sensors, algorithm development, and a built-in actuator system capable of avoiding falls should bump the price up, making the anti-fall cane a more expensive product when compared to a normally available market solution. However, this price range is still very competitive within the identified market, since both canes cannot avoid falls and the Helite Hip'Safe does not prevent the fall event itself.

Also, the complexity level of the cane, associated with need no. 2, was transformed into the time necessary to make the cane usable. From the moment that the user touches the cane to the moment the

user starts moving with the device, a maximum time window of three seconds was established. With this time limitation, the cane has to be easy to set up and use, with familiar mechanisms taken from the classic cane, or, if needed, a turn on/off button.

4.2.2. Distance from the user's wrist crease to the floor

The distance from the user's wrist crease to the floor is associated with the need no. 3. Most elders have inappropriate devices, a direct consequence of a faulty prescription process [245], as stated during the introduction chapter. An incorrect cane length can lead to a large change in the biomechanics of the user's gait [21]. For instance, a long cane induces greater postural sway requiring postural corrections to control balance [246]. It changes the angle at which horizontal forces (necessary for breaking and propulsion) are applied, increasing the chances that the cane can slip/skid or tip over [21,240]. It does not allow adequate weight transmission through the arm [247–249]. On the other hand, a short cane is no good either. The user leans towards the stick and bends when the device is placed forward [247,250], increasing the stress on the lumbosacral region [251]. Fundamentally, an incorrect cane length results in discomfort, influencing postural stability, resulting in an increased risk of falling [21,245,246,252,253]. As the final goal of this dissertation is to contribute to the reduction of the probability of falls, as well as possible injuries related to that event, it is very important to get the cane height right. There are two commonly used methods for determining proper cane length, as seen in Fig. 16:

- Method 1: The length of the cane is adjusted so that the top of the cane corresponds to the top of the greater trochanter [240], [246], [251], [254–256];
- Method 2: The cane length is adjusted so that the top of the cane matches the distal wrist crease [21], [240], [241], [245–247], [250–258].

Both methods have been validated through multiple scientific articles. However, for the work in question, method 2 was selected because it has more support, mostly related to the registered elbow flexion angle. Studies have found that a 15° to 30° degree angle of elbow flexion is biomechanically ideal for the cane gait and that cane length obtained through method 2 is the most adequate to keep elbow flexion within the standard recommendation [241,251–253,256,259].



Figure 16: Discussed methods to determine proper cane height. 1: The distance from the greater trochanter of the femur to the floor; 2: The distance from the distal wrist crease to the floor [253].

The cane length is measured with the users standing upright with both hands relaxed at the side of the body with the wrists in a neutral position, and the user wears everyday shoes that would be worn when walking. As for the range of lengths, the "ISO 11334-4:1999 Walking aids manipulated by one arm – Requirements and test methods – Part 4: Walking sticks with three or more legs " [260] gives a minimum walking stick height of 350 mm and a maximum height of 1100 mm.

4.2.3. Handle design and ergonomics

One of the most important parts of a cane is the handle as the user is constantly gripping it while using the device. Good handle design is important in all kinds of daily activities and it is also important to make devices that are efficient, safe, and attractive to buy and use [261]. To turn the CNs for an ergonomic handle to specific metrics, the power grip with a precision component was identified as the type of grip applied in the cane handle. Also, measures like handle length, width, and slope were identified as key to obtaining an ergonomic handle, as they can directly affect performance and biomechanical stress on the hand, as seen in Fig.17.

Handle length, i.e., the dimension of the handle measured longitudinally, is important to fit the palm of the user, many users report wrist pain due to cane use, and in some cases, that is linked to poor palm fitting design [262].

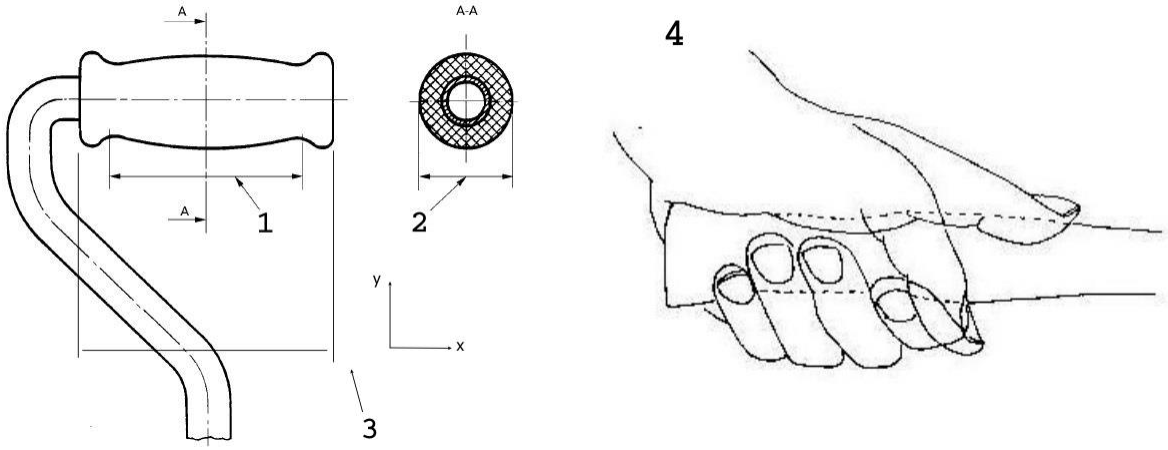


Figure 17: Explored handle parameters. 1: Handle length [260]; 2: Handle width [260]; 3: Handle slope; 4: Representation of the power grip with a precision component applied in the cane handle [261].

Looking at the results from the literature, a range between 100 – 150 mm is defined. However, looking at the ISO 11334-4:1999, the length of the cane handle is determined accordingly to the user and cane height, with a range of 65 – 110 mm [260]. Therefore, this is the adopted range for the present work.

Handle width, i.e., the dimension of the handgrip measured horizontally at the thickest point, should allow the thumb to just cover the end of the index and middle fingers [261], with a range of 25 – 45 mm of width. Looking again at the previously mentioned international standard, the range of handle width is 25 – 50 mm [260], which is much closer to the literature when compared to the handle length. Once again, this is going to be the adopted range for this dissertation.

As for handle slope, the ISO 11334-4:1999 does not provide any information. However, it was possible to obtain some pieces of information regarding the handle angle and its effects on wrist posture, perception of wrist deviation, and effectiveness of the handle/hand interface [263,264]. Lee et al. [263] studied the effect of the inclination in a walker handle and the loads applied on the wrist joints, with a 15° handle being less likely to trigger secondary lesions in the wrist joints when compared to the standard handle. In the present work, the adopted range for the handle slope is 0 – 15°. Table 9 summarizes all information found in the literature regarding handle parameters.

Table 9: Measures of handle length, width, and slope found in the literature.

Article	Handle length	Handle width	Handle slope

Wang and Cai [265]	100 – 125 mm	30 – 45 mm	10°
Patkin [261]	100 – 150 mm	30 – 40 mm	NA
Wang et al. [266]	NA	NA	30 – 45°
Lee et al. [263]	NA	NA	15°
Design-In Ergonomic Guidelines [267]	100 – 130 mm	25 – 40 mm	NA
Rossi et al. [268]	NA	34.1 mm	NA
Drury et al. [264]	NA	NA	0 – 10°

Finally, there is one last piece left in the handle design, the surface on the handgrip. There should be no sharp edges or high spots in the area of grip, they decrease comfort, strength, security of grip, and potentially cause injuries [261]. Assuming the design does not include any of the previous defects, the surface of the handle is equal to the material used for the handgrip - the part of the cane normally held when the device is being used. That material will come in contact with the human body and it needs to be assessed for biocompatibility using the "ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" [269]. Therefore, this metric is rendered to a binary test value.

4.2.4. Safety of the device

A device must not harm its user under normal conditions, even more, when talking about an assistive device, like the cane, that is potentially used in more frail contexts, such as mobility rehabilitation and fall prevention. ISO 11334-4:1999 states that all parts of the walking stick have to be free from burrs, sharp edges, or projections that could cause damage to clothing or discomfort to the user. Assuming this is the case, the international standards refer to stability, separation, and friction tests [260,270].

The stability test is designed to evaluate the tipping angle and is divided into two components: the inwards and outwards stability test, as seen in Fig. 18. Both are performed by applying a static force of 250 N ± 2% in the midpoint of the handgrip and tilting the plane, while simultaneously recording the maximum angle that the plane reached when the walking stick is at the point of tilting. For the inwards test, that angle shall be not less than 2°, while for the outwards test, the angle shall not be less than 5° when testing a tripod walking stick, and not less than 7.5° when testing a quad-cane [260].

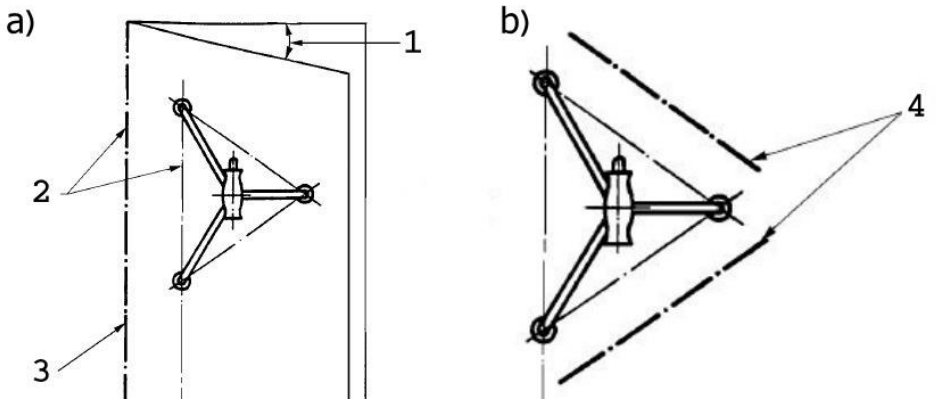


Figure 18: Stability apparatus for the tripod stability testing. a) Tripod inwards stability test; b) Tripod outwards stability test. Parts description: 1 tilt angle; 2 the device and apparatus have to be parallel; 3/4 centreline of the hinge [260].

The separation test is only applicable to walking sticks which are joined together by two or more parts only when the joint is not part of the height-adjustment mechanism. As the explored concept is not clear at this stage of the project, this should be a possibility for further consideration. This test is conducted by applying a pulling force of 500 N ± 2 % to the lower and upper parts of the walking stick. That force shall be gradually applied over 5 seconds up to the maximum force and kept at maximum force for 10 seconds. During the test, the upper and lower parts of the canes cannot come apart [260]. A representative scheme of this separation test is represented in Fig. 19.



Figure 19: Separation test scheme for a tripod cane.

Another key concern regarding user safety is the frictional performance of the tips attached to the bottom of the walking stick, which are in contact with the walking surface. Friction between the tips and

the walking surface is an extremely important factor that gives the user not only a safety factor but a sensory cue as well, allowing the normal progression of the walking motion.

The "ISO 24415-1:2009 Tips for assistive products for walking – Requirements and test methods – Part 1: Friction of Tips", offers a standard method to test said friction [270]. The entire apparatus is represented in Fig. 20. The loading mechanism exerts an axial loading force of 50 ± 1 N to the tip, while the pulling mechanism gives a constant test velocity of 500 ± 25 mm/min, and the recording system needs to be able to measure at least 200 N. For a positive evaluation, the minimum frictional force shall be not less than 25 N [270].

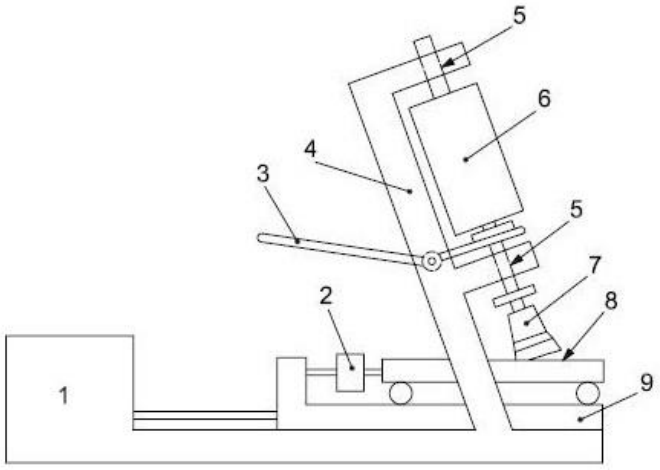


Figure 20: Example of a mechanism to test the frictional performance of the cane [222]. Parts description: 1 pulling mechanism; 2 load cell; 3 lever to lift the tip during return movement; 4 frame; 5 guide; 6 loading mechanism; 7 tip; 8 test track; 9 sliding table.

4.2.5. Supporting the user

As previously stated, canes decrease weight bearing on lower limbs, by supporting it themselves [251]. An example of this is shown in Fig.21, an illustration comparing total force across the hip joint with and without a cane. This corresponds to need no.8, the cane needs to offer support to the user. Canes partially support the user's weight during the gait cycle, and as the user walks, the weight they transfer to the cane keeps changing. The maximum force is applied on the cane when it is fully vertical [271].

A literature search was performed to gather more information about how the relationship between cane loading and weight transfer. Nine studies were found, fully analysed, and summarized in table 10. The load applied on the cane was calculated, when possible, using the patient maximum mass, and using the conversion 1 kgf ≅ 9,80665 N. It is possible to observe that the Body Weight (BW) transferred to the cane varies heavily since the load on the cane depends on the person's weight, but even more on their condition, e.g. users with poor health condition need more assistance [271].

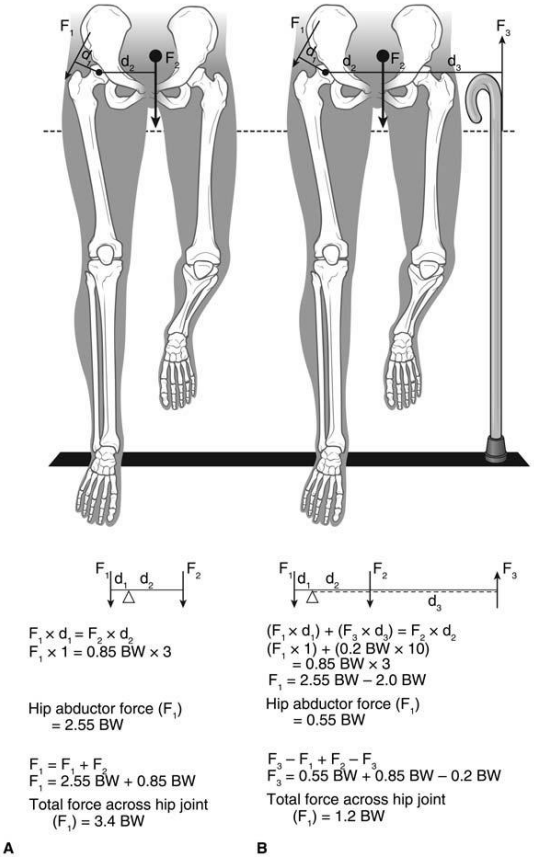


Figure 21: Illustration of the total force across the hip joint without a cane (A), and with a cane (B). F_1 represents the force of the hip abductors; F_2 is the force of gravity acting on the mass of the body (excluding the stance leg); and F_3 the force applied to a standard cane [251].

All the registered BW was the maximum value for the respective study since the cane needs to withstand the maximum load value without permanent deformation. Thus, metric no.11, associated with need no. 8, is a load test applied to the handle and shaft.

Regarding the range of values for the test, the main problem is that seven of the nine studies analysed do not disclosure neither the mass of the users nor the load applied to the cane, only the percentage of BW transferred to the cane. This poses a problem to define the threshold of values as it would be very wide. The Assistive Product Specification (APS) draft for walking canes, tripods, and quadripods, disclosures a 400 N static load test, applied to the central part of the handle and the shaft, in the upright position [272]. As for the ISO 11334-4:1999, a static loading test is defined as in the APS draft, however, the specified loading force is 1000 N ± 2 % with a minimum value of 350 N ± 2 %. During this load test, the cane is inspected and it shall not be damaged to a degree that will render it unsafe to use, and no part of the device shall crack or break [260]. These are much higher values than anything

present in the literature. That may occur because the walking sticks in the international standard have three or more legs. However, as these are target specifications, the adopted range for the static load test will be 350 – 1000 N.

Table 10: Values regarding applied load and BW transferred to canes.

Article	BW (Kg or weight %)	Load (N)
Ballesteros et al. [271]	29 kg	284.39
Laufer et al. [273]	7.5 %	N/A
Jung et al. [274]	10.37 %	N/A
Aragaki et al. [275]	11 %	N/A
Jayakaran et al. [276]	10 %	N/A
Hart et al. [277]	19.8 %	N/A
Simic et al. [278]	20 %	N/A
Inai et al. [279]	20 % , 11.68 kg	114.52
Youdas et al. [280]	25 %	N/A

4.2.6. The durability of the cane

For the durability of the cane, ISO 11334-4:1999 discloses a fatigue test. The setup is equal to the previously described static load test, but this time it is applied a cyclic force of 450 N ± 2 %, with a minimum value of 157.5 N ± 2 %, with a frequency of 1 Hz through 200000 cycles. During this test, the walking stick shall not be damaged to a degree that will render it unsafe in use, no part of the cane shall break or crack [260].

Another important part of the durability need is the durability of the cane tips. As discussed before, tips are an important part of user safety when using a walking stick. They are continuously and repeatedly subjected to load and friction while walking. Therefore, it is relevant to test the durability of these tips against such repeated loads both for safety and for cost-effectiveness. The "ISO 24415-2:2011 Tips for assistive products for walking – Requirements and test methods – Part 2: Durability of tips for crutches" [281] describes a standard test shown in Fig. 22. The motion control mechanism applies a tilt angle, the loading force mechanism exerts a loading force on the tip that alternates from 0 N at the beginning and 500 + 20 N when the loading rod is perpendicular to the test track, which corresponds to the end of the test cycle. This is repeated 500 thousand times with a frequency of less than 0.8 Hz. After having been

tested, the condition of the tip is verified, to pass the test the tip can't have any inner part or tear visible and it has to be correctly fixed on the loading rod [281].

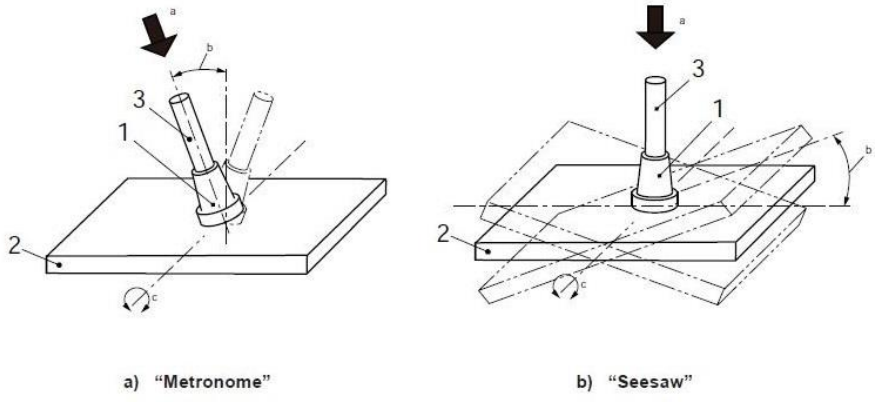


Figure 22: Apparatus to test the durability of tips where 1 tip; 2 test track; 3 loading rod; a loading force; b tilt angle; c axis of relative rotation. a) "Metronome" method - the test track is stable and the tip oscillates; b) "Seesaw", where the tip is stable.

4.2.7. Efficiency and reliability

To consider the anti-fall cane an efficient device is to consider that it successfully prevents falls. That can be analysed using a target ACC value for the prototype. In this case, ACC can be defined as the ability to differentiate the fall events and non-fall events correctly [282], determined by eq. 4.1.

$$ACC = \frac{TP+TN}{TP+TN+FPT+FN} \quad (4.1)$$

Looking at the literature review results, the lowest ACC value is 84%, found in Chen et al. [165]. Therefore, that will be the minimum target ACC for the anti-fall cane. Reliability is related to consistency/ reproducibility. Therefore, tests need to be conducted over a pre-determined period of time to evaluate the consistency of the anti-fall cane. This is based on the test-retest reliability tool, where the same task is repeated by the same subjects, and the results are expected to be roughly consistent over time [283]. This means that the anti-fall cane is reliable if its ACC remains roughly the same over the expected life of the product. Usually, the reliability is assessed using the test-retest correlation strength between sets of scores, typically done by calculating Pearson's *r* [284]. This *r* can be anywhere between -1 and +1, the stronger the correlation, the closer the correlation coefficient comes to +1. An *r* equal to or greater than +0.8 was defined since this value range is considered a strong correlation [285].

Table 11: Relationship between customer needs and metrics, with the respective relative importance, units, and value range associated with them.

Metric no.	Need no.	Metric Description	Importance	Units	Value Range
1	1	Cane manufacturing cost	3	€	150 - 650
2	2	Time necessary to make the cane usable	2	s	< 3
3	3	Distance from the user's wrist crease to the floor [260]	5	mm	350 – 1100
4	4	Handle length	5	mm	65 – 100
5	4	Handle width	5	mm	25 – 50
6	4	Handle slope	5	°	0 – 15
7	4	Handgrip surface material biocompatibility test (ISO 10993-1:2018) [269]	5	Binary	Pass/Fail
8	5	Stability test (ISO 11334-4:1999) [260]	5	Binary	Pass/Fail
9	5	Separation test (ISO 11334-4:1999) [260]	5	Binary	Pass/Fail
10	5	Friction test (ISO 24415-1:2009) [270]	5	Binary	Pass/Fail
11	6	Total mass of the cane	5	Kg	≤ 6
12	7	The cane is stylish	1	Subj.	NA
13	8	Static load test (ISO 11334-4:1999) [260]	4	Binary	Pass/Fail
14	9	Possible ways of obtaining the cane	1	List	NA
15	10	ACC performance	5	%	≥ 84
16	11	Fatigue test (ISO 11334-4:1999) [260]	3	Binary	Pass/Fail
17	11	Durability of tips (ISO 24415-2:2011) [281]	3	Binary	Pass/Fail
18	12	Reliability test	5	N/A	≥ +0.8

To represent the relationship between needs and metrics, a needs-metrics matrix was constructed, represented in Fig. 23. The rows of the matrix correspond to consumer needs, and the columns correspond to the metrics. A dot in a cell of the matrix means that the need and the metrics are associated with each other. This allows for a quick and simple representation of a somewhat complex interaction.

	Need \ Metric	1 Cane manufacturing cost	2 Time to turn on the cane and use it	3 Distance from the user's wrist crease to the floor, when standing upright with arms relaxed	4 Handle length	5 Handle diameter	6 Handle angle	7 Handgrip surface material biocompatibility test (ISO 10993-1:2018)	8 Stability test (ISO 11334-4:1999)	9 Separation test (ISO 11334-4:1999)	10 Friction test (ISO 24415-1:2009)	11 Total mass of the cane	12 The cane is stylish	13 Static load test (ISO 11334-4:1999)	14 Possible ways of obtaining the cane	15 Accuracy performance	16 Fatigue test (ISO 11334-4:1999)	17 Durability of tips (ISO 24415-2:2011)	18 Reliability test
1	is affordable	•																	
2	is easy to set up and use		•																
3	has the correct height			•															
4	of the cane is ergonomic				•	•	•	•											
5	is safe to use								•	•	•								
6	is light											•							
7	is stylish												•						
8	offers support													•					
9	can be easily obtained														•				
10	is effective															•			
11	is durable																•	•	
12	is reliable																		•

Figure 23: Needs-metrics matrix established for the anti-fall cane.

4.3. Discussion

Setting target specifications is a challenging process, what metrics are related to what needs is not always clear. This is because the needs are expressed in the langue of the consumer, and by setting specifications for the anti-fall cane, there is a translation of those needs into technical metrics.

A great part of this translation was done using international standards and the expertise provided by ORTHOS XXI. These give critical information about the setup of the test and what values the parameters should have. The available information about de Dring and iStand smartcanes is vague and can not be used to set specifications. Nonetheless, the information available in online catalogs sources should always be independently verified and observed [244]. This is a process that involves purchasing, testing, and disassembling said products. This is an impossible investment for this dissertation. Also, the present work aims to develop a product that has no market presence, which complicates every step of the benchmarking process.

A good example of the complications that arise when tackling a problem without market presence is related to variables such as the mass. The author can not control the mass directly, because it depends, e.g., on the material chosen for the device. Therefore, the total mass of the anti-fall cane is considered a dependent variable since it varies accordingly with other independent choices.

Nonetheless, specifications were created and determined for every consumers' need. The relative importance was inherited directly from the relative importance established during the CNs. Therefore, it replicates the same intention related to functionality over style. However, these specifications are preliminary, target values that are subject to change. In future phases of the product development, once the concept is selected and tested, new concept-specific metrics and target values can appear, and old values changed [244]. As a direct result of the CNs previously identified, these target specifications will drive the remaining development effort, leading next to the concept generation and selection.

5. Concept Generation, Scoring, and Selection

After identifying a set of customer needs and establishing target product specifications, the next step is the generation of concepts that potentially will tackle those same needs and specifications. However, it is often hard to think and generate solutions for a relatively complex problem, as is the present case for the anti-fall cane. Furthermore, the exploration of alternatives in this phase of the project is very important since it reduces the chances of the creation of other superior concepts later in the development process by the author, future teams, or even, the market competitors. To reduce possible problems along this process, a method, proposed by Ulrich and Eppinger [286], was followed, and it was further complemented by other literature elements [287–290].

At this stage, the mission statement was elaborated, consumer needs identified, product specifications determined and concepts generated that, through different solutions, resolved the main problem, an actuator capable of avoiding falls. However, it is necessary to choose the best concept for further elaboration, refinement, and production. This can be one of the hardest and most important phases during the development process. Therefore, a structured method, proposed by Ulrich and Eppinger [291], was used to obtain the most competitive design among all the generated possibilities.

5.1. Functional decomposition of the anti-fall cane

As previously mentioned, the problem is a complex one, so naturally, the first step is to clarify it. This clarification is achieved through the general understanding of the problem and then breaking it into

subproblems. This process is called problem decomposition and in this dissertation, a functional decomposition scheme is elaborated [290].

Understanding functionally is essential to a successful design. For the present work, the definition used for *function* is "things a designed device or system is supposed to do" [287], considering what the product does and not how it does it [290]. Functions must remain solution-neutral, the objective is not the generation of some concept and then create a functional analysis [290]. By remaining solution-neutral at this stage, it is less likely to ignore more adequate solutions, and when future technologies become available it will be easier and quicker to replace the old technology while the function structure remains the same [289,290].

5.1.1. Black box

The starting point for the functional analysis is expressing the overall function of the design in terms of the relationship between inputs and outputs. This is commonly referred to as a black box, which is a graphic of the product design with inputs entering the left side and outputs leaving the right side, along with the overall function [290], [287]. The black box for the anti-fall cane is shown in Fig. 24.

The overall function determined for the anti-fall cane is: assist in the gait cycle. In previous chapters, it was possible to assert that canes are mainly used by people with gait disorders, so above all, the cane has to assist the user during the gait cycle, providing the necessary conditions to walk safely.

However, from the point of view of the anti-fall cane, this is a complex function because the cane needs to provide a normal cane gait, simultaneously considering both the possibility of a fall and the possibility of a non-fall event. In the case of the first situation, it needs to detect the fall event and an actuator intervenes, in the second possibility the system remains neutral. Considering this, the chosen input was the cane gait pattern, and the output results in the recovery of the normal cane gait.



Figure 24: Black box for the anti-fall cane, with the input on the left and the output on the right.

5.1.2. Functional structure

The black box contains all the functions which are necessary for transforming the inputs into outputs, but it is not clear at this stage how this conversion happens. That is why the black box needs to be converted into a transparent/glass box [287,289,290]. The overall function can be broken down into subfunctions of lower complexity. All the subfunctions form the function tree of the design, it represents the actions and sequences needed to perform the main function of the black box [289,290]. These subfunctions inside the glass box need to be organized in a systematic and logical order to enable the execution of individual actions that lead to a successful conversion of the input into the output [290].

To get the final functional structure, the flow of materials, information, and energy is discriminated and a system boundary is designated [289]. The functional structure for the anti-fall cane is represented in Fig. 25.

The boundary of the system is represented in the function structure by the broken line and it marks the inside and outside of that structure, closing the system and avoiding loose inputs and outputs. In this case, the anti-fall cane is considered an original design since there is no record of a previously established function structure [290].

Using the initial input, the device needs to allow normal gait, this means the device does not have any special requirements to be safe and comfortable to use, support the user's weight and be movable, allowing the gait progression. The cane itself is a portable product by nature, so the anti-fall cane needs to store external energy allowing sensor signals to be processed and to detect high fall risk situations at any time of its use. A signal is sent to activate an actuator that provides the balance recovery to the user.

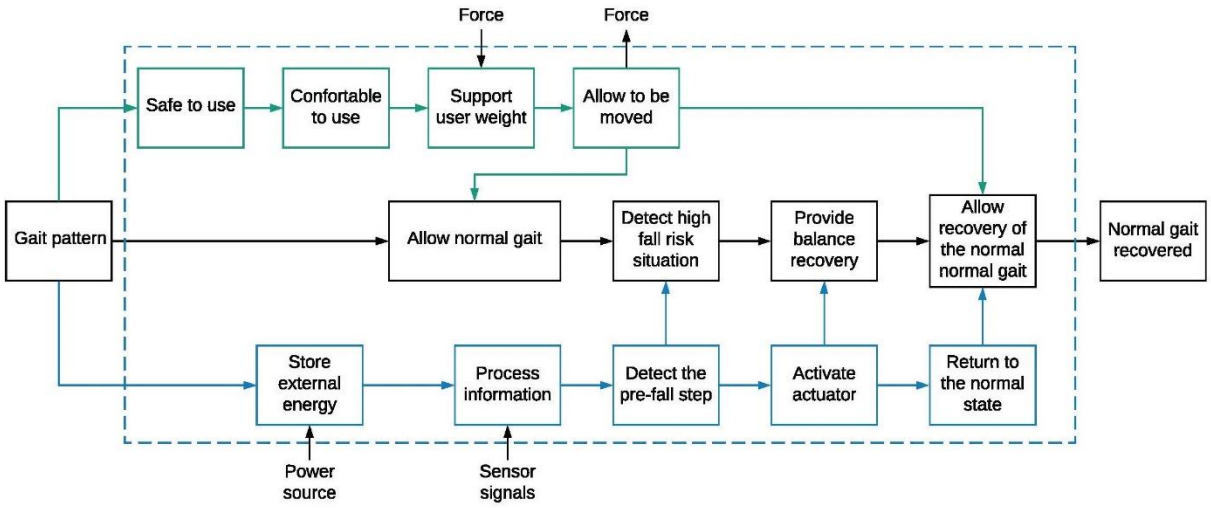


Figure 25: Functional structure of the anti-fall cane.

When balance is recovered, the cane has to return to the normal state, allowing the user to progress the gait in a normal manner.

Once again, the cane needs to be safe and comfortable to use, support the user's weight, and be movable. Thus, the user walked normally while using the cane, lost balance, recovered balance, and returned to the normal gait while using the cane.

5.2. Finding solutions

With the problem decomposition finished, it is now possible to look into the simpler subfunctions and find solutions for each of them more easily and efficiently. However, it is recommended to identify the most critical subproblem in the function structure, since that is the one that can benefit from creative and new concepts. In the case of the anti-fall cane, that would be the balance recovery of the user, since it needs an effective actuator that is yet to be determined.

The second step recommended by Ulrich and Eppinger [286], is to search externally through interviews with lead users, consultation of experts, patent and literature search, and benchmark-related products. Unfortunately, the interview with lead users and benchmarking based on market products was not conducted. However, the patent and literature review was previously conducted in the state of the art chapter, and the consultation of experts was possible because of the authors' advisors and ORTHOS XXI personnel.

The last step in this process leads to an internal search that relies on the creativity of the team to generate solutions to the previously mentioned critical subproblem. Some methods can be used in this internal search such as individual and group sessions, brainstorming, analogies, among many others [286]. In the end, several concepts were created and discarded along the process. Some of the most promising included the use of instantaneous and removable glue, an active tripod cane, and a cane tip inspired by the gecko paws. However, through some discussion, three concepts were selected for further discussion and refinement, namely the double servo cane, the rolling cane, and the vacuum cane. The concepts are described next with a small description and hand-made sketches.

5.2.1. Double servo cane

This system is similar to a gimbal or a joystick, it offers rotation in the roll and pitch axis creating a two Degrees Of Freedom (DOF) joint and it relies on two servos mounted perpendicular to each other. When the pre-fall phase is detected, during the cane swing, both servos position the tip of the cane contrary to the direction of the fall, creating a lever that helps the user regaining balance, avoiding the fall. For this concept, three different sketches were created, all of them are using the same concept, only through different setups. One of them is represented in Fig. 26, the other two sketches can be seen in appendix II.

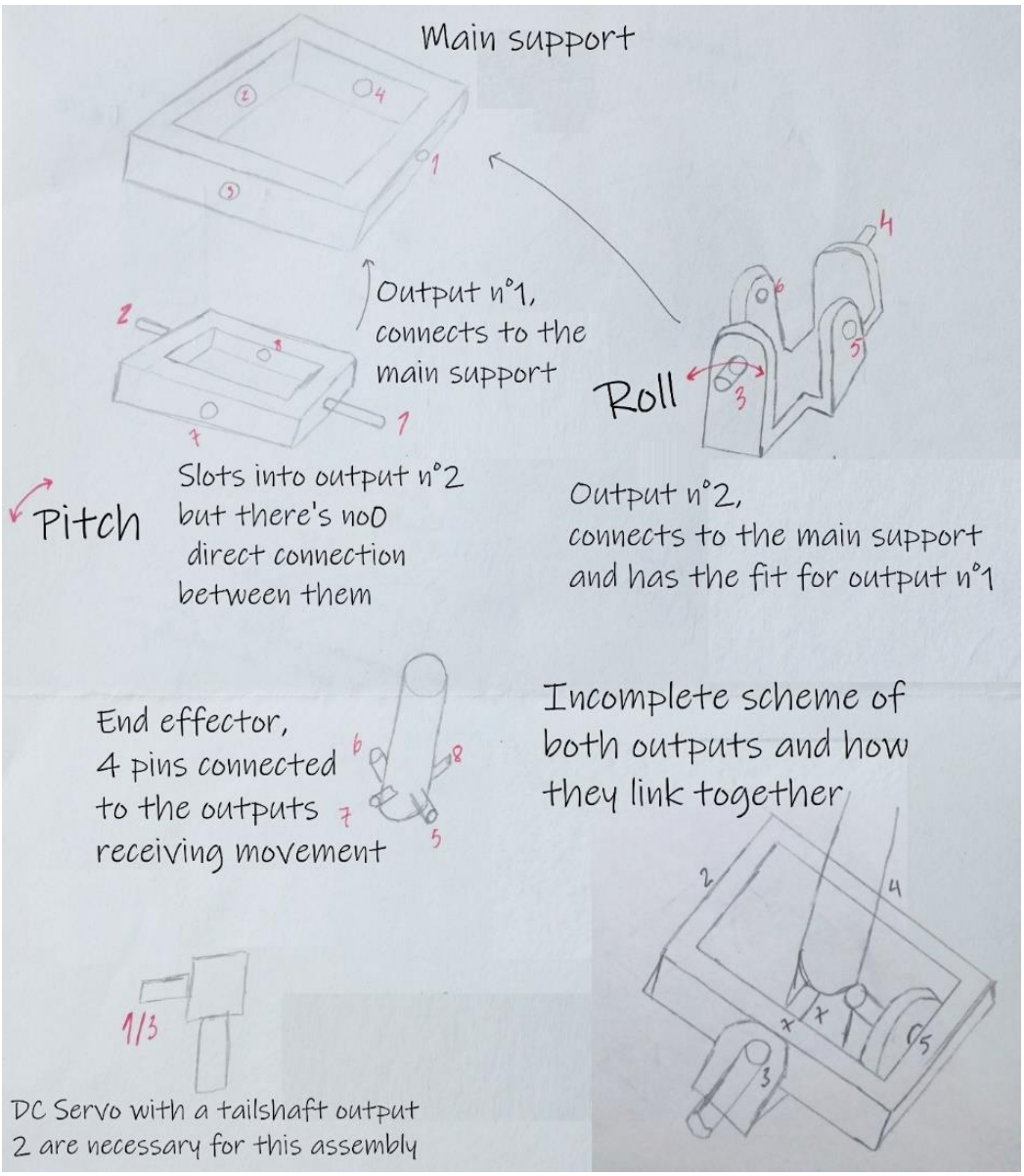


Figure 26: Representative sketch of the actuator for the double servo cane concept.

5.2.2. Rolling cane

The second concept was inspired by the most common cane-related result identified during the literature research, called the Rolling Cane. This concept takes inspiration from the wheeled walker, applying the wheels in the cane, creating a cane that does not need to be lifted. This is important because one of the most impactful factors on these types of devices is the weight, and with the wheels, that importance is reduced dramatically. The wheels are omnidirectional and motorized, allowing the cane to be moved with ease. When a high-risk fall situation is detected, the cane moves in the opposite direction of the fall [152]. Also, the motors can brake, locking the wheels in place and turning the rolling cane into a secure pole that the user grasps to recover balance. The handle and cane shaft can be connected to a universal joint to accommodate changes in force and direction during motion, smoothing the operation of the device.

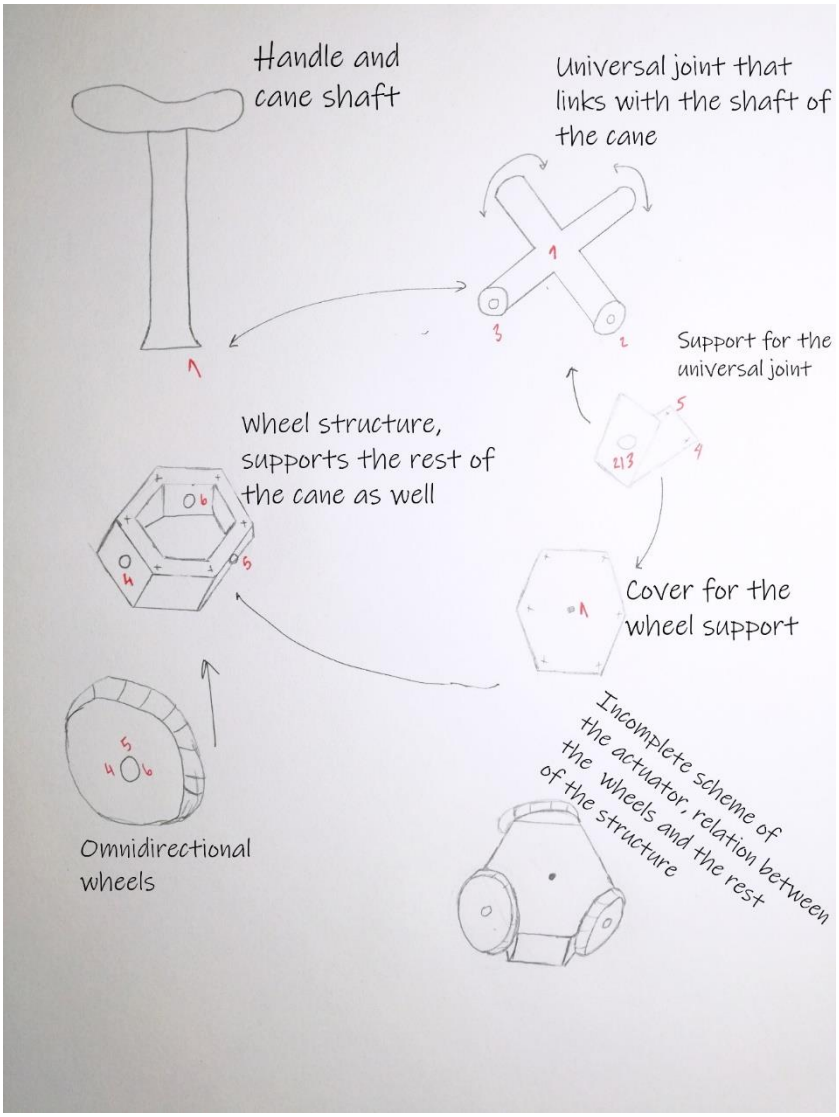


Figure 27: Representative sketch of the actuator for the rolling cane concept.

5.2.3. Vacuum clamping cane

The third and last concept is inspired by another cane prototype, previously developed in BiRD Lab. This one is called Vacuum Clamping cane, and it relies on vacuum forces to clamp the ground with enough force, turning the cane into a secure vertical pole that the user can grasp and recover balance. There were two hypotheses developed using this concept, the first one is using an integrated air container into the cane shaft and the second is using an electric air pump to pump. When the pre-fall phase is detected, upon the next contact of the cane tip with the floor, a spring compresses allowing the tip to recoil and the suction cups to contact the floor. At this moment, if the former hypothesis is used, valves would open allowing the air inside the suction cups to flow into the container, creating a vacuum, in case of the latter, the pump would suck out the air of the suction cups creating a vacuum as well. Instead of suction cups, vacuum pads can be used for the same effect.

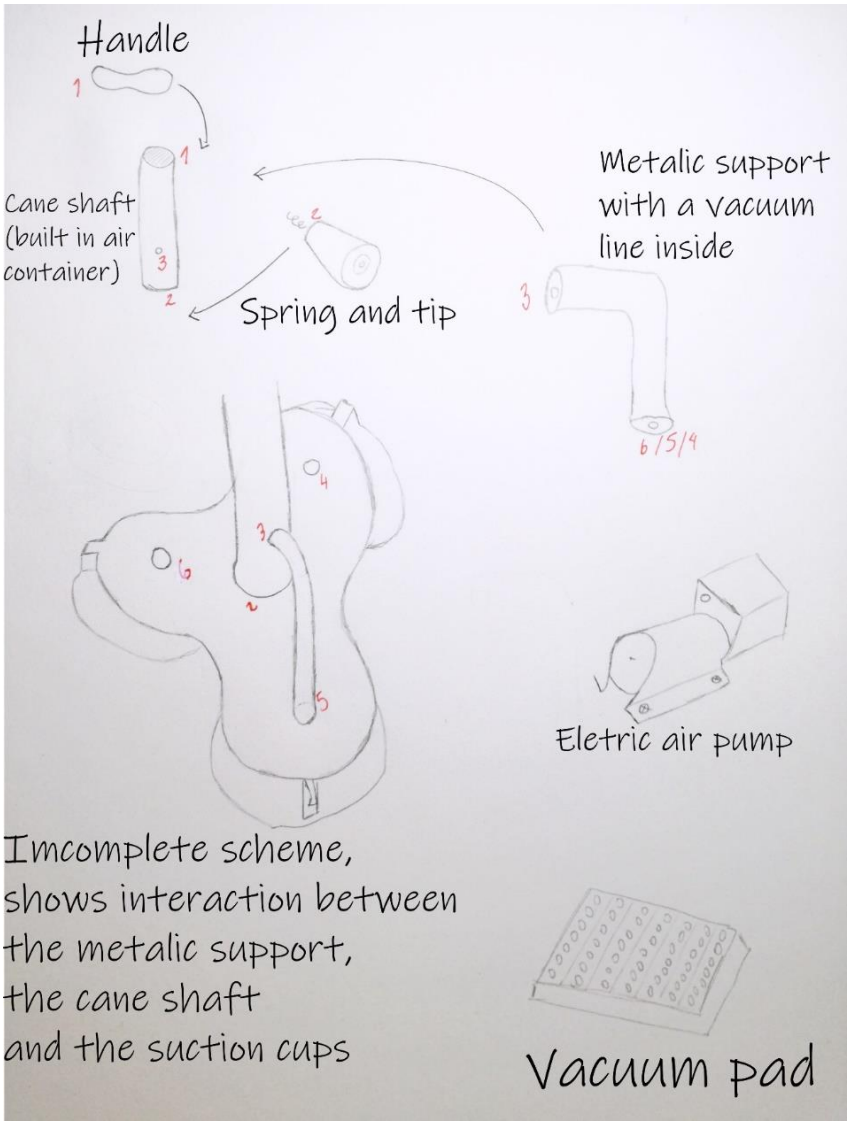


Figure 28: Representative sketch of the actuator for the vacuum cane concept.

5.3. Decision matrix

After the creation of the concepts, it is necessary to choose one among them, for further development. This dissertation will use decision matrices as the method to determine which is the best concept, which allows the rating of each concept against a set of selection criteria that contain different weights, influencing the final result in different ways [291].

These matrices are useful during concept screening and concept scoring. The former is a quick and general evaluation of several concepts and the latter a more careful and detailed analysis of the remaining few concepts. The screening phase has been happening since the inception of the project so, there will be no screening matrix because there is no need to filter concepts. Instead, there will be only concept scoring, which is done using a scoring matrix.

5.3.1. Decision matrix inputs

As previously stated, one of the main objectives of using a structured method is obtaining a consumer-focused product. Naturally, one of the inputs is the selection criteria, listed on the left side of the matrix. These criteria are chosen based on CNs previously identified, they are organized on a hierarchical structure derived from the primary and secondary needs. This increases the level of detail during the scoring phase and helps differentiate between the concepts.

However, sometimes those customer needs cannot be directly translated to selection criteria. In the actuator scoring matrix, some primary and secondary needs were not included because they do not apply to this concept category. The selection matrix does not include the ergonomic needs, the secondary need for an anti-slip tip, and the needs regarding accessibility and height adjustment. In the affordability section, the secondary need linked to the cane's price was changed from "cheap" to manufacturing cost. The cane's market price is not entirely derived from the manufacturing costs, however, it does represent an important part essential to the economic success of the product.

The other input required for the matrix is the concepts created in the previous chapter. They are allocated at the top row of the matrix, with each concept getting a rate and weighted score column.

5.3.2. Importance weights

After the inputs are done, importance weights are added to the matrix. The scheme used in this case is the allocation of 100 points between them. The different weights for the primary selection criteria were determined by the relative importance scale done on the consumer needs chapter. The consumer needs that have the highest score translate into a higher importance weight. The safety and effectiveness

criteria have the highest score, followed by the reliability and weight of the cane. All these had maximum relative importance as consumer needs. However, there was a need to differentiate between them in the concept selection phase. The lowest score goes, once again, to the style criteria. Although this was identified as a consumer need, it simply is not a priority for the present work. The weights of the secondary criteria were determined together with the advisors and ORTHOS XXI members.

5.4. Concept Rating

The next step in the process is to rate the concepts. Within this phase, the selection criteria – and, by implication, CNs – can be evaluated independently [291]. This process is done through the discussion of the merits of every concept for one criterion at a time and arranging the scores on a 9-point scale, 1 being the worst performance, and 9 the best. Once again, this process was conducted with the help of the authors' advisors and ORTHOS XXI.

Once the ratings are entered for each concept, weighted scores are calculated by multiplying the raw scores by the criteria weights. The total score for each concept is the sum of the weighted scores [291]. This is translated into the eq. 5.1:

$$S_j = \sum_{i=1}^{n} r_{ij}\, w_i \tag{5.1}$$

where S_j is the total score for the concept j; n gives the number of criteria; r_{ij} represents the raw rating of concept j for the i criterion and w_i the weight for the i criterion [291]. With the final scores for each concept calculated, it is possible to rank them following that final score. The final score for each concept of the actuator for the anti-fall cane is present in table 12.

5.5. Discussion

The concept generation represents a process that allows for the exploration of new ideas that can be commercially successful and represent value to the consumer. Therefore, it is an important step in the design and development of the anti-fall cane. To minimize the probability of failure, the functional structure of the cane was successfully elaborated, leaving another tool that can be utilized, or even updated, when the project reaches future phases, facilitating the design and development process. Also, the most critical subproblem, an actuator capable of avoiding falls, was isolated. To solve this problem, concepts were generated and transformed into hand-made sketches.

Table 12: Complete decision matrix for the anti-fall cane actuator concept.

			Concept				
		Rolling Cane		Double Servo		Vacuum Clamping	
Selection Criteria	**Weight**	**Rating**	**Weighted Score**	**Rating**	**Weighted Score**	**Rating**	**Weighted Score**
Affordability	7						
No hidden costs	1	5	5	4	4	4	4
Maintenance-free	1	3	3	2	2	1	1
Manufacturing costs	2	7	14	5	10	6	12
Covered by financing programs	1	5	5	4	4	5	5
Cost-free warranty	1	5	5	5	5	5	5
Easy to Set Up and Use	6						
User-friendly interface	1	9	9	5	5	8	8
Automatically turns on	1	7	7	6	6	7	7
Operates independently of other devices	1	6	6	4	4	5	5
Learned with ease	1	8	8	1	1	7	7
Easily transported	1	9	9	5	5	3	3
Equally easy to use in the right or left hand	1	7	7	7	7	7	7
Safe to Use	20						
Provokes no physical reactions	15	6	90	3	45	5	75
Can be used everywhere	5	5	25	4	20	3	15
Style	2						
Compatible with the consumer's ideals	1	5	5	4	4	4	4
Customizable	1	2	2	2	2	2	2
Weight	15	7	105	5	75	4	60
Offers Support	10	7	70	6	60	6	60
Effectiveness	20						
Prevents a fall	15	6	90	5	75	7	105
Meets the consumer's needs	5	6	30	7	35	5	25
Reliability	15						
Breakdown free	5	3	15	2	10	1	5
Doesn't need any special conditions to properly function	3	7	21	4	12	1	3
Remains dependable under repeated use;	5	6	30	5	25	3	15
Suffers no damage if not properly operated	2	3	6	2	4	3	6
Durability	5						
Durable without expensive maintenance	2	4	8	3	6	2	4
Lasts it's expected life	2	5	10	6	12	2	4
Lasts longer than it's expected life	1	2	2	3	3	1	1
Total Score			587		441		448
Rank			**1**		**3**		**2**

Subsequently, these concepts were scored, and the rolling cane concept has the highest score with 587 points, followed by the vacuum clamping concept in second and the double servo cane in third. The rolling cane finishes ahead of second place by 139 points. This difference is obtained in selection criteria like the weight, where this concept has the advantage that does not need to be constantly lifted, leaving some room for a heavier device. Since the user is not lifting the product, this also reduces the probability of negative physical reactions, such as complications with the upper limbs. Being a wheeled device, similar to the wheeled walker, it can be considered more familiar, easier to use, and accept by the consumer. Also, the use of omnidirectional wheels increases the range of situations where the device can be used effectively.

At this point, the rank gives information about what concept is most likely to succeed in the market. However, it does not represent a final decision for the team. In some cases, a concept with a lower score can be chosen when it represents lower uncertainty when compared to other higher-rated concepts that may prove less desirable further into the project [291]. In this case, the difference is clear, and the rolling cane appears to be the superior concept. Therefore, it is the concept that will be further developed and refined, a process explored in-depth during Chapter 6, the prototype conception.

6. PROTOTYPE CONCEPTION

After determining the winning concept, it is necessary to begin its approximation to an actual product, and that is exactly the objective of prototyping. Ulrich and Eppinger [292] define a prototype as "an approximation of the product along one or more dimensions of interest", creating scenarios that facilitate answers to learning, communication, and/or integration problems.

In this chapter, both the analytical and physical prototypes will be explored. Analytical prototypes represent an intangible model of the product, usually in a visual manner (computer models of 3D geometry) [292]. Different technologies used to create prototypes have emerged over the decades. However, for the last two decades, three-dimensional computer-aided design (3D CAD) is the dominant mode of design representation. Arguably, the biggest advantage of using this type of software is the ability to easily visualize the 3D form of the design in the early stages of the prototype development, allowing, for example, the detection of unwanted interactions between parts.

Physical prototypes are tangible models based on what the product would look and feel like, proof-of-concept prototypes created with built-in features with experimental hardware, used primarily for testing, experimentation, and validation of the functionality of the said prototype. Both prototypes were created with the resources and expertise of ORTHOS XXI, a company that offers a wide range of inclusive solutions, including the production and commercialization of walking aids.

For this dissertation, the main objectives for this phase are to determine and choose the components that the prototype of the anti-fall cane should have. Also, it is important to verify the interconnection of components and subsystems and demonstrate a certain level of functionality. This will facilitate future communication with interested parties.

All the designed pieces will use plain carbon steel as raw material, which was selected in SolidWorks. This will be useful for estimations and simulations, such as total mass. The photo-realistic images were obtained using PhotoView 360, a SolidWorks add-in that produces photo-realistic renders of SW models. All the technical drawings and hardware data sheets are present, in order of appearance, in appendix III.

6.1. Technical description

On a more technical level, the anti-fall cane prototype has hardware and software components. In this chapter, the hardware portion will be further explored. The hardware is integrated into the device and can be classified as: 1) sensory unit; 2) actuator unit; 3) control unit; 4) power unit.

6.1.1. Sensory unit

To successfully implement the sensory unit on the anti-fall cane, all the implemented technology needs to be modern, efficient, minimalistic, and low-cost. This includes an inertial system and a context-aware system. The inertial system comprehends the use of an IMU, capable of real-time analysis of the anti-fall cane angular velocity, and acceleration. These parameters will be used to monitor the gait cinematic, essential to evaluate the fall risk. The context-aware unit includes the use of sonar devices, allowing the early detection of possible obstacles in the environment of the anti-fall cane. Also, the use of an RGB camera, capable of capturing colour and depth images of the user's feet and legs. This information will be used in the future to power the software component of the device, based on AI algorithms. Some of the signals acquired are similar to the ones found during the literature review, such as angular velocity and acceleration. Also, methods like image processing and parameters like displacement and velocity were associated with real-time fall prevention. Table 13 summarizes the purpose and context of the sensory unit included in the prototype.

Table 13: Contextualization of the anti-fall cane sensory unit.

Sensory Unit Purpose	Signals Acquired	Parameters/Processes
Gait analysis	• Camera footage; • Acceleration; • Angular velocity; • Anti-fall cane orientation.	• Spacial: stride length; • Temporal: stride and support phase duration, cadence, and velocity.
Fall risk assessment	• Camera footage.	• Displacement, velocity, and orientation; • Fall risk assessment and correlation with the quality of life.
Fall detection	• Camera footage.	• Image processing.

6.1.2. Actuator unit

The actuator unit is based on the, previously selected, rolling cane concept. Therefore, this unit comprehends three omnidirectional wheels, powered by three DC motors. This allows the movement of the anti-fall cane on flat surfaces. Also, this movement will be essential to the actuator's success in fall prevention. To correctly choose the motors, the kinematic and dynamic models of the anti-fall cane actuator will be developed. Therefore, it is important to determine how fast does the platform needs to

move. This was determined by the lateral speed, lateral acceleration, rotational speed, and rotational acceleration [293,294].

To determine the lateral speed, studies that evaluated gait speed were analysed. Liu et al. [295] studied the range of walking speeds in healthy subjects. The maximum registered speed was equal to 1.56 m/s. In another study, more focused on older adults, Kyrdalen et al. [296] registered a maximum speed of 1.03 m/s. Also, the Task Force of the International Academy on Nutrition and Aging classifies speeds above 1.3 m/s as fast, the highest category [297,298]. Therefore, the maximum lateral and rotational speeds are set at 1.3 m/s and 1.3 rad/s, respectively.

However, for the remainder of the parameters, due to the lack of information, the author, together with its advisors and ORTHOS XXI, set the values of lateral acceleration, and rotational acceleration at 1 m/s^2, and 1 rad/s^2, respectively. Table 14 summarizes these values, the cane weight was defined earlier during the target specifications. Also, the load the user might put on the cane needs to be taken into account. During the exploration of the anti-fall cane metrics, the maximum weight the user exerts in the device, in kilograms, was equal to 29 kg [271]. Therefore, considering the cane weight and user payload, the total maximum mass of the system is 35 kg.

Table 14: Actuator specifications, used to correctly choose the motors.

Specification	Value
Cane weight	< 6 Kg
Payload	29 Kg
Lateral speed	1.3 m/s
Lateral acceleration	1 m/s^2
Rotational speed	1.3 rad/s
Rotational acceleration	1 rad/s^2

6.1.3. Control unit

The control unit is the “brain” of the system since it is responsible for storing and processing all the information provided by other units. Also, it is responsible for communicating the necessary commands to the anti-fall cane systems. For the success of the anti-fall cane as a real-time fall prediction system, the process of information needs to be highly efficient. Therefore, a CPU will be implemented, capable of quick and accurate data interpretation. Also, since the data gathered by the sensory system must be stored for further analysis and investigation, a storage device is included in the control unit.

6.1.4. Power unit

As part of the mission statement, if a power source was needed in the anti-fall cane, it should be a rechargeable one. After studying the CNs, it can be easily seen that it would go against those same needs if the anti-fall cane needed a battery change every time it fully discharges. Therefore, a rechargeable battery is implemented as part of the power unit, responsible for powering all the hardware components implemented in the anti-fall cane. This battery should last for 60 minutes of continuous use, allowing the monitorization and assistance between short sessions.

6.2. Hardware Dimensioning

After identifying the technical units present in the prototype, the respective hardware needs to be dimensioned. This is important to further approximate the prototype to a market product. A 3D CAD of the anti-fall cane was developed using SolidWorks 2013, a CAD licensed software provided by ORTHOS XXI. To ensure a timely and economic solution for the project, it was decided that the best course of action was to adapt the P1 tripod, a three-legged cane inserted in the company walking aid catalog, seen in Fig. 29. In an initial phase, this adaptation includes the removal of the rubber tips and the creation of an entirely new frame responsible for the housing of all the features included in the project, such as the anti-fall actuator. Also, all the necessary components to make a functional prototype of the anti-fall cane are dimensioned.



Figure 29: P1 tripod, a three-legged cane sold by ORTHOS XXI [292].

6.2.1. Holonomic base

The starting point for the prototype is the holonomic base. This platform was designed, with the main purpose of creating space and a stable environment for all the features that are going into the anti-fall cane. Based on the way robots move, they can be classified as “holonomic” or “non-holonomic” drive robots. This is determined by the relationship between controllable DOF and total DOF present in the said robot, and when both are equal, the robot is considered “holonomic” [299]. These robots are capable of moving in any direction without changing orientation and can also change to any desired orientation while in motion [300], [301]. This is especially important for the anti-fall cane, having the ability to easily manoeuvre around tight spaces can dramatically influence the performance of the product.

This platform is made of plain carbon steel with three millimetres of thickness, obtained through laser cutting. Three holes are cut on the top flat surface where the feet from the P1 tripod will be welded. Also, there are three sides bent to 90° that will support the DC motors, each of them has four M5 holes and a bigger one in the middle, destined for the motor housing and its shaft. Finally, there are two M3 holes destined to secure the IMU in place, and the remaining slots were created to hold the grooves of the battery and CPU supports, making the welding process much simpler and precise. The 3D renders of the holonomic base can be seen in Fig. 30.

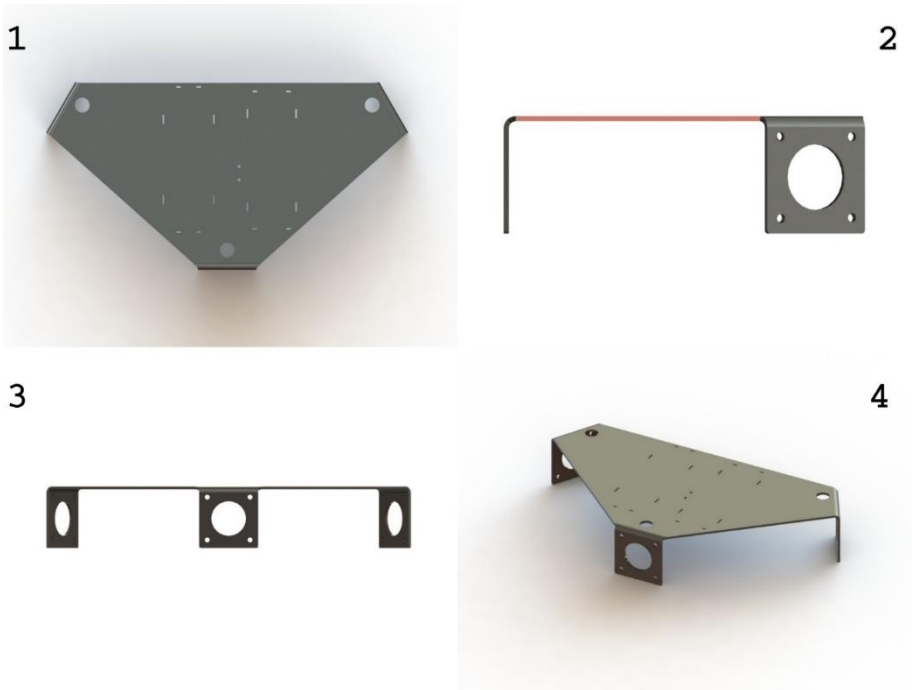


Figure 30: Holonomic base for the anti-fall cane. 1: top view; 2: right view; 3: front view; 4: trimetric view.

6.2.2. Omnidirectional wheels

As previously stated, the performance of this concept is dramatically influenced by the capability of moving in congested spaces. Therefore, two types of wheels were considered to achieve this high mobility. The first type is called the mecanum wheel, which is capable of omnidirectional movement, but its price and weight were not compatible with the current prototype. The second type is the so-called classic omnidirectional wheel, which as the name says, is capable of omnidirectional movement and is much cheaper and lighter, while it has a simpler structure and design when compared to the mecanum wheel [302]. Therefore, it was the selected type for the anti-fall cane prototype.

Manufacturing these wheels would be unwise since they are commercially available in different specifications. A quick market research was conducted to find the most suitable omnidirectional wheels for the project, where European stores were privileged. The chosen wheels were the 100mm double plastic Omni wheels with central bearing, sold by Robot Shop [303]. The increased diameter and 18 rollers give these wheels a higher load capacity and they weigh 0.35kg per unit. A visual representation was constructed in SolidWorks, seen in Fig. 31. This representation helps to better estimate the wheels' interaction with other system components.



Figure 31: 1: Omnidirectional wheel for the anti-fall cane [303]; 2: Visual model constructed in SolidWorks.

6.2.3. DC motors, the kinematic, and dynamic model

This is another important choice, not only for the actuator unit but also for the success of the prototype. During the literature review, it was possible to observe that detection times from different systems are always very low (under 1 second). Therefore, speeds and accelerations were set to the maximum gait speed during the technical description of the actuator unit. These values are expressed on a system level and need to be translated into a component level. This is done through the kinematic and dynamic model of the actuator, where global acceleration and velocity are expressed in torque and angular velocities of the omnidirectional wheels [293,294].

Starting with the velocity first, a kinematic model will be developed for the holonomic base. Defining a global frame [x, y], seen in Fig. 32, the robots' location and orientation can be represented as (x, y, θ). Therefore, the global velocity of the robot can be written as ($\dot{x}$, $\dot{y}$, $\dot{\theta}$). The local frame [x_L , y_L] is attached to the holonomic base, and it coincides with the Centre Of Mass (COM) of the actuator.

It is possible to calculate the angular velocity of the wheels, $\underline{\dot{\phi}}$, using the relationship between the inverse Jacobian for the actuator, J_{inv}, and the global velocity vector, $\underline{\dot{u}}$, as expressed in eq. 6.1 and 6.2 [294].

$$\underline{\dot{\phi}} = J_{inv}\, \underline{\dot{u}} \tag{6.1}$$

$$\begin{bmatrix} \dot{\phi}_1 \\ \dot{\phi}_2 \\ \dot{\phi}_3 \end{bmatrix} = \frac{1}{r} \begin{bmatrix} -\sin(\theta) & \cos(\theta) & D \\ -\sin(\theta+\alpha_2) & \cos(\theta+\alpha_2) & d \\ -\sin(\theta+\alpha_3) & \cos(\theta+\alpha_3) & D \end{bmatrix} \begin{bmatrix} \dot{x} \\ \dot{y} \\ \dot{\theta} \end{bmatrix} \tag{6.2}$$

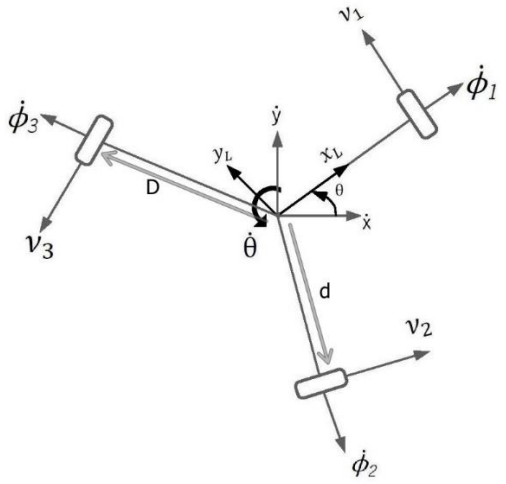


Figure 32: Kinematic representation of the actuator unit.

Considering the local axis x_L as the starting point, and the clockwise direction as positive, the three omnidirectional wheels are located at $\alpha_1 = 0^\circ$, $\alpha_2 = 107^\circ$, $\alpha_3 = 214^\circ$. Also, *D* represents the distance from the COM to wheels no. 1 and 3, equal to 0.185 m.

The distance between wheel no.2 to the COM is represented by *d*, and is equal to 0.121 m. The wheel of the radius is equal to 0.05 m, represented by *r*. Since the lateral and rotational speed were defined earlier, the global velocity vector is $\underline{\dot{u}} = [1.3, 0, 1.3]'$. Therefore it is possible to transform eq. 6.2 into eq. 6.3.

$$\begin{bmatrix}\dot{\phi}_1\\ \dot{\phi}_2\\ \dot{\phi}_3\end{bmatrix} = \frac{1}{0.05}\begin{bmatrix}-\sin(\theta) & \cos(\theta) & 0.185\\ -\sin\left(\theta+\frac{137\pi}{180}\right) & \cos\left(\theta+\frac{137\pi}{180}\right) & 0.121\\ -\sin\left(\theta+\frac{214\pi}{180}\right) & \cos\left(\theta+\frac{214\pi}{180}\right) & 0.185\end{bmatrix}\begin{bmatrix}1.3\\ 0\\ 1.3\end{bmatrix} \tag{6.3}$$

By programming a Matlab file to incrementally change θ from 0 to 2π radians, the maximum output velocity is obtained, equal to, approximately, 30.81 rad/s or 295 rpm. Therefore, this will be the minimum value of the shaft output velocity for the motor of the prototype.

To calculate torque, a dynamic model of the actuator is elaborated. The necessary torque is obtained by calculating all forces acting on each wheel. However, for this dissertation, only the force necessary to overcome the inertia of the prototype was calculated. Therefore, the necessary force to overcome friction and inertia between components was not taken into account. The required force can be calculated using Newton's second law, represented in eq. 6.4 [293].

$$\underline{F} = \underline{M\ddot{u}} \tag{6.4}$$

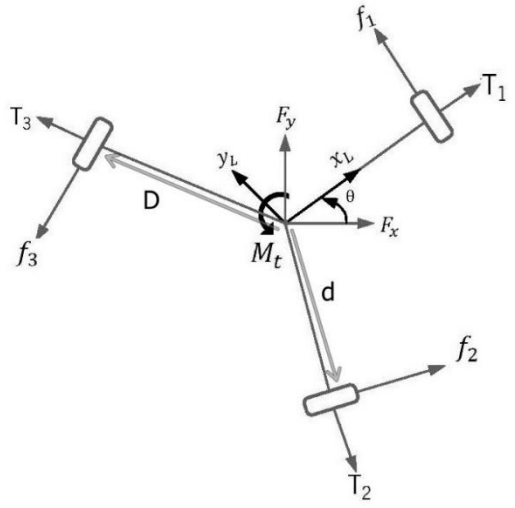


Figure 33: Dynamic representation of the actuator unit.

Creating a representation of the dynamic model, seen in Fig. 33, the sum of the global forces, F_x and F_y, can be obtained using the mass M, moment M_t, and the moment of inertia J_z, which can be calculated using eq. 6.4, assuming that the holonomic base is a triangle.

$$J_z = \frac{Mh^2}{6} \tag{6.5}$$

Replacing the global forces with the sum of the x and y components, and M_t with the product of the combined local force vectors and the distance they work on, the total torque, $\underline{T}$, can be expressed with eq. 6.6 to 6.8 [293].

$$\underline{F} = \underline{A}\,\underline{f} \tag{6.6}$$

$$\underline{f} = \underline{A^{-1}M\ddot{u}} \tag{6.7}$$

$$\begin{bmatrix} T_1 \\ T_2 \\ T_3 \end{bmatrix} = r \begin{bmatrix} -\sin(\theta) & -\sin(\theta+\alpha_2) & -\sin(\theta+\alpha_3) \\ \cos(\theta) & \cos(\theta+\alpha_2) & \cos(\theta+\alpha_3) \\ D & d & D \end{bmatrix}^{-1} \begin{bmatrix} M & 0 & 0 \\ 0 & M & 0 \\ 0 & 0 & J_z \end{bmatrix} \begin{bmatrix} \ddot{x} \\ \ddot{y} \\ \ddot{\theta} \end{bmatrix} \tag{6.8}$$

The maximum mass was previously set to 35 kg, and J_z is equal to 0.04 kg/m^2. Also, the lateral and rotational accelerations were defined earlier, the global acceleration vector is $\underline{\ddot{u}}$ = [1, 0, 1]'. Therefore, it is possible to transform equation 6.8 into equation 6.9.

$$\begin{bmatrix} T_1 \\ T_2 \\ T_3 \end{bmatrix} = 0.05 \begin{bmatrix} -\sin(\theta) & -\sin\left(\theta+\frac{137\pi}{180}\right) & -\sin\left(\theta+\frac{214\pi}{180}\right) \\ \cos(\theta) & \cos\left(\theta+\frac{137\pi}{180}\right) & \cos\left(\theta+\frac{214\pi}{180}\right) \\ 0.185 & 0.121 & 0.185 \end{bmatrix}^{-1} \begin{bmatrix} 35 & 0 & 0 \\ 0 & 35 & 0 \\ 0 & 0 & 0.04 \end{bmatrix} \begin{bmatrix} 1 \\ 0 \\ 1 \end{bmatrix} \tag{6.9}$$

Once again, a similar Matlab file was constructed to incrementally change θ from 0 to 2π radians. The maximum output torque obtained is equal to, approximately, 1.47 Nm. Therefore, this will be the minimum value of the shaft output torque for the motor of the prototype.

With the motor specifications determined, a quick market search was conducted to find the most suitable motors for the prototype, European stores were privileged. The chosen motor was the Nema23 (RMCS-2255) produced by Rhino Motion Control Solutions [304]. This DC motor is intended for operation at 12V, it has a holding torque of 30 kg/cm, equal to, approximately, 2.94 Nm. It draws a maximum of 7.5 amperes of current, and with a maximum rotational speed equal to 300 rpm, weighing 0.18 kilograms per unit, it matches the needs for the anti-fall cane. This motor also comes with an encoder, essential to

determine the speed and control the prototype. The motor and its SolidWorks counterpart can be seen in Fig. 34.

A possible limitation of the 3D model is related to the M3 securing hole, seen on the left of Fig. 34. There is no available information about its placement, and after a failed attempt to contact the manufacturer, an M3 hole was created in the middle of the shaft, seen on the right of Fig. 34. This output shaft is 16.3 mm long and 6mm in diameter which will connect to the omnidirectional wheel via a set screw hub.



Figure 34: 1: Nema-23 RMCS-2255 [303]; 2: Visual representation produced on SolidWorks.

6.2.4. Set Screw Hub

To link the shaft movement and the omnidirectional wheels a set screw hub was designed using both components as a reference, ensuring full compatibility. The coupler is constituted by 2 separate pieces. First, the bigger circle is created using laser cutting on a metal sheet with 6mm of thickness, creating the six M5 mounting holes that will connect with the omnidirectional wheel and the hole for the second piece of the coupler. This second piece is turned using a lathe, creating the 6mm hole for the shaft and the M3 hole that will connect the coupler to the motor. Finally, both pieces are welded together creating the motor-to-wheel coupler. The 3D model for the set screw hub can be seen in Fig. 35.

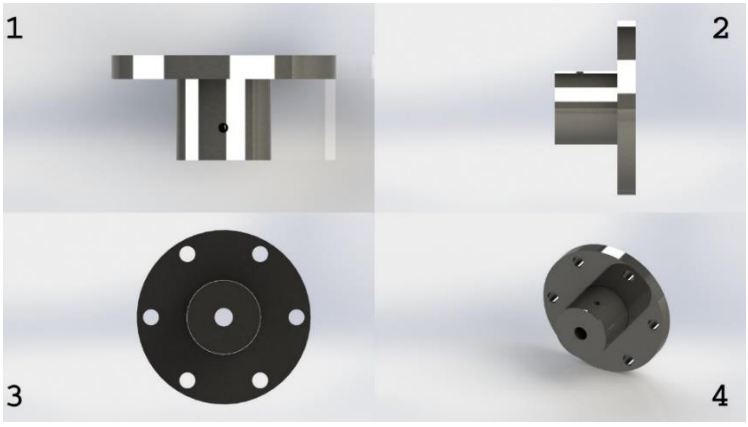


Figure 35: A 3D model for the motor-to-wheel coupler. 1: top view; 2: right view; 3: front view; 4: trimetric view.

Figure 36 demonstrates how all the components comprehended in the actuator unit, interact between them, taking into account the bolts, washers, and nuts from the SW toolbox. This confirms that there are no clearance issues within the hardware explored so far.

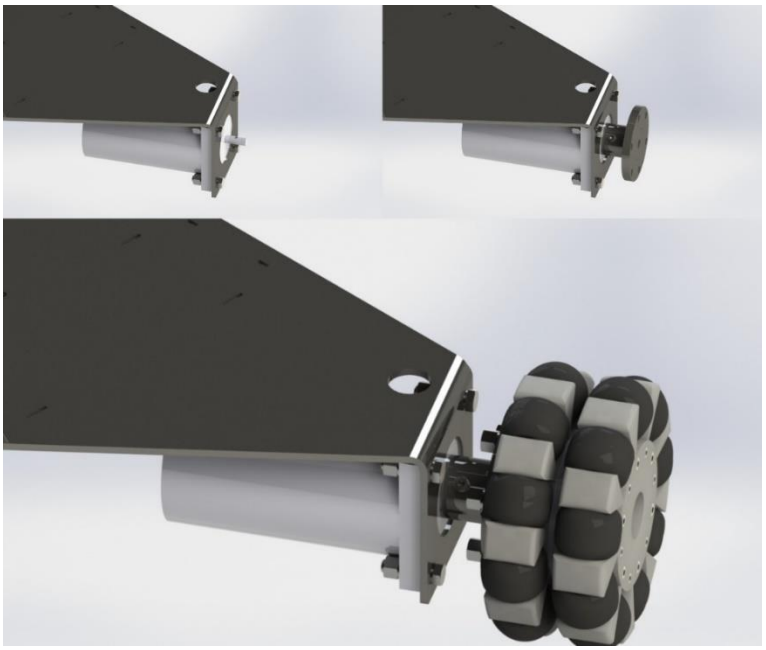


Figure 36: Interaction between the holonomic base, DC motor, coupler, and omnidirectional wheel.

6.2.5. Camera

The first component dimensioned, for the sensory unit, is the camera. The choice came down to small size, low weight, and high performance, as the target specifications and the concept itself dictate. The OV2710 USB camera matched all the needs of the project. With a small package, and an excellent performance capable of high-resolution recording (1920 x 1080p), and a diagonal FOV of 145° [305], it ensures that the user's legs and feet can be recorded with the necessary quality. The camera and its SW representation can be seen in Fig. 37.

To hold the camera in place and help fulfil its objective, a camera support was designed specifically for this case. A metal sheet with 1.5 mm of thickness is laser cut to create four M2.5 holes that secure the camera, and the centre slot, designated for the camera lens. The support is welded into the holonomic base. The assembly of the camera plus the support is represented in Fig. 38.

As space is limited in the cane, it is important to determine the best position for the camera. For this purpose, the camera function of the SW was used. This mode allows the simulation of the camera position, rotation, and FOV. These parameters are essential to pre-determine what the camera will capture.

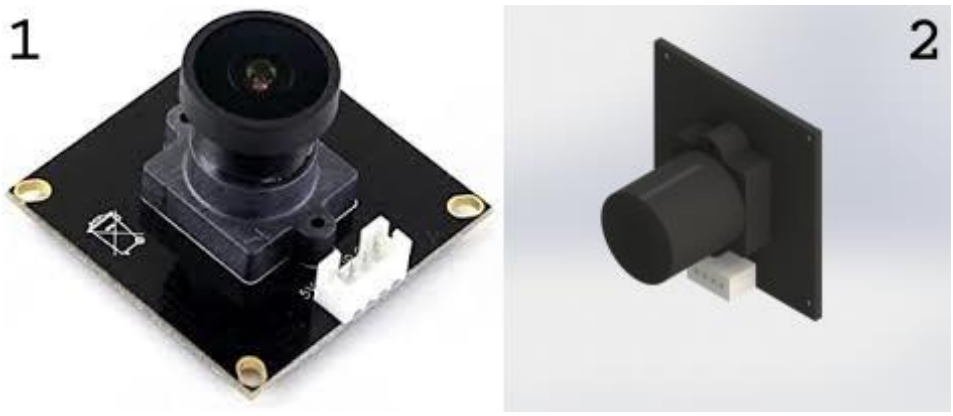


Figure 37: 1: OV2710 USB camera [291]; 2: The SW equivalent.

Using an anatomic model of a human, 1.8m tall, and knowing that the camera records with a resolution of 1920x1080p, which corresponds to a 16:9 aspect ratio [306], and has a FOV of 145°, it is possible to simulate the final position of the camera.

During the study of CNs, one of the secondary needs identified was the ease of using the cane regardless of handedness. With that in mind, a second projection was made for left-hand users, which was mirrored based on the right-hand camera, ensuring that the user does not have any constraints based on their dominant hand. Also, as it was possible to see what the camera would capture, the inclination of the support was set at 105°, which gives a good capture window of the feet and legs of the user. Figure 39 represents the camera final position and the interaction with the surrounding components.

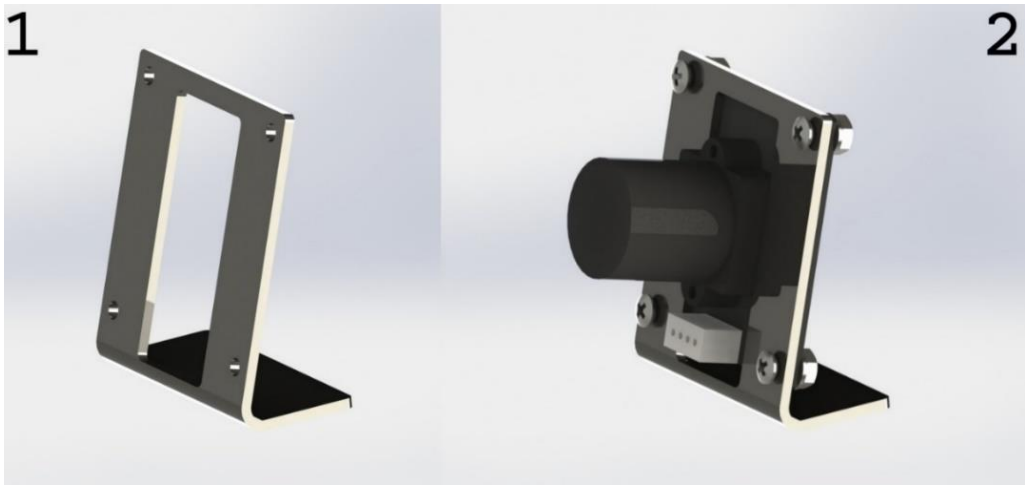


Figure 38: Assembly for the camera and the support. 1: Camera support; 2: Camera mounted on the support

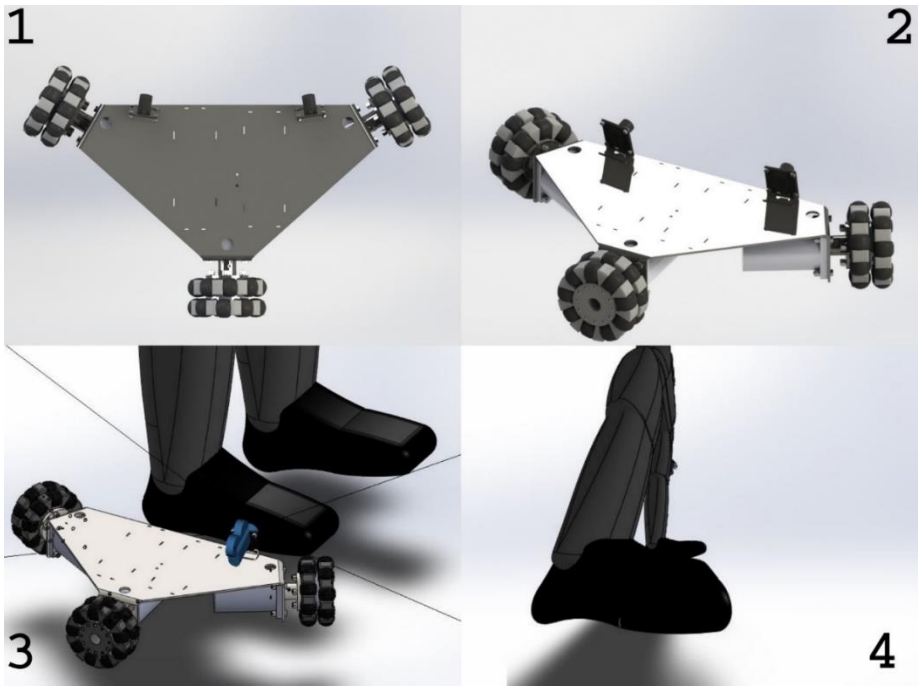


Figure 39: Interaction between the camera and all the previous components. 1: top view including cameras for left and right-hand users; 2: trimetric view including cameras for left and right-hand users; 3: SW camera mode; 4: simulated camera view

6.2.6. Inertial Measurement Unit

Also part of the sensory unit, an IMU is implemented in the centre of the holonomic base. In general, IMUs are relatively small and light, so, the choice for this component came down to performance and price. As all hardware reviewed so far, availability is important as well, so, European stores were privileged.

The chosen IMU was the InvenSense MPU-6050, one that was also identified during the literature review [128]. It features a 3-axis gyroscope and 3-axis ACCM. The package dimensions of this IMU are only 15 x 20 x 3 mm, a very small and light device perfect for the prototype, and the peak current consumption, corresponding to all 6 motion sensing axes operating at the same time, is 3.5 mA [307]. As seen in Fig. 40, it is held in the centre of the holonomic base by two M3 bolts.

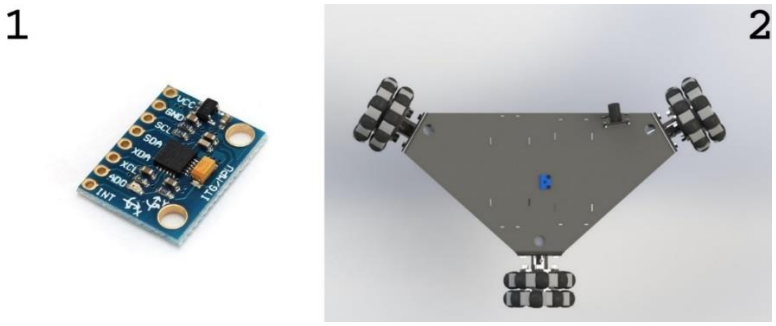


Figure 40: 1: IMU MPU-6050 [307]; 2: interaction between the IMU and the holonomic base.

6.2.7. Sonar and tripod legs

The final piece of the sensory system of the prototype is the sonar devices. To ensure that the cane does not collide with close objects and walls, it is necessary to determine the distance between the anti-fall cane and the surrounding environment. For this purpose, sonar and laser technology were investigated. All laser ranging operations are based on the use of some type of LRF, that emits a pulse of laser radiation that travels from the laser ranger to the object being measured and returns to the instrument after having been reflected. As the speed of light is accurately known, the LRF measures the precise time interval that has elapsed between these events, determining the distance between the LRF and the measured object [308].

In the case of sonar technology, the principle is the same but, instead of using light, sonar sensors use acoustic pulses and their echoes to measure the distance to an object. Since the sound speed is known, the object distance is proportional to the echo time. At ultrasonic frequencies, the sonar energy is concentrated in a beam, providing directional information in addition to range [309]. A scheme for sonar principles is represented in Fig. 41. This technology was chosen over the laser due to the wider range of the beam, its low cost, lightweight, low power consumption, and low computational effort, all important parameters for the anti-fall cane prototype.

The SRF10 Ultrasonic Range Finder (URF), seen in Fig. 42, was chosen for the anti-fall cane prototype. As would be expected, this sensor is small and can measure objects between 4 cm and 6 m, with an operating current of 15 mA [310], ideal for this prototype.

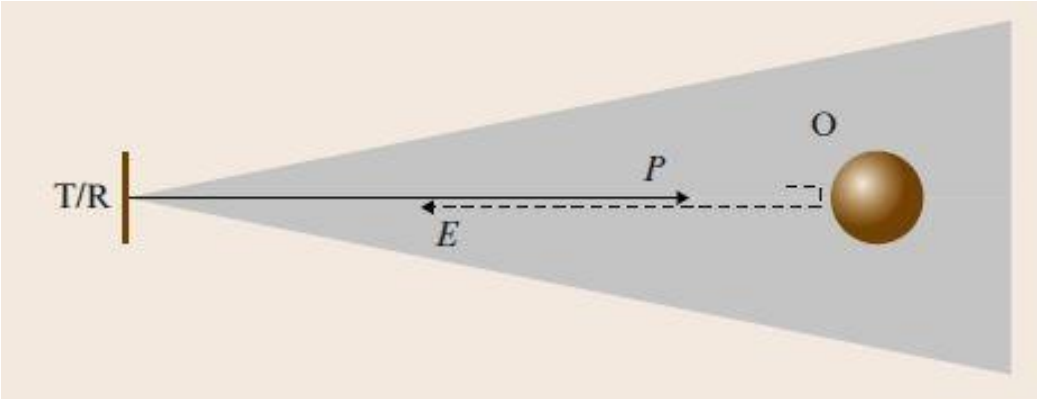


Figure 41: Sonar sensing principles [309]. T/R corresponds to both the transmitter (T) of an acoustic pulse (P) and the receiver (R) of the echo (E) reflected by an object (O).

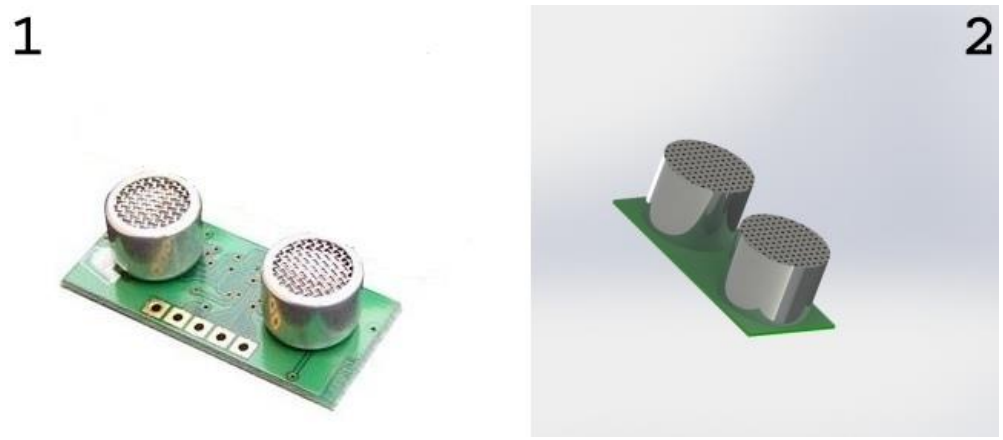


Figure 42: 1: SRF10 URF [309]; 2: SW visual representation

For the prototype, the main objective of the use of sonar sensing is obstacle avoidance. As the wheels correspond to the furthest points from the centre of the holonomic base, they are the most likely to contact objects/walls. Therefore, sonars should be placed on top of each wheel. However, other parts of the anti-fall cane can contact foreign objects.

It is necessary to study the pattern of the beam produced by the SRF10 to determine the ideal number of URFs that need to be used. In the ultrasonic rangefinder FAQ, a graphic shows that the beam covers, approximately, 72°. To simulate this beam pattern in SW, a cone with 72° was projected through the emitter of the sonar, allowing a visual representation of the area each sonar can cover, as seen in Fig. 43.

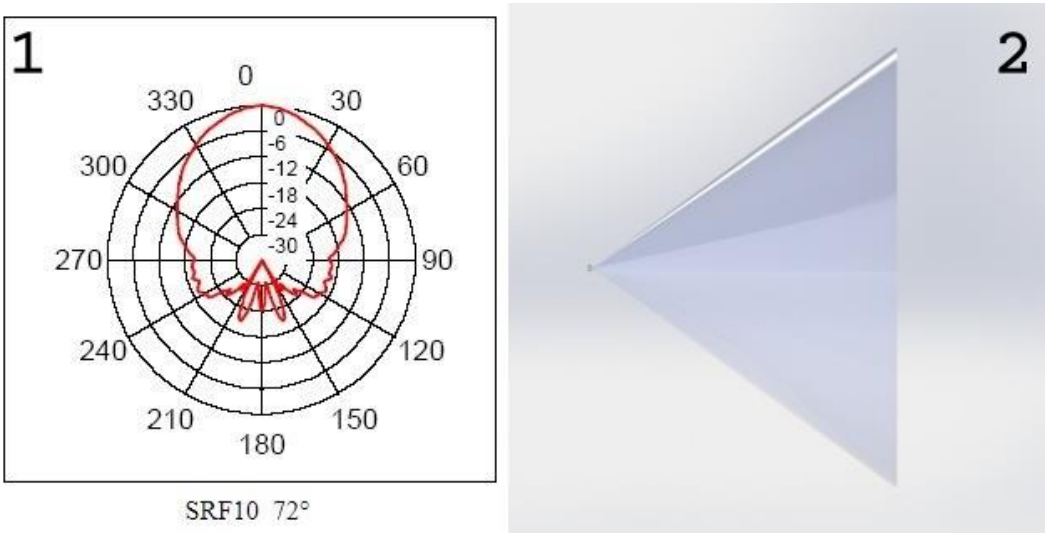


Figure 43: 1: beam pattern of the SRF10 URF [310]; 2: SW simulation of the beam pattern.

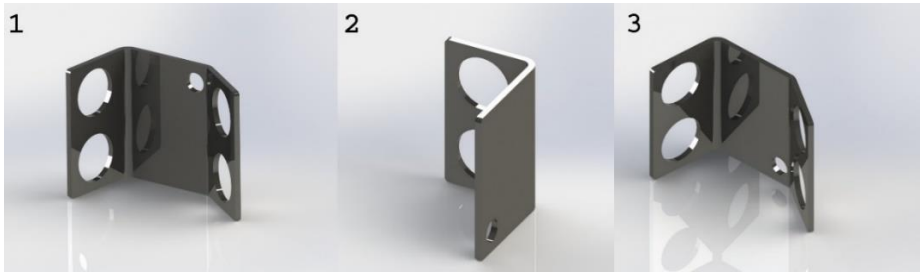


Figure 44: Trimetric views of the sonar supports. 1: left sonar support; 2: front sonar support; 3: right sonar support.

The ideal scenario would be 360° coverage, however, for this prototype, the user is not considered an obstacle, so, a 70° area was given to the user to walk freely. This was possible by designing the sonar's supports to account for 35° on each side of the prototype, giving coverage of, approximately, 290°. The supports can be obtained through laser cutting a 1.5 mm thick metal sheet, and later bent accordingly. These supports can be seen in Fig. 44.

As previously stated, the best spot to place the sonars would be on top of each wheel. As the tripod legs are welded to the base directly on top of said omnidirectional wheels, the sonar supports are attached to the tripod legs. This way, there is no interference with the rest of the design. These legs are similar to the original P1 tripod legs, the only difference being the M5 hole that will secure the sonar support in place. These interactions are represented in Fig. 45.

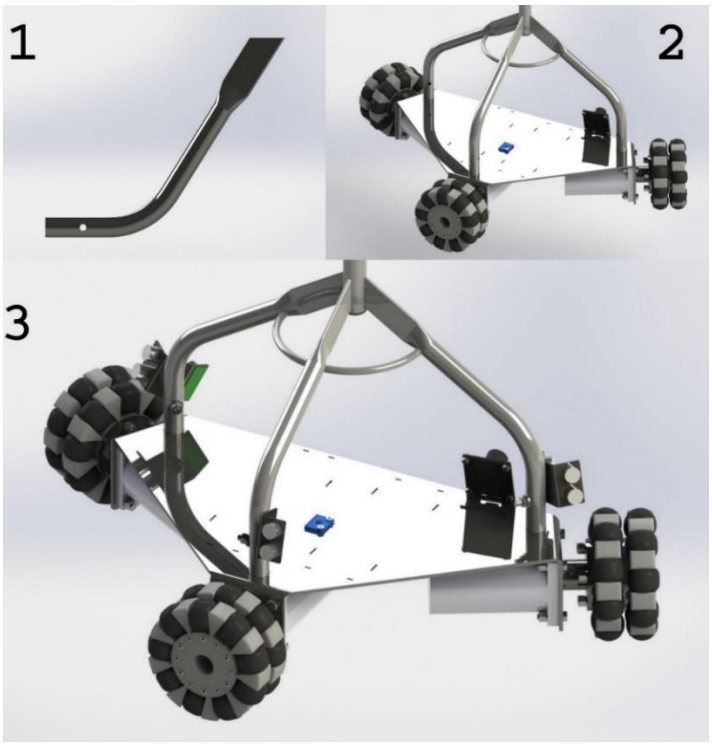


Figure 45: Interactions between the tripod legs, sonars, and respective supports.

Accounting for the possibility of some adjustment, the sonar support can be tilted up or down as needed, by unscrewing the M5 bolt, adjusting the inclination of the sonar, and screwing it back in. To create the smaller package possible, the SRF10 has no mounting points. Instead, it must be held by two grommets that should be fitted into the sonar support. This is not represented in the SW model, however, all the dimensions of the support already account for this adaptation. Recurring back to the anatomic model used during the camera module, it is possible to simulate the area covered by the five sonars, seen in Fig. 46.

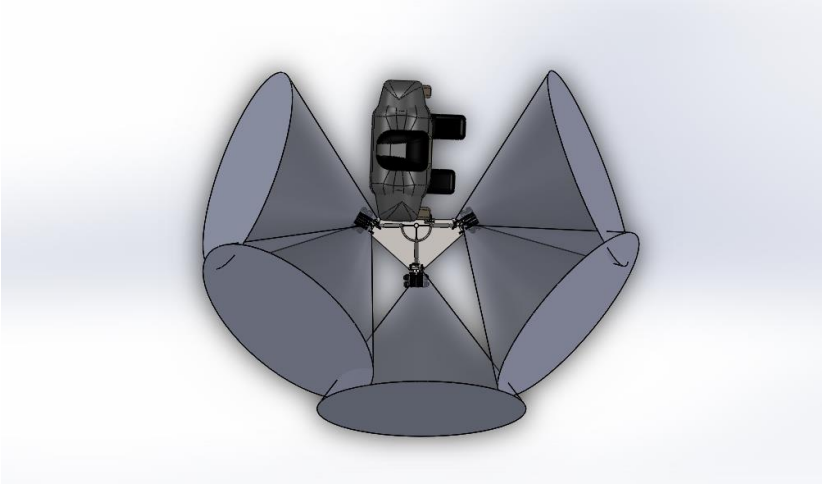


Figure 46: Visual representation of the interaction between the five sonars and the environment.

6.2.8. Central Processing Unit

To process, in real-time, all the information retrieved from all the other hardware components, a powerful CPU is required. However, CPUs are usually big, heavy, and expensive. As good as it would be to have a very powerful CPU, it is just impossible due to size and weight limitations. One option that was considered was the BMAX MaxMini B4 Pro [311], a robust computer with a slim design (112 x 47 x 125 mm) and only weighing 0.45 kg. However, it is only sold in international stores with long shipping times, so another solution was found.

Considering the state of the project, and its necessities, the NVIDIA Jetson Nano [312] was deemed ideal to prove the anti-fall cane concept. It weighs 0.141 kg, it is smaller measuring only 100 x 80 x 29 mm, and it is cheaper when compared to the previous option. This is possible by sacrificing some computational power.

To hold the CPU in place, a simple bracket was designed. It consists of two pieces of steel, obtained through laser cutting a 1.5 mm thick metal sheet, which are subsequently welded together. The groves seen in the support were created alongside the slots in the holonomic base. These create the

necessary guidance to weld the CPU support to the base in the intended place. This is important because of the limited space that the prototype has. The final support and its constituents can be seen in Fig. 47.

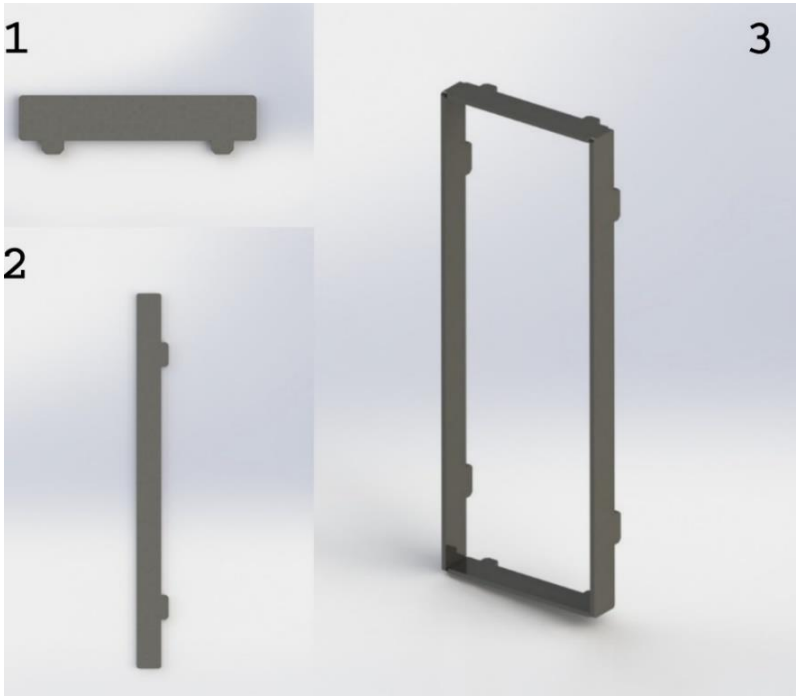


Figure 47: CPU support and its constituents. 1: smaller bracket of the CPU support; 2: bigger bracket of the CPU support; 3: welded CPU support.

As previously said, the NVIDIA Jetson Nano can be replaced for, potentially, better options. For this reason, these brackets are bigger than the Jetson Nano but can be adapted for this CPU as well. Also, this creates a designated place for other hardware components that can make it into the anti-fall cane, in future phases. Figure 48 shows the biggest CPU-support combination possible.



Figure 48: Interaction between the support and CPU with the other components. 1: Trimetric view of the CPU support; 2: Back view of the CPU and its support, checking for clearance with the bigger CPU option.

6.2.9. Battery unit

The last piece of the prototype is the power unit, constituted by the rechargeable battery. As all components explored so far, dimensions, weight, and price are all important limitations imposed on battery choice. Furthermore, there are battery intrinsic characteristics that need to match the needs of the prototype and its hardware, namely the type of current, voltage, and capacity.

Starting with the type of current, with some exceptions, batteries work with DC (Direct Current), and all the hardware components for this prototype work with DC as well. For the voltage, there were the 12 V and 24 V options, however, amongst the hardware components, the highest operating voltage was 12 V, and so that was the operating voltage for the battery. However, since not all the components work at the same voltage, 2 voltage regulators will be needed. As for battery capacity, it is usually measured in Ah (Ampere-hour), and it is obtained using the Peukert equation, written in eq. 6.10:

$$C_p = I^p \times t \tag{6.10}$$

where Cp is Peukert's battery capacity in Ampere-hours (Ah), p is Peukert's exponent which depends on different battery architectures and chemistries, I is the discharge current in Amperes (A), and t is the time of operation in hours [313,314].

The total current that is drawn by the prototype can be estimated by the sum of the maximum current drawn from all the parts of the system, which correspond to the DC motors, CPU, IMU, sonars, and camera, approximately equal to 23 A. Initially, the time of operation was set to one hour, however, the batteries that correspond to this capacity were simply too big and heavy. However, this operation time is continuous and corresponds to the maximum current drawn from the system, and, for this prototype, it is expected that the device only operates at peak performance through small bursts of time. So, a compromise in the operation time was made, reducing it from one hour to twenty minutes. This gives the final battery capacity equal to, approximately, 8 Ah, calculated using eq. 6.11.

$$C_p = 23 \times \frac{20}{60} = 7.67\text{Ah} \tag{6.11}$$

This way was possible to find the Gens Ace lithium-polymer battery [315]. It has a capacity of 8 Ah, meeting the previously identified battery capacity, and a voltage of 14.8 V, accounting for any possible voltage drops during operation. As for the battery type, lithium-polymer was the chosen one because of its higher safety, lightweight (0.74 kg), and low profile (157 x 53 x 43 mm), ideal for the anti-fall cane prototype. A visual representation of the battery can be seen in Fig. 49.

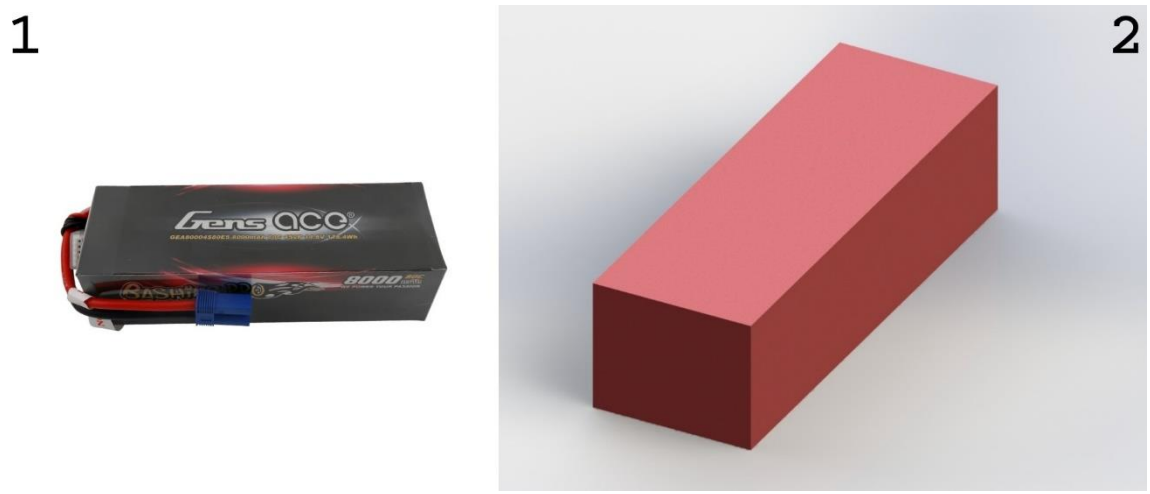


Figure 49: 1: Gens Ace Li-Po battery [315]; 2: SW visual representation

To hold the battery in place, a battery support was designed in the same style as the CPU support, with the only difference being the dimensions (length and width). The final render for the holonomic base and all the surrounding system units can be seen in Fig. 50.

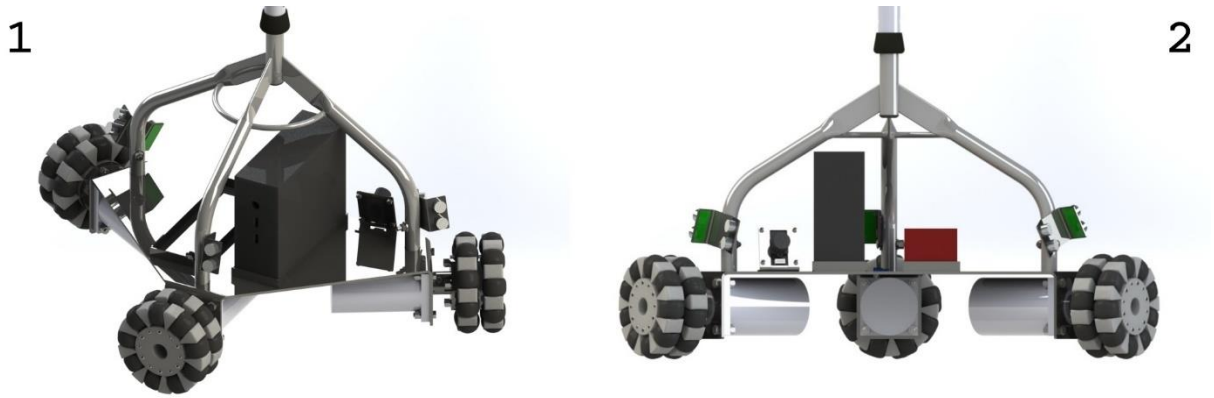


Figure 50: Render of the holonomic base with all the surrounding hardware components. 1: Trimetric view of the interaction between battery support and the holonomic base; 2: Back view checking for battery clearance.

6.2.10. Summary

To summarize all the designed parts and hardware components suggested for the anti-fall cane prototype, table 15 compiles the available information at the time, such as quantity, price, and current drawn. All the weight estimations were done within SW, using plain carbon steel as the material, or using the available information for the item in question. Also, the final renders for the anti-fall prototype cane can be seen in Fig. 51.

Table 15: Summary of all components explored during the analytical prototype elaboration.

Component	Quantity	Weight (Kg)	Current Drawn (A)	Price (per unit)
Holonomic Base	1	1.478	N/A	4.61 €
Omnidirectional Wheel	3	0.35	N/A	22.86 € [303]
DC Motor	3	0.18	7.5	76.75 € [316]
Set Screw Hub	3	0.178	N/A	3.27 €
USB Camera	1	0.048	N/A	33.8 € [317]
Camera Mount	1	0.02	N/A	N/A
IMU	1	N/A	0.0035	4.9 € [318]
Sonar	5	0.011	0.015	35.9 € [319]
CPU	1	0.141	0.42	66.41 € [320]
CPU Support	1	0.05	N/A	0.99 €
Sonar Support (1S)	1	0.01	N/A	N/A
Sonar Support (2S)	2	0.02	N/A	N/A
Battery	1	0.7	N/A	107.22 € [321]
Battery Support	1	0.053	N/A	1 €
Voltage Regulator	2	0.1	N/A	12 € [322]
P1 tripod	1	1	N/A	3.52 €
Total	28	5.919 kg	22.9385 A	733.6 €



Figure 51: Final render of the anti-fall cane prototype, with all the proposed components and features. 1: front view; 2: top view; 3: trimetric view.

6.3. Analytical Validation

Part of the reason for the creation and use of analytical prototypes is the possibility to use and different types of computer-based analyses. This analysis is performed against the target specifications earlier defined, where stress distribution and other Computer-Aided Engineering (CAE) processes can help identify and avoid problems with the model, potentially, eliminating one or more physical prototypes, representing a major time and economic save [292].

In the case of the anti-fall cane prototype, the incorporation of a commercially available product, in the P1 tripod, allows some target specifications to be ignored. Therefore, all the target specifications related to the handle were not verified. Furthermore, the stability, durability, friction, and reliability tests were not validated analytically. Also, the time necessary to make the cane usable, the ACC performance, the style of the cane, and the possible ways to obtain the anti-fall cane were not possible to validate using CAE methods.

6.3.1. Cane manufacturing cost

The price range set during the target specifications chapter was a maximum of 650 €, and the final estimation was, approximately, 734 €. This price is way higher than the established range, mostly because this is the target specification and not the final specification. Furthermore, this is not the price for the final product, rather the first physical prototype of a potential future commercially available product. Thus, all the pieces are one-offs, and all the hardware components are experimental, which later into the project can be deemed unnecessary, unwanted, or overengineered.

6.3.2. Prototype height.

The anti-fall cane height was one of the highest-grade specifications that were previously established, simply because of its importance to the safety and comfort of the user. ISO 11334-4:1999 [260] defines a height value range of 350 – 1100 mm. As seen in Fig. 52, it is possible to predict the cane minimum and maximum height by measuring the distance between the handle and the floor, with the minimum and maximum extension selected. This is done using the measure command, available within SW, between the handle and a fake floor.

Looking at the "dY" coordinate, the predicted height range for the anti-fall cane is, approximately, 846 – 998 mm, values which are well inside the previously defined range. This height range was expected since the original values of the P1 tripod were 800 – 950 mm [323].

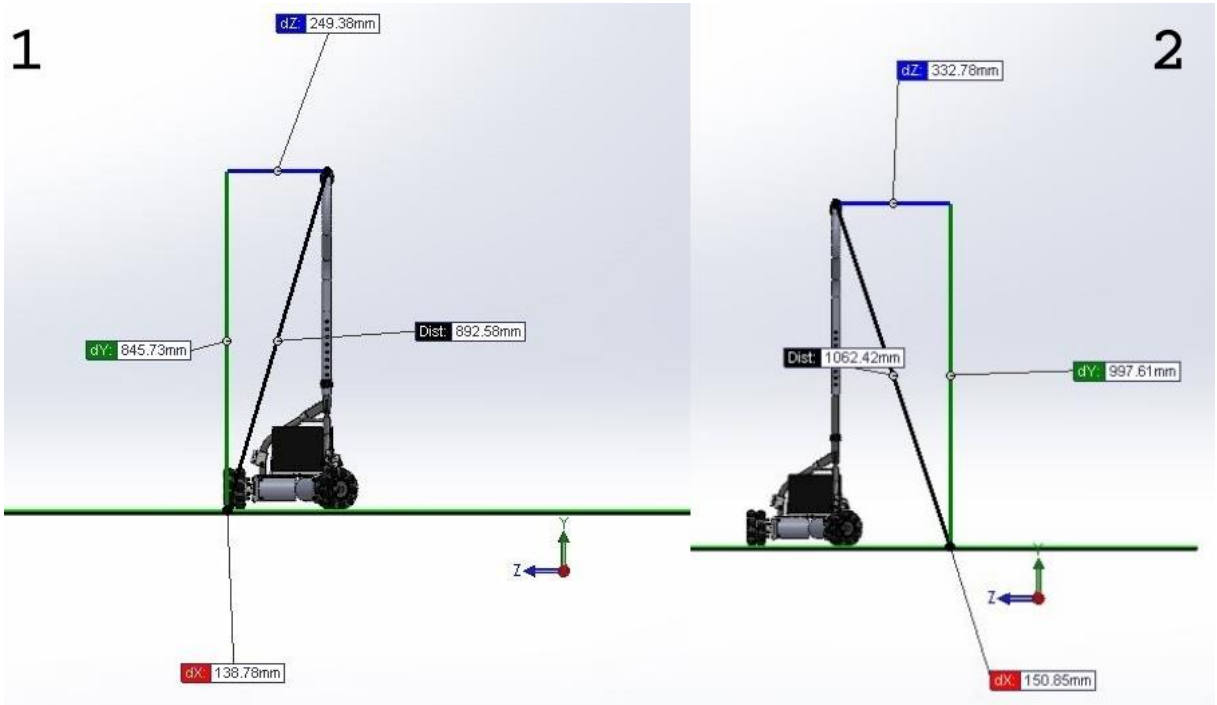


Figure 52: Height prediction of the anti-fall cane prototype. 1: minimum height; 2: maximum height

6.3.3. Static load simulation

Supporting the user is a classic use of the cane, and in the case of this prototype, the ability to support the user's weight without failure is also very important. As previously stated, ISO 11334-4:1999 defines 350 – 1000 N [260] as the range for this test.

The whole point of simulating the static load is to verify if the design will fail under stress. As the selected material for the model is plain carbon steel, a ductile material, the chosen fail criterion was the von Mises's theory which states that a ductile solid will yield when the energy density reaches a critical value for that material (from a uniaxial point of view) [324]. This is translated into eq. 6.12:

$$\sigma_{VM} = \sigma_Y \tag{6.12}$$

where σ_{VM} represents the von Mises's maximum stress and σ_Y the material yield strength (in this case, considered equal to the compression strength). This yield strength represents the limit of elastic behaviour and the beginning of plastic behaviour. If the maximum stress is higher than the yield strength then plastic deformation will occur, resulting in some form of permanent deformation [325]. Naturally, the ideal result would be that the maximum von Mises's stress is lower than the yield strength.

Using the simulation solutions for SW, a static study was conducted on a numbed-down model of the anti-fall cane prototype. Since this test is aimed at the designed actuator, the P1 tripod main aluminium body was removed, leaving only the three legs where the force is distributed, the omnidirectional wheels were also simplified, and all the bolts and nuts were imported using the connectors command within SW simulation. This simplification is detrimental to obtain simulation results that apply to more complex assemblies.

Applying a total force of 1000 N distributed between the three legs, the maximum σ_{VM} is equal to 6.429 e+07 N/m^2, which is lower than the plain carbon steel σ_Y, equal to 2.20594 e+08 N/m^2, as seen in Fig. 53. Therefore, the $\sigma_{VM} < \sigma_Y$ condition is verified and the holonomic base should not fail due to plastic deformation. The minimum FOS equal to 3.4, the maximum strain is 2.011e-04, and the maximum displacement equal to 2.778e-01 mm, which should be negligible since the material always operates in the elastic domain. All the details about the material, mesh, results, and plots for the strain, resultant displacement, and Factor of Safety (FoS) are present in appendix IV.

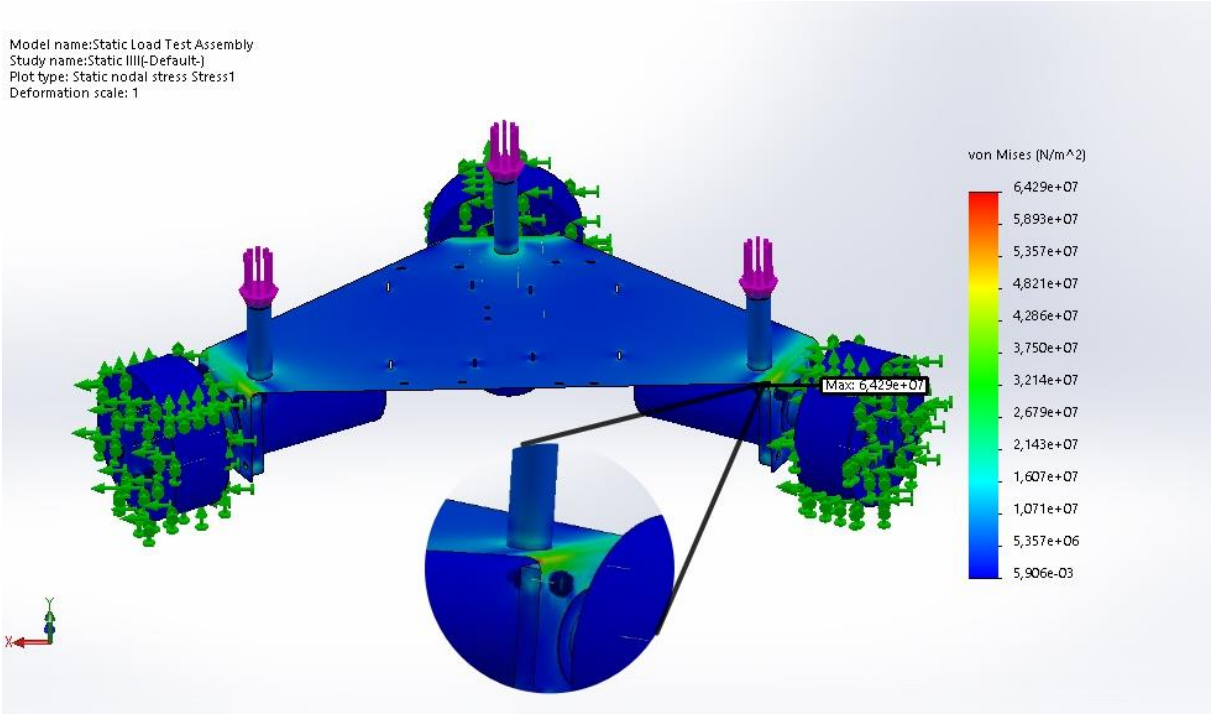


Figure 53: Stress plot obtained in the static load test simulation, where the maximum von Mises's stress is equal to 6.429 e+07 N/m^2, which is lower than the yield strength for plain carbon steel, given by the SW library.

6.3.4. Separation test

A separation test is performed using the same model used in the previous test. The main difference is that a force of 500 N is applied to the lower and upper parts of the prototype. The test is successful if the upper and lower parts do not come apart.

The maximum σ_{VM}, equal to 2.84e+07 N/m^2, is registered in the connection points between the DC motor and the holonomic base, as seen in Fig. 54. Unfortunately, the material that constitutes the motor is not specified. Therefore, searching through the material library of SW, the chosen material for the DC motor was the AISI 1045 steel, a common material used in gears, shafts, and bolts. This metal has a σ_Y equal to 5.3e+08 N/m^2, higher than the plain carbon steel. Therefore, the $\sigma_{VM} < \sigma_Y$ condition is verified and there should not be any fails due to plastic deformation, and no separation between parts of the anti-fall cane. The minimum FOS is 7.4, the maximum strain is 1.230e-04, and the maximum displacement equal to 8.398e-02 mm. Once again, all the details about the material, mesh, results, and plots for the strain, resultant displacement, and FoS are present in appendix IV.

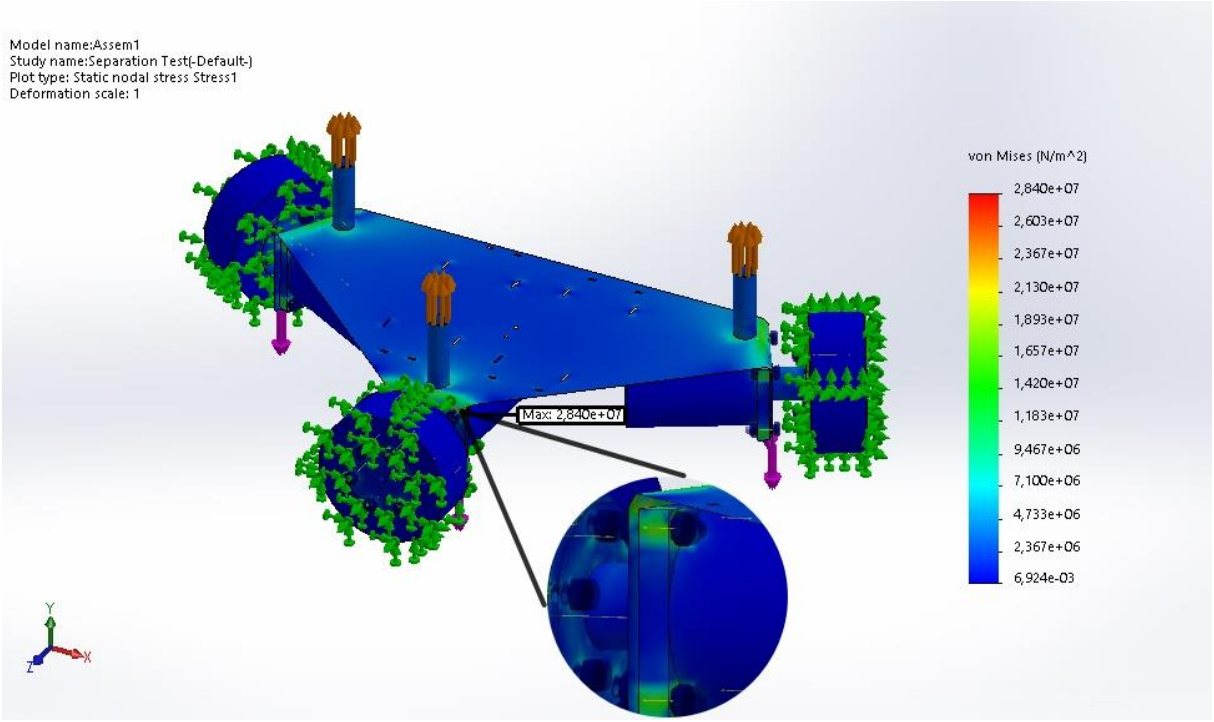


Figure 54: Stress plot obtained in the static load test simulation, where the maximum von Mises's stress is equal to 2.84e+07 N/m^2, value registered in the connection points between the DC motor and the holonomic base.

6.3.5. Fatigue test

One option available within SW advanced simulation solutions is the realization of a fatigue test simulation, which coincides with another specification previously defined. This is possible by using the respective S-N curve model for the material being studied, which compares the alternating stress versus the number of cycles that takes to cause failure [326], [327]. A major setback is that there is no available S-N curve for plain carbon steel, the primary material used in the model. As the fatigue test simulation is heavily influenced by the S-N curve utilized, the fatigue data for the simulation was obtained using the S-N curve for 0.53% Carbon Steel, obtained using the SW material library.

Utilizing the data obtained during the static load simulation, a fatigue test was simulated where a cyclic force of 450 N is applied to the cane during 200000 cycles, as described by the ISO 11334-4:1999 [260]. However, using this setup, no failures occur, indicating that the stress level amplitude is below the endurance limit. The endurance limit represents a stress level below which the material does not fail, and can be cycled infinitely [328]. This corresponds to the infinite life region of the material. Increasing the scale of the load by a factor of 6, for 200000 cycles, the fatigue simulation shows that the highest damage percentage is equal to 77.32%, as seen in Fig. 55, and it occurs in the region on higher stress, identified during the static load simulation. It also shows that, at 6000 N, the model has an approximately life cycle of 258700 cycles, before fatigue failure. These numbers are well above the target

specification, and no fatigue failure is expected. All the details about the material S-N curve and the number of life cycles are present in appendix IV.

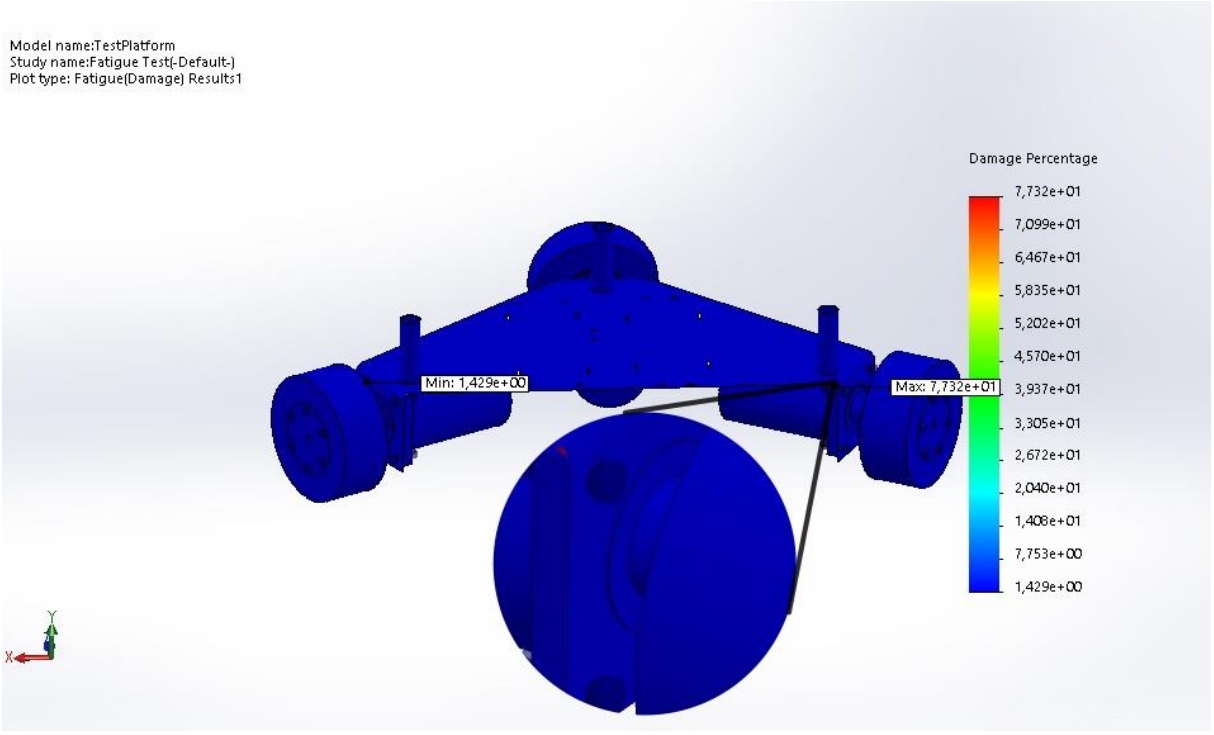


Figure 55: Damage percentage obtained during the fatigue test simulation for a 6000 N fully reversed cyclical force distributed between the three legs. The maximum model damage is equal to 77.32%.

6.4. Physical prototype

The physical prototype is an important part to determine production cost, evaluate and test the device, create a patent, and put the product on the market, as well as, find issues with all the steps mentioned before [292]. For this dissertation, this will be the first physical prototype of the anti-fall cane. Therefore, the main objective is to demonstrate some functionality of the device.

Together with ORTHOS XXI, some features were deemed unnecessary for this phase of the project, namely, all the components and changes related to the sonar and camera system. This would allow for a lower cost and quicker prototype fabrication, without affecting the desired level of functionality.

As previously said, the tripod of the P1 cane had the rubber tips removed. Instead, it is welded to the holonomic base, in pre-determined spots. The holonomic base was created to accommodate the P1 tripod, with the minimal interference possible. This way, the probability that the device introduces dangerous or abnormal gait changes is reduced. Also, the support for the battery and CPU are welded in the pre-determined spots. The transformation process of the anti-fall cane prototype can be seen in Fig. 56. The three motor-to-wheel couplers can be seen on the left, hanging from the top of the tripod.



Figure 56: Exoskeleton of the anti-fall cane prototype, during the fabrication process.

Despite the best efforts of the author, its advisors, and ORTHOS XXI, the final assembly of the anti-fall cane prototype, presented in this dissertation, does not include the hardware components previously dimensioned. Due to bureaucratic problems and shipping stalling, it was not possible to include those components in this build. Nonetheless, they are paid for and on the way to be incorporated into this exoskeleton, with full compatibility. The final build of the anti-fall cane prototype can be seen in Fig. 57.



Figure 57: Final assembly of the anti-fall cane exoskeleton.

6.5. Discussion

After selecting the concept, further development is needed to bring it to reality. This process can be done through prototyping. To simplify this process, the anti-fall cane was divided into four different units. The first big challenge appears when analysing the actuator unit, during the selection of the DC motors. To select the best option, kinematic and dynamic models of the actuator were created and values for angular velocity and torque were obtained. However, the output torque of the selected motor is double the defined value. This difference is explained because there is no information about how much weight the user is going to apply to the device. The information gathered from the literature is related to the classic cane concept, when the cane is fully vertical. There is no way of determining how this specific prototype affects the weight transfer between user and device, especially during a fall-related event. Also, this weight transfer is affected by the condition of the user itself. Considering all these unknown variables, a large safety margin was introduced during the market search for the DC motor.

During the analytical validation, a final estimation of the price was determined to be, approximately, 734 €. This value is above the target specification, 650 €. As said before, this price is subject to change. In this dissertation, optimizations to the prototyping process were done by creating technical models of the product, that help to predict the performance of the components against a set of ideal specifications. Also, a bill of materials for the prototype was developed, however, the model is incomplete because of the unavailability of the manufacturing costs for the pieces that were not produced for the physical prototype. Nonetheless, all the available price information at the time was included, as seen in table 15. When the physical prototype validation is concluded, this cost model will help future teams to refine the specifications, make necessary trade-offs, and set the final manufacturing cost, as well as, all the other final specifications. For example, if tests reveal that the motors are too over-dimensioned, it will be possible to cut costs in the new motors, and battery duration might even increase, with the same hardware.

Another important topic of discussion is the fatigue test simulation. As mentioned before, the simulation setup is not ideal since there is no available S-N curve for the plain carbon steel. Furthermore, the percentage of carbon present is very important for the behaviour of steel. Higher carbon concentrations change hardness, plasticity, and ductility, influencing yield strength, and the S-N curves [329,330]. Nonetheless, considering the results of the simulations, it is possible to state that the holonomic base has an infinite-life design [328] since the anti-fall cane should never operate with 6000 N of force applied to it.

One detail that these simulations reveal is that the maximum stress is applied in the corners of the holonomic base. This is a direct consequence of the holonomic base design. As mentioned during the physical prototype description, the base was designed to accommodate the P1 tripod, with the minimum gait interference possible. Therefore, only a small edge of steel is left between the user and the base, and the stress accumulates on the edges of the base. Also, during the torque calculation, the highest value was found in wheel no. 2, the wheel located furthest from the user. This is also a consequence of the holonomic base because that wheel has a smaller distance to the COM when compared to the other two.

Nonetheless, as the simulation results show, there should not be any failure due to stress or fatigue. Therefore, with all this information, the anti-fall cane prototype can be successfully validated.

7. Conclusions

During this master's thesis, it became evident to the author that fall-related events are a serious problem, resulting in high associated costs, and, more worryingly, can result in death. Therefore, it is detrimental that a highly efficient system is developed to reduce, or even, eliminate falls. Also, the author analysed the trend of cane usage, which was revealed to be ever-increasing. Thus, a hypothesis was formulated - to create a cane-type robot device for real-time fall prevention. The state-of-the-art reveals that most of the scientific efforts are directed to wearable devices, that only detect the fall and have no means to avoid it. Most importantly, there are no anti-fall cane devices commercially available. Thus, a clear market and scientific opportunity were identified, the creation of an anti-fall cane device, capable of detecting, in real-time, the pre-impact phase and avoid the fall.

However, the innovative aspect of this product reveals some challenges. If classic cane itself suffers from abandonment and rejection, by patients well aware of the benefits associated with its use, the anti-fall cane could be affected by the same or even worse problems. Therefore, to reduce the possibility of outcome failure, the author followed a consumer-oriented methodology linked with product design. These steps are important to create a concept, prototype, and future product that align with the end-user, and not impose a device on the consumer. The work developed during this dissertation addresses the lack of implemented tools to evaluate what the user wants and what the product needs to become. Also, an anti-fall cane prototype is proposed and validated.

Chapter 3 tackles what the consumer wants and needs in the cane. Using some of the most common conditions related to high fall rates, broad strokes about what the device could become are set in the

mission statement. After analysing more information regarding typical uses, likes, dislikes, and suggested improvements associated with canes, the result is a hierarchical list of consumer needs, divided into 12 primary needs and 33 secondary needs.

Transforming these needs into metrics, Chapter 4 addresses the translation of the CNs into target specifications. This task was made harder since there was no possibility to benchmark the competitive market, either for unavailability or lack of answers. Nonetheless, resorting to international standards and information available in the literature, every consumer's need was translated into a metric, resulting in a hierarchical list of 18 ideal metrics.

In Chapter 5, a decomposition of the anti-fall cane is performed, creating its functional structure. With the balance recovery mechanism identified as the most critical subproblem in this structure, a creative internal search was conducted with the author, its advisors, and ORTHOS XXI. To select the best concept that originated from this process, a decision matrix was created. Each concept was compared to the product target specifications earlier defined. The result was the selection of the rolling cane concept, with the highest score, equal to 587 points.

With the winning concept selected, further development was done to approach this concept to a real product. This process was done with ORTHOS XXI alongside the author and its advisors. In the first phase, analytical prototypes were created using SolidWorks. These would come a long way in helping the team understand how the working space would be and what its physical appearance/interactions would be. Also, using the data gathered along the development process, components were dimensioned and proposed for each suggested feature. The final result was the analytical validation, where load, separation, and fatigue simulations were performed. The anti-fall cane prototype passed in all of them. Also, an exoskeleton of the prototype was developed with the help of ORTHOS XXI. The team awaits the arrival of the hardware components to progress for physical tests.

The work herein presented enables to answer the RQs outlined in Chapter 1:

- **RQ1:** What a consumer wants and needs when looking to buy and use a cane-related device? This RQ is addressed in Chapter 3.

  The CNs of a cane device are complex, either in quantity or relation. They were summarized in table 7 and 8, where 12 primary needs and 33 secondary needs are categorized in terms of relative importance. Needs such as correct cane height, ergonomy, safety, effectiveness, weight, and reliability being attributed maximum relative importance. On the other hand, needs related to fashion and how easy the device can be obtained were not considered

important for this phase of the project and dissertation. Therefore, minimum relative importance was attributed.

- **RQ2:** What are the metrics associated with consumer needs, that can be translated into real and observable parameters? This RQ is addressed in Chapter 4.

  Table 11 summarizes all the 18 metrics that were identified during this process. As with CNs, every metric needs to be taken into account during product development. However, trade-offs are necessary when future phases arrive. Therefore, metrics related to the handle dimensions, handgrip biocompatibility, the distance from the user's wrist crease to the floor, stability, separation, reliability and friction tests, the total mass of the cane, and ACC performance were attributed maximum relative importance. Once again, the style of the cane and the list of possible ways to obtain the cane were not a priority in this dissertation.

- **RQ3:** What would be the functional structure of the anti-fall cane, essential to generate and select a winning concept? This RQ is addressed in Chapter 5.

  A functional structure for the anti-fall cane was created, since there was no record of previous functional structures for the anti-fall cane, and none was identified in the literature. The first step was the creation of a black box, represented in Fig. 24, where the input is the gait pattern, and the output would be the recovery of the normal gait. The overall function determined for the anti-fall cane is: provide assistance during the gait cycle. Using this function, a functional decomposition was performed, seen in Fig. 25, where the most critical subproblem is identified. As the big problem with this potential product is how the cane would prevent the fall, a search for solutions was conducted. The result was 3 concepts translated into sketches, all potential candidates to solve the identified problem. To select one for further development, a selection matrix was constructed, using all the available information gathered during the previous chapters. The winning concept was the rolling cane, with 587 points.

- **RQ4:** Is the selected concept a valid candidate for further research and development? This RQ is addressed in Chapter 6.

  The final prototype of the anti-fall cane was analytically validated. After selecting the concept that would be further investigated, technical objectives and parameters were defined early, so that maximum probability of success was achieved. Together with ORTHOS XXI and the

author's advisors, an analytical prototype was designed using SW. All the components were dimensioned and proposed, to address the features earlier defined. Taking into account information available in international standards and general literature, simulations were conducted to evaluate how the prototype would perform in certain scenarios. The load, separation, and fatigue tests were all successfully passed. Also, the cane height was not badly influenced by the addition of the actuator unit. The only parameter that was negatively influenced was the manufacturing price. Also, the exoskeleton of the anti-fall cane was assembled, and all the hardware components, except for the sonar and camera systems, were bought.

7.1. Future Work

In future work, one of the most important steps will be the installation of the hardware components, such as the motors and battery. This should be the next phase since all the hardware is already ordered. As the analytical validation of the prototype reveals, there is no reason to believe that the components would not fit, or have any other negative interaction between them or the device. However, all the information and specifications were obtained online, through different sources. Therefore, some parameters that were predicted might differ, e.g., the cane total weight. So, there should be a physical validation of the prototype, to guarantee that all the pieces are up to spec.

If the team deems this prototype without any major design flaw, a protective shell needs to be designed. Since all the components are exposed in the actuator unit, the user should not be in contact with any of them. This can cause safety issues for the patient, and component failure for the device.

The prototype should then be used to evaluate real-life applications, and gait patterns/behaviour. These tests should be performed using all the information available in Chapter 4. This is another step in the right direction since this could reveal problems that are impossible to predict using only analytical methods. This dissertation approximates the prototype to a real product through different tools, however, testing, if possible, with cane users with pathologies previously identified, can reveal and solve some of the most complex problems. For example, the motors used could have the correct characteristics, or be too over-engineered.

Also, during these trials with patients, the consumer needs and their relative importance, should be addressed. Thus, the more direct approach with the end-user will surely reveal useful information. The incorporation of previous work developed in the BiRD Lab, regarding the instrumentation of anti-fall cane, will be crucial for the market success of the anti-fall cane. Also, together with the development of intuitive

graphical solutions and other advanced computational tools, the final specifications of the product can be set. This would lead to the creation of a potential second prototype, a more refined version of the anti-fall cane prototype.

In more distant phases, the fashion/style of the can should be addressed. Also, if this concept reveals itself to be successful in all the tasks that need to be performed on flat surfaces, a search for potential adaptations or solutions to integrate this system in other contexts should be a priority. The inclusion of GPS and other connectivity tools should approximate the anti-fall cane to a broader audience, increasing the chance of success of this device.

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APPENDICES

Appendix I

This appendix contains examples of the mobility assessment tools explored during the second chapter.

Table 16: Elderly Mobility Scale (EMS) [331]

Task	Date			
Lying to Sitting	2 Independent 1 Needs help of 1 person 0 Needs help of 2+ people			
Sitting to Lying	2 Independent 1 Needs help of 1 person 0 Needs help of 2+ people			
Sitting to Standing	3 Independent in under 3 seconds 2 Independent in over 3 seconds 1 Needs help of 1 person 0 Needs help of 2+ people			
Standing	3 Stands without support and able to reach 2 Stands without support but needs support to reach 1 Stands but needs support 0 Stands only with physical support of another person			
Gait	3 Independent (+ / - stick) 2 Independent with frame 1 Mobile with walking aid but erratic/unsafe 0 Needs physical help to walk or constant supervision			
Timed Walk (6 meters)	3 Under 15 seconds 2 16-30 seconds			

Table 16: Elderly Mobility Scale (EMS) [331]

Task	Date			
	1 Over 30 seconds 0 Unable to cover 6 meters *Recorded time in seconds*			
Functional Reach	4 Over 20 cm 2 10-20 cm 0 Under 10 cm *Actual reach in centimeters*			
	Scores	/20	/20	/20

Table 17: MDS-UPDRS Score Sheet [206]. Each part and sub-part has further instructions to the examiner and the patient.

Patient Name or Subject ID	Site ID	(mm-dd-yyyy) Assessment Date	Investigator's Initials
_____	___ ___ ___	_____ - _____ - _____	___ ___ ___

MDS UPDRS Score Sheet

1.A	Source of information	☐ Patient ☐ Caregiver ☐ Patient + Caregiver	3.3b	Rigidity– RUE	
			3.3c	Rigidity– LUE	
Part I			3.3d	Rigidity– RLE	
1.1	Cognitive impairment		3.3e	Rigidity– LLE	
1.2	Hallucinations and psychosis		3.4a	Finger tapping– Right hand	
1.3	Depressed mood		3.4b	Finger tapping– Left hand	
1.4	Anxious mood		3.5a	Hand movements– Right hand	
1.5	Apathy		3.5b	Hand movements– Left hand	
1.6	Features of DDS		3.6a	Pronation- supination movements– Right hand	
1.6a	Who is filling out questionnaire	☐ Patient ☐ Caregiver ☐ Patient + Caregiver	3.6b	Pronation- supination movements– Left hand	
			3.7a	Toe tapping– Right foot	
1.7	Sleep problems		3.7b	Toe tapping– Left foot	
1.8	Daytime sleepiness		3.8a	Leg agility– Right leg	
1.9	Pain and other sensations		3.8b	Leg agility– Left leg	
1.10	Urinary problems		3.9	Arising from chair	
1.11	Constipation problems		3.10	Gait	
1.12	Light headedness on standing		3.11	Freezing of gait	
1.13	Fatigue		3.12	Postural stability	
Part II			3.13	Posture	
2.1	Speech		3.14	Global spontaneity of movement	
2.2	Saliva and drooling		3.15a	Postural tremor– Right hand	
2.3	Chew ing and sw allow ing		3.15b	Postural tremor– Left hand	
2.4	Eating tasks		3.16a	Kinetic tremor– Right hand	
2.5	Dressing		3.16b	Kinetic tremor– Left hand	
2.6	Hygiene		3.17a	Rest tremor amplitude– RUE	
2.7	Handw riting		3.17b	Rest tremor amplitude– LUE	
2.8	Doing hobbies and other activities		3.17c	Rest tremor amplitude– RLE	
2.9	Turning in bed		3.17d	Rest tremor amplitude– LLE	
2.10	Tremor		3.17e	Rest tremor amplitude– Lip/jaw	
2.11	Getting out of bed		3.18	Constancy of rest tremor	
2.12	Walking and balance			Were dyskinesias present?	☐ No ☐ Yes
2.13	Freezing			Did these movements interfere w ith ratings?	☐ No ☐ Yes
3a	Is the patient on medication?	☐ No ☐ Yes		Hoehn and Yahr Stage	
3b	Patient's clinical state	☐ Off ☐ On	**Part IV**		
3c	Is the patient on levodopa?	☐ No ☐ Yes	4.1	Time spent w ith dyskinesias	
3.C1	If yes, minutes since last dose:		4.2	Functional impact of dyskinesias	
Part III			4.3	Time spent in the OFF state	
3.1	Speech		4.4	Functional impact of fluctuations	
3.2	Facial expression		4.5	Complexity of motor fluctuations	
3.3a	Rigidity– Neck		4.6	Painful OFF-state dystonia	

Table 18: Modified HY scale [211]. Compared to the original HY scale, the modified version added the 1.5 and 2.5 stages for a better description of the progression of Parkison's disease. The descriptions of each stage are summaries of the original and more narrative descriptions.

Modified Hoehn and Yahr Staging Scale	
Stage	Description
1.0	Unilateral involvement only
1.5	Unilateral and axial involvement
2.0	Bilateral involvement without impairment of balance
2.5	Mild bilateral disease with recovery on pull test
3.0	Mild to moderate bilateral disease; some postural instability; physically independent
4.0	Severe disability; still able to walk or stand unassisted
5.0	Wheelchair-bound or bedridden unless aided

Table 19: Berg Balance Scale (BBS) [332]. Each item has further instructions for the examiner and the patient.

Berg Balance Tests and Rating Scale	
Patient Name:	
Date:	
Location:	
Rater:	
Item description score	Score (0-4)
1. Sitting to standing	_____
2. Standing unsupported	_____
3. Sitting unsupported	_____
4. Standing to sitting	_____
5. Transfers	_____
6. Standing with eyes closed	_____
7. Standing with feet together	_____
8. Reaching forward with outstretched arm	_____
9. Retrieving object from floor	_____
10. Turning to look behind	_____
11. Turning 360 degrees	_____

Table 19: Berg Balance Scale (BBS) [332]. Each item has further instructions for the examiner and the patient.

Berg Balance Tests and Rating Scale	
12. Placing alternate foot on stool	_____
13. Standing with one foot in front	_____
14. Standing on one foot	_____
	TOTAL _____

Appendix II

This appendix englobes the two extra hand-made sketches for the double servo cane concept, produced during Chapter 5.

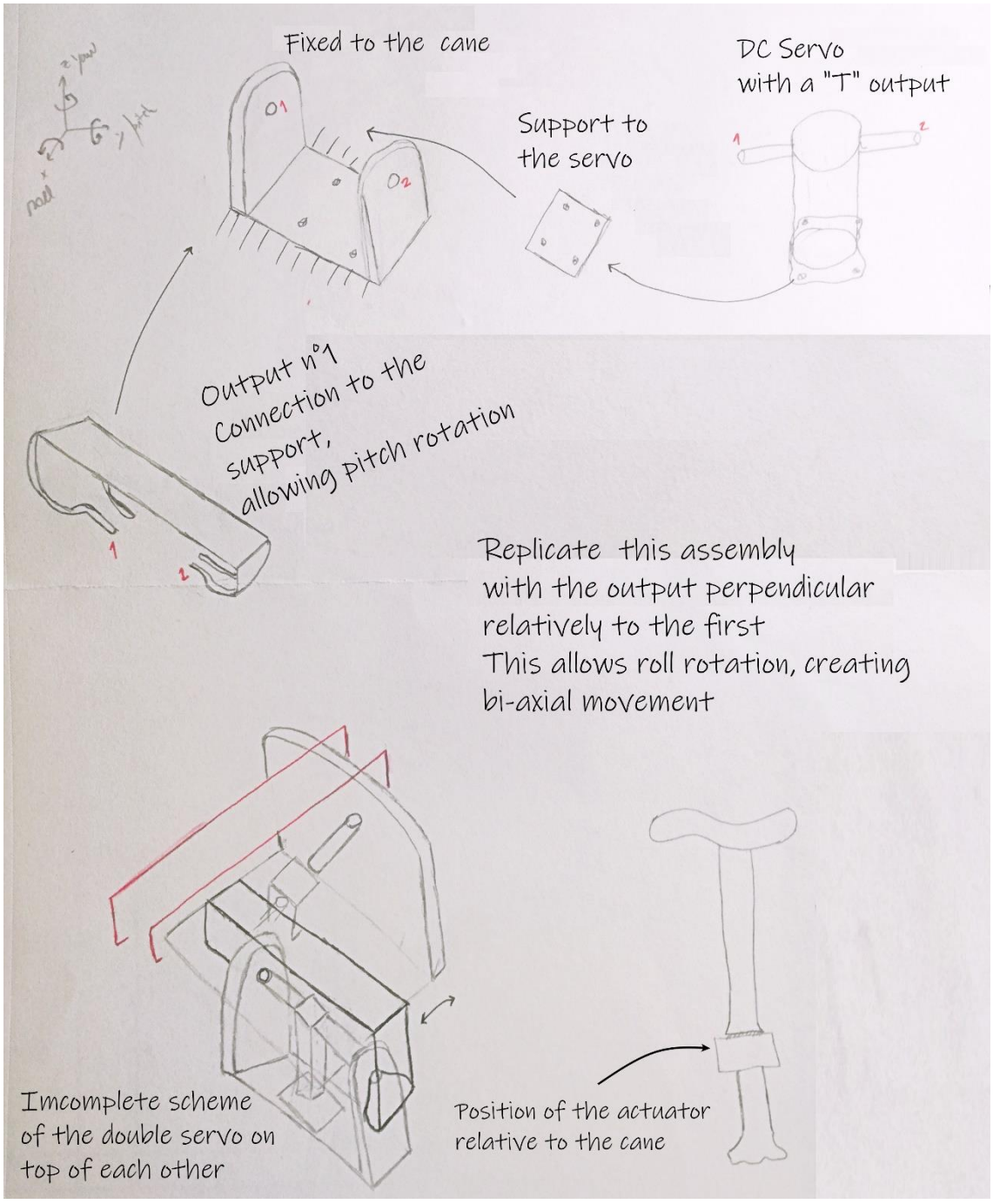


Figure 58: Second representative sketch of the actuator for the double servo cane concept.

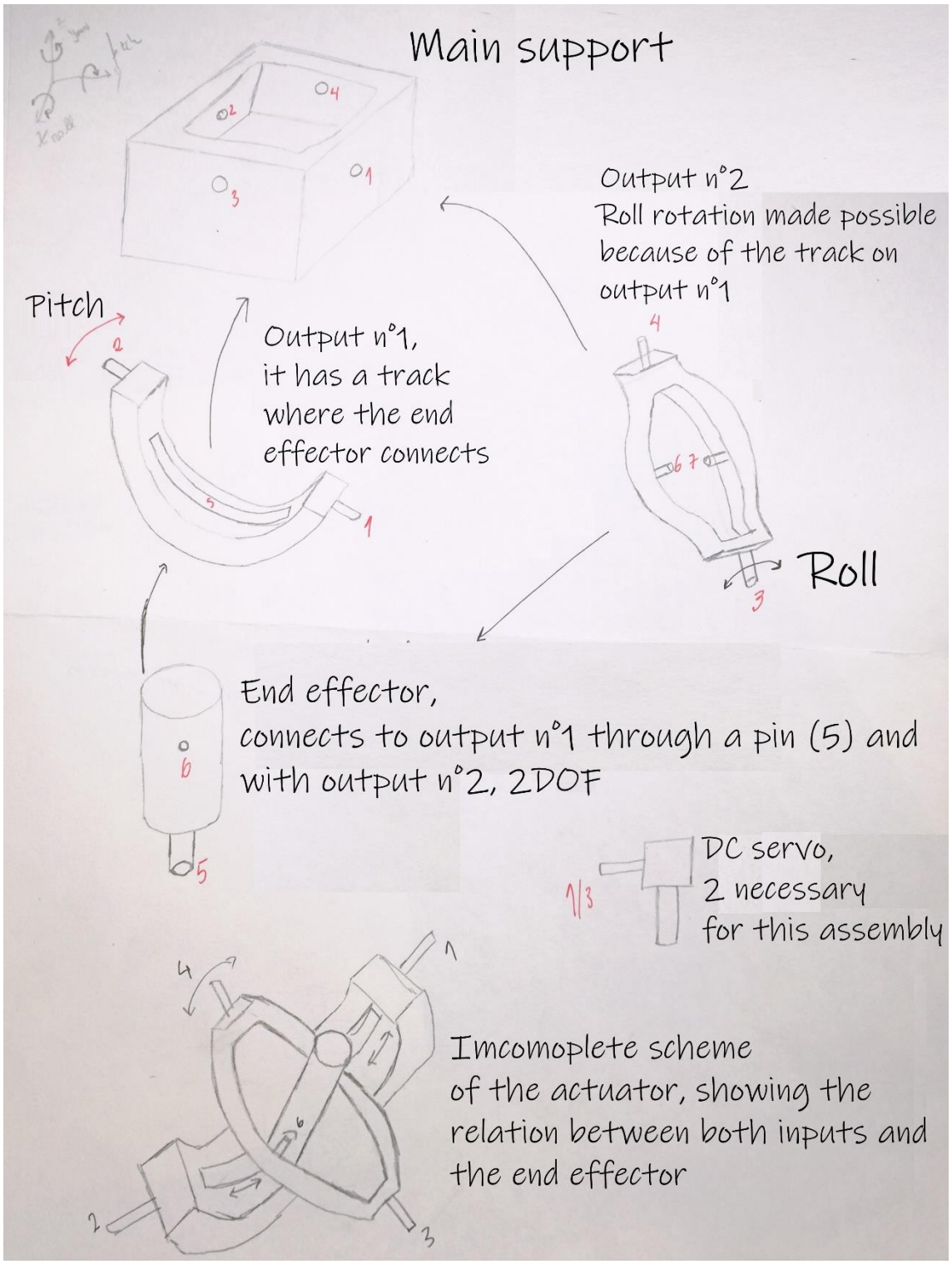


Figure 59: Third representative sketch of the actuator for the double servo cane concept.

Appendix III

This appendix contains all the 2D technical drawings constructed during the prototype build and other technical information for the remaining hardware components.

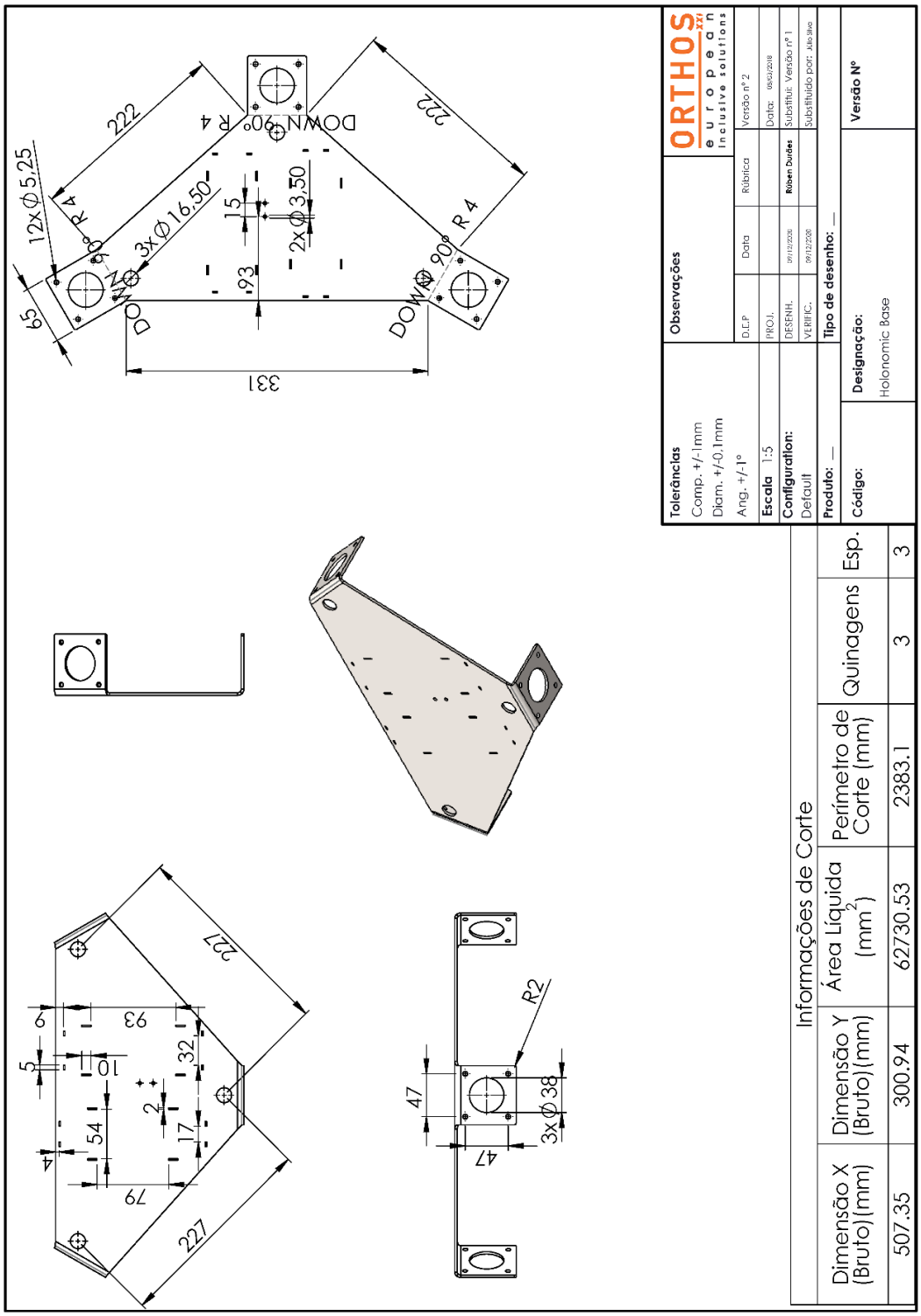


Figure 60: 2D drawing of the holonomic base, all dimensions are in millimeters. This piece is obtained by laser cutting.

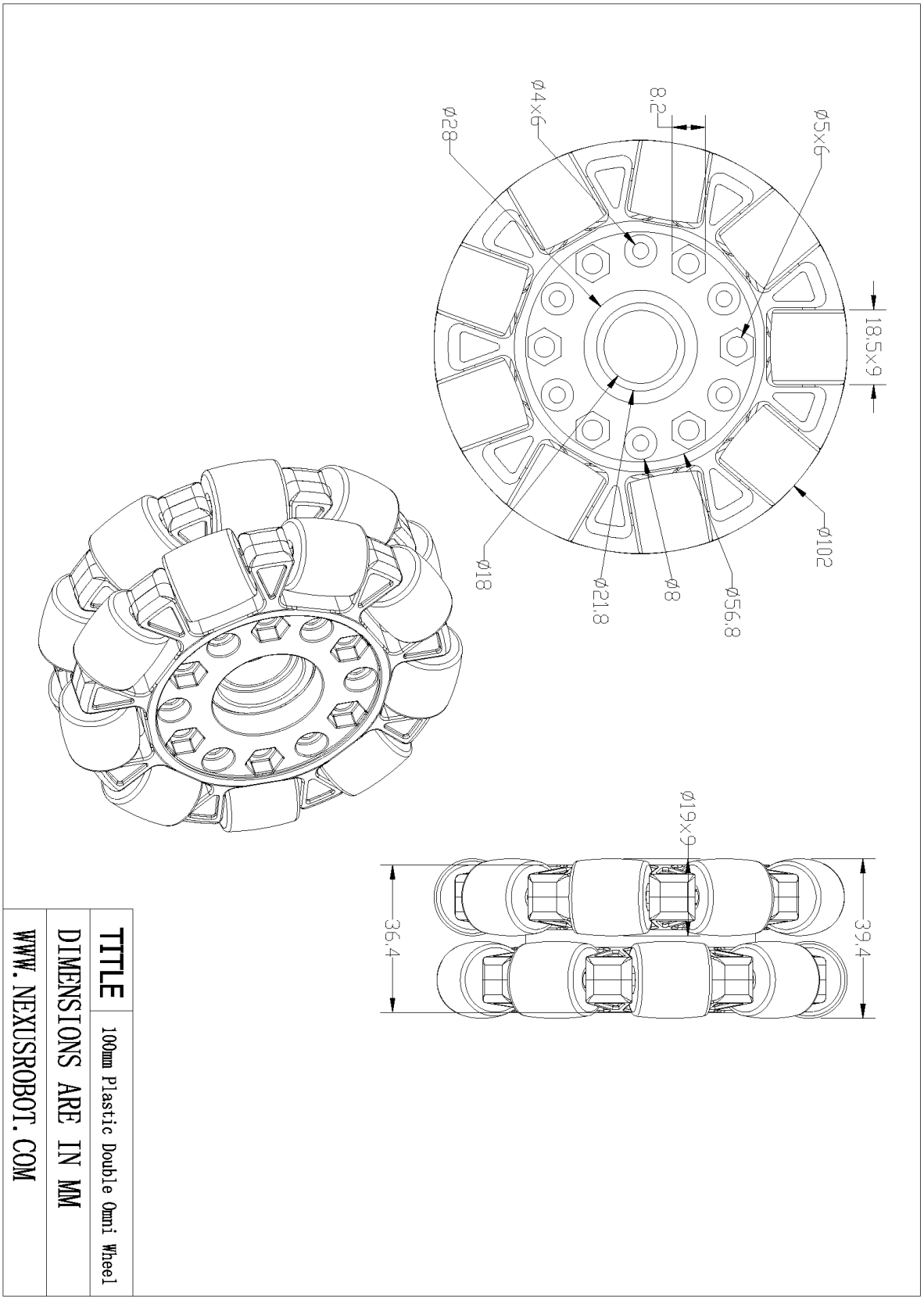


Figure 61: Omnidirectional wheel layout.

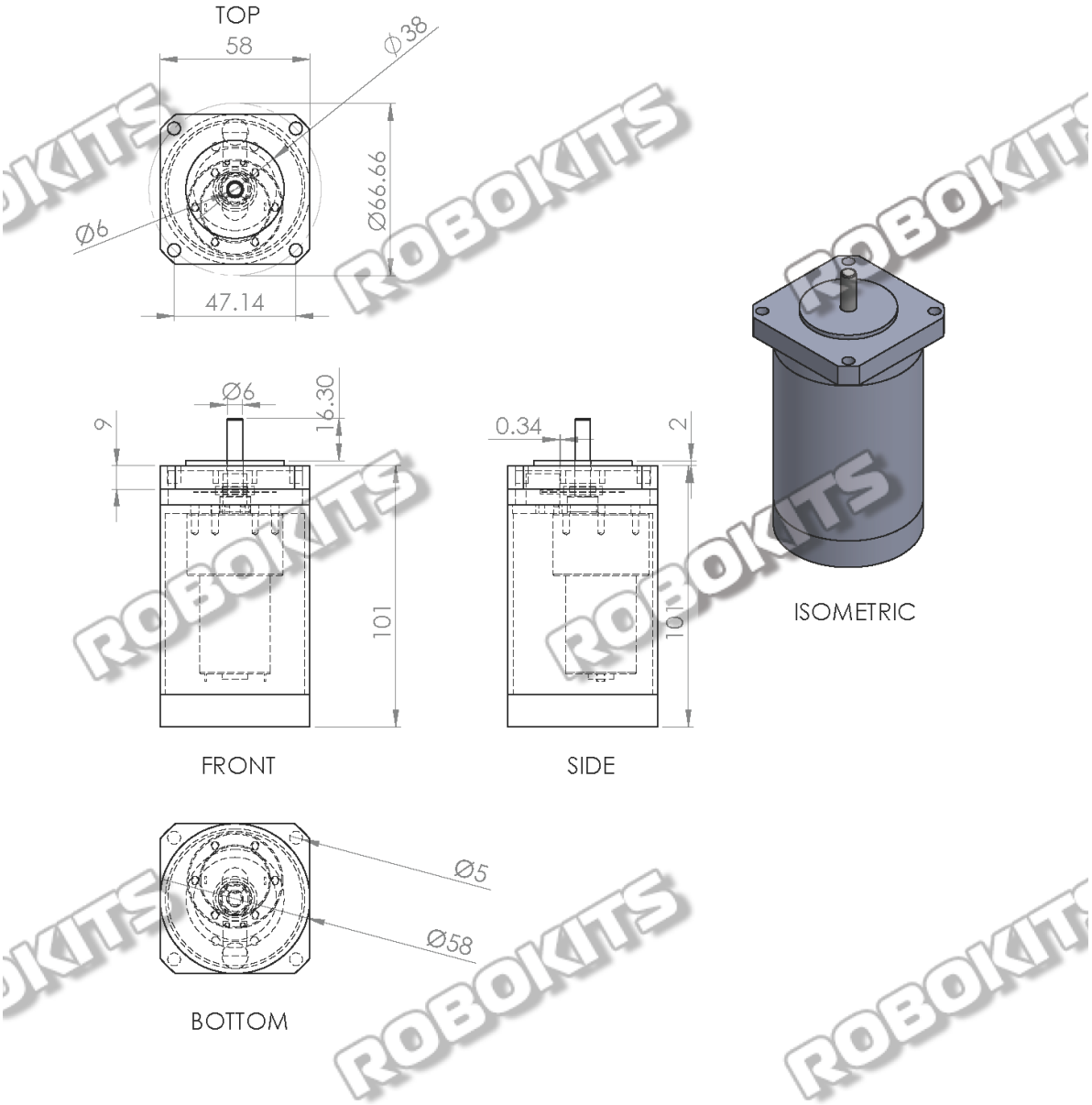


Figure 62: Dimensions, in millimeters, for the DC motor RMCS-22xx [304]

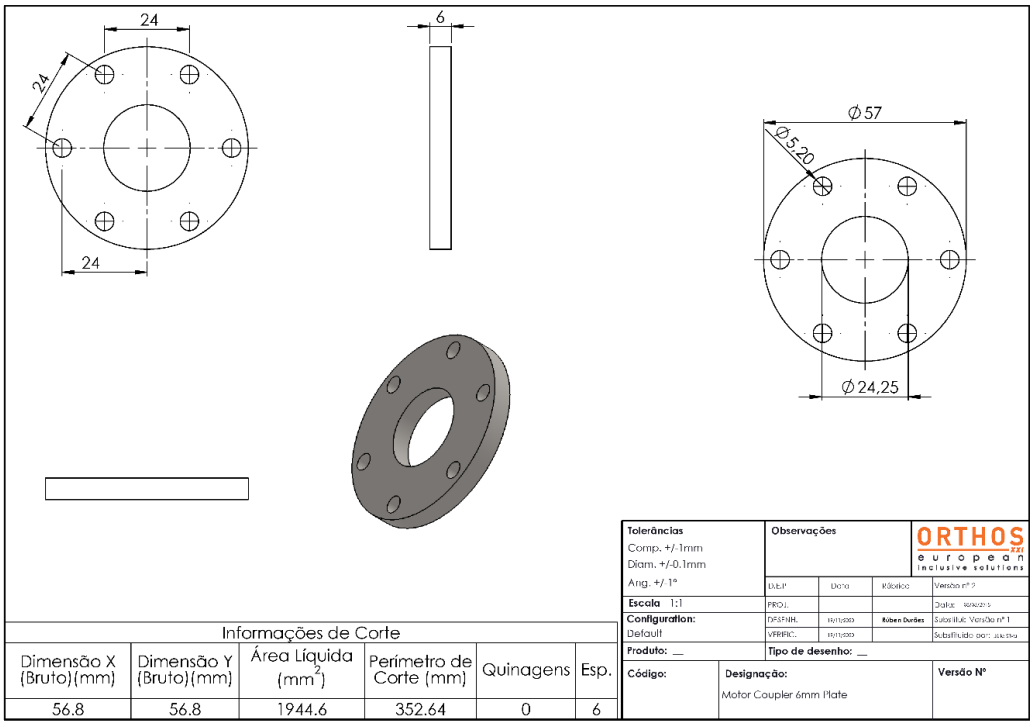


Figure 63: 2D drawing for one of the pieces of the set screw hub, all dimensions are in millimeters. This plate is obtained using laser cutting

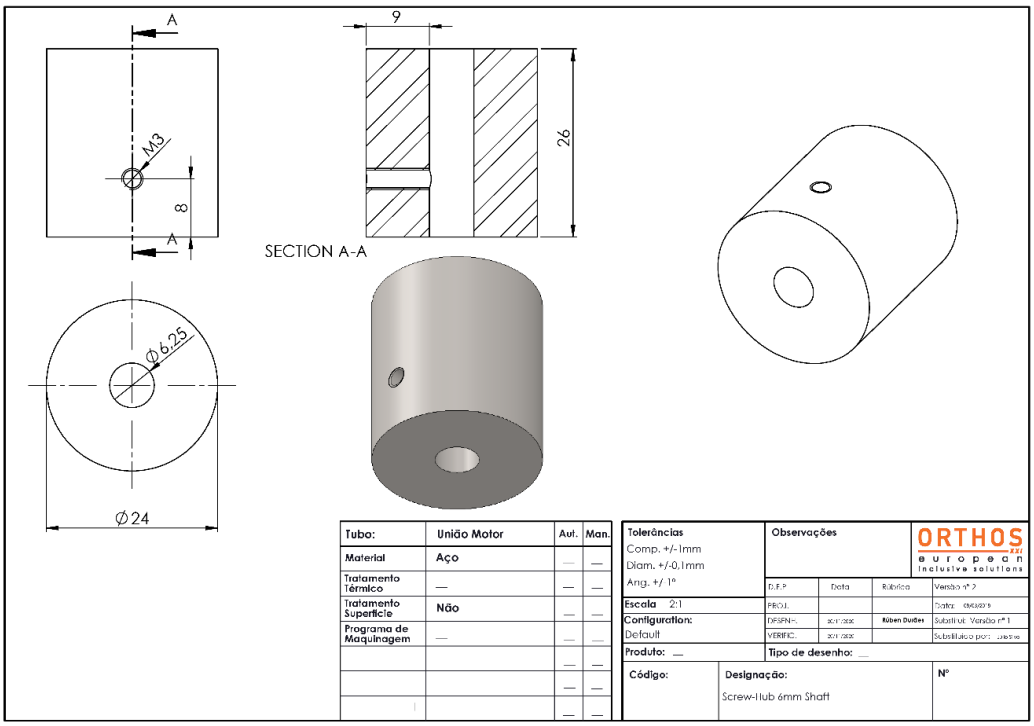


Figure 64: 2D drawing of the second piece of the set screw hub, all dimensions are in millimeters. This piece is obtained using a lathe.

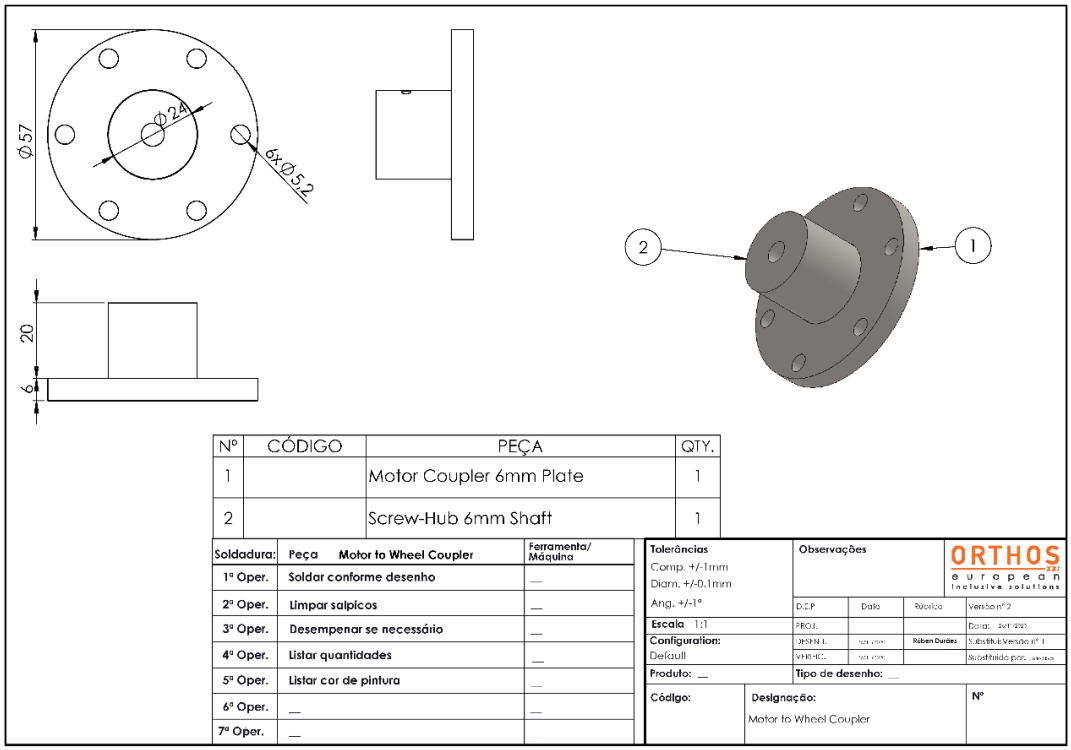


Figure 65: Welding instructions for the set screw hub, all dimensions are in millimeters.

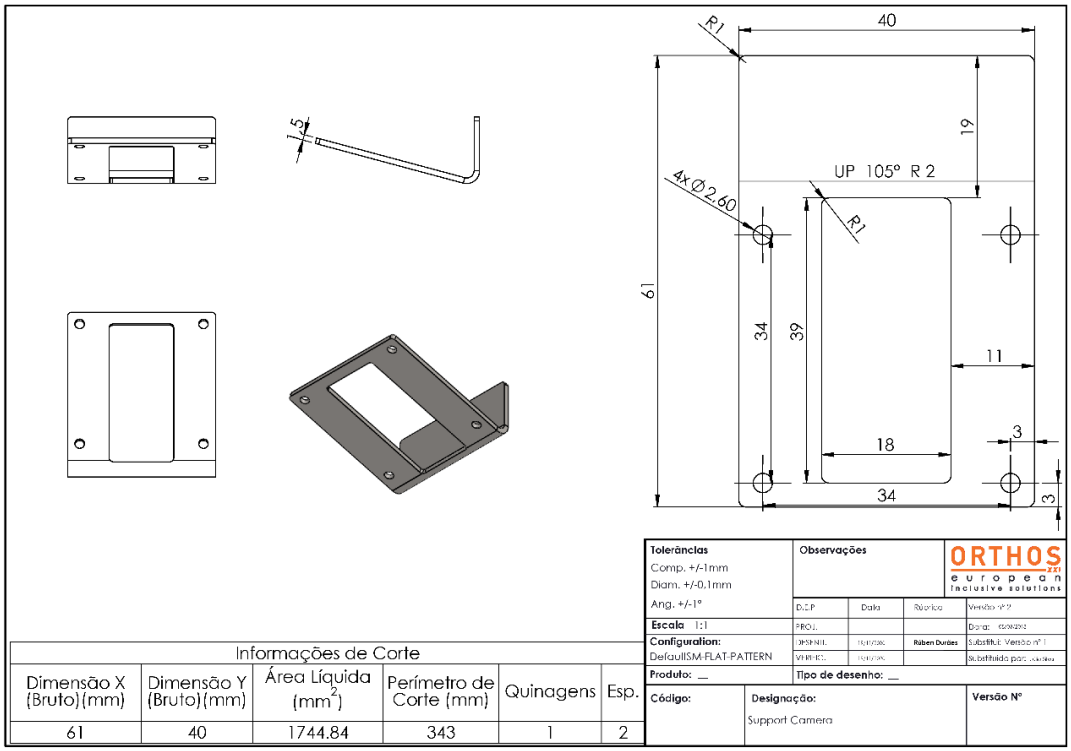


Figure 66: 2D drawing for the camera support, all dimensions are in millimeters. This piece is obtained using laser cutting.

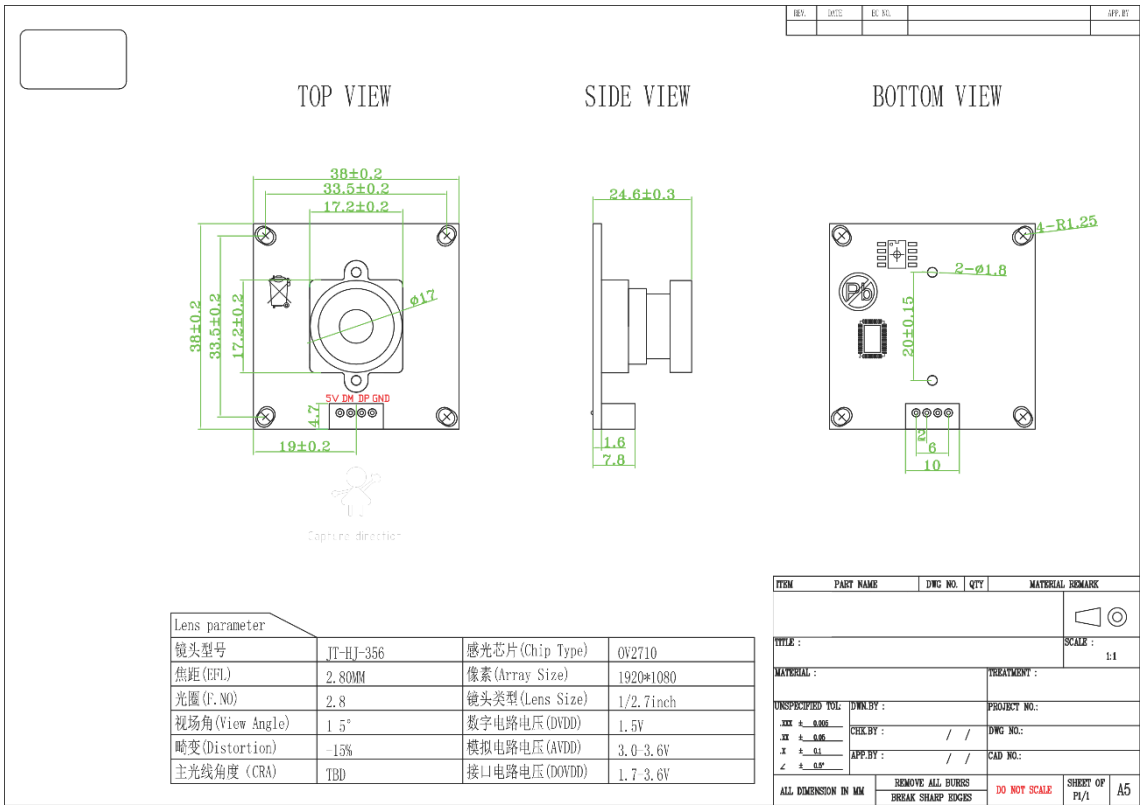
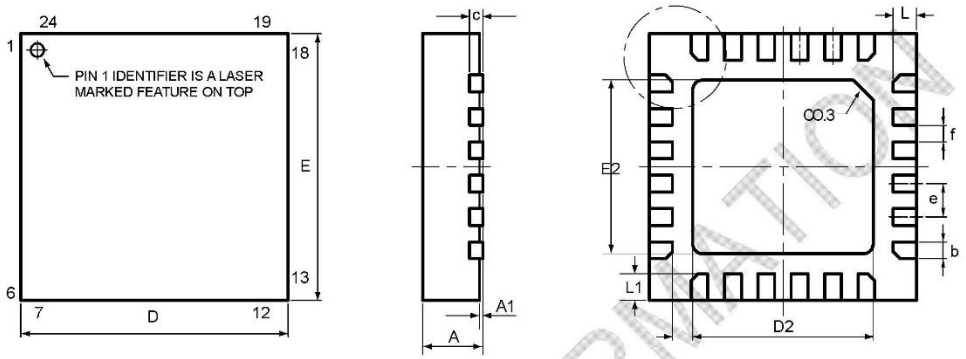
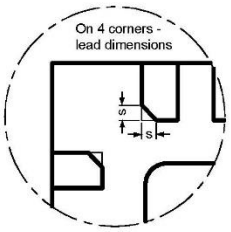


Figure 67: Datasheet for the USB camera, all dimensions are in millimeters [305].

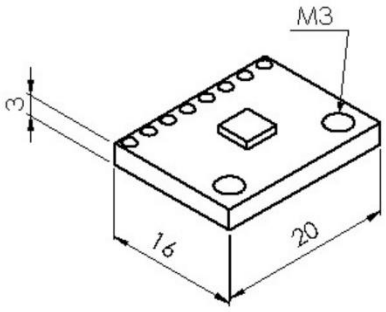
11.2 Package Dimensions

24 Lead QFN (4x4x0.9) mm NiPdAu Lead-frame finish



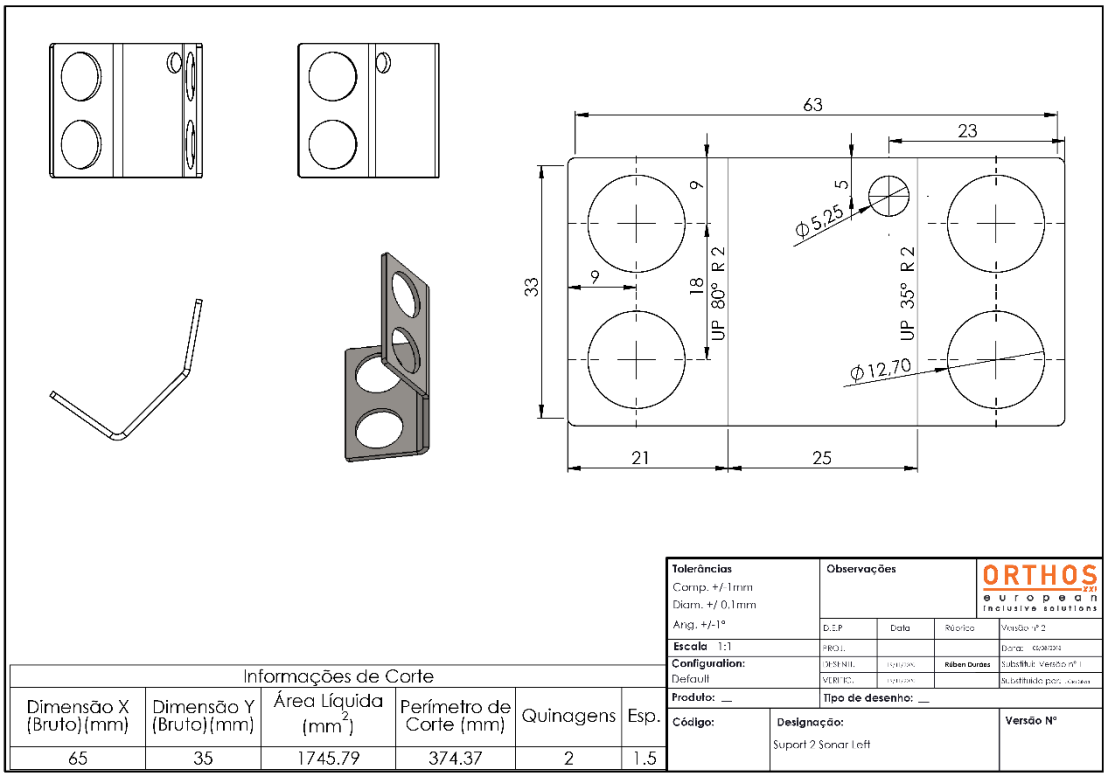


SYMBOLS	DIMENSIONS IN MILLIMETERS		
	MIN	NOM	MAX
A	0.85	0.90	0.95
A1	0.00	0.02	0.05
b	0.18	0.25	0.30
c	---	0.20 REF	---
D	3.90	4.00	4.10
D2	2.65	2.70	2.75
E	3.90	4.00	4.10
E2	2.55	2.60	2.65
e	---	0.50	---
f (e-b)	---	0.25	---
K	0.25	0.30	0.35
L	0.30	0.35	0.40
L1	0.35	0.40	0.45
s	0.05	---	0.15



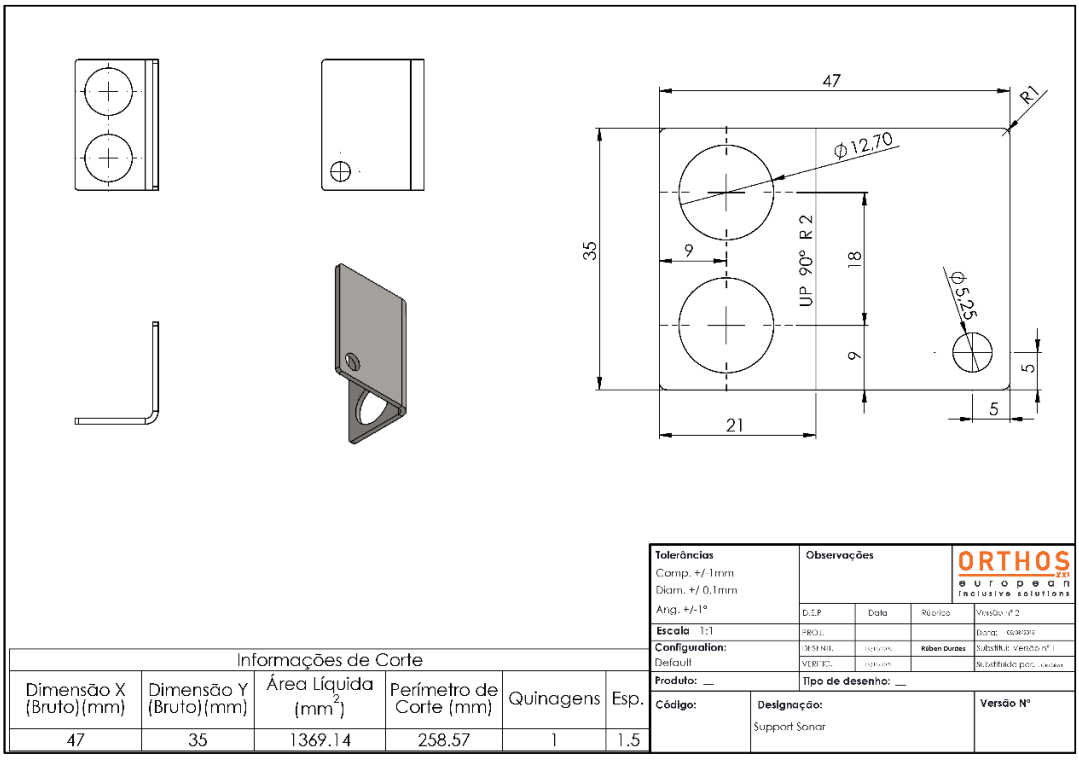
ADVANCE INFORMATION

Figure 68: Package dimensions of the IMU MPU-6050, all dimensions are in millimeters. [307]



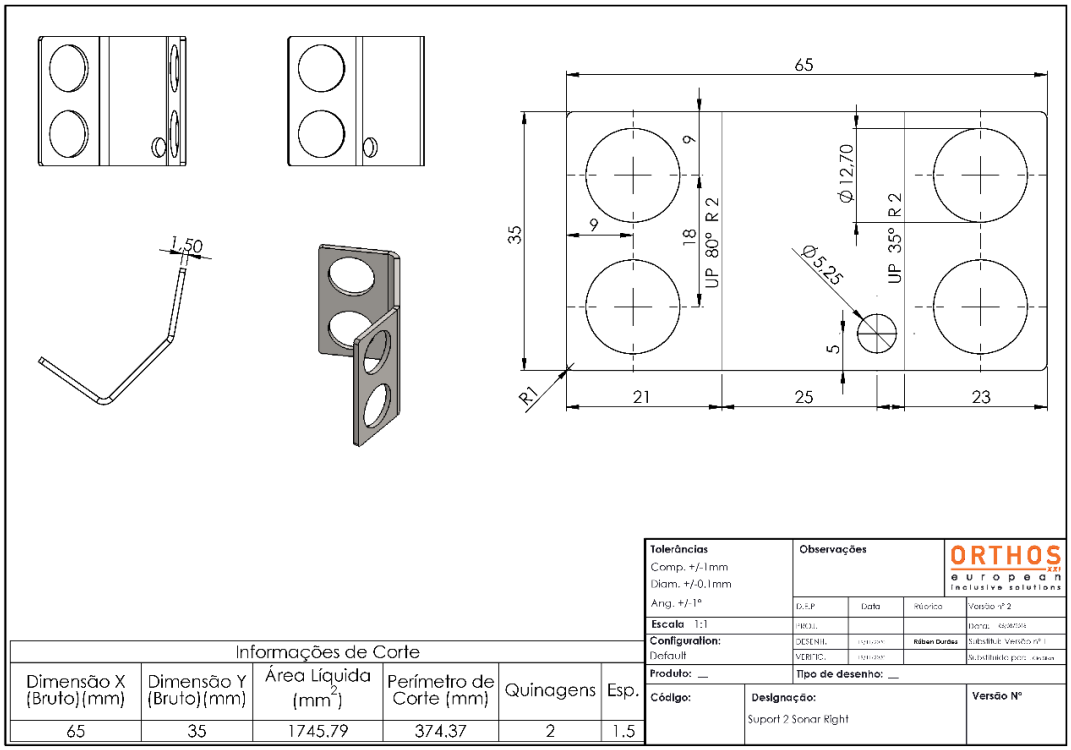
Informações de Corte					
Dimensão X (Bruto)(mm)	Dimensão Y (Bruto)(mm)	Área Líquida (mm^2)	Perímetro de Corte (mm)	Quinagens	Esp.
65	35	1745.79	374.37	2	1.5

Figure 69: 2D drawing for the left sonar support, all dimensions are in millimeters. This piece can be obtained using laser cutting.



Informações de Corte					
Dimensão X (Bruto)(mm)	Dimensão Y (Bruto)(mm)	Área Líquida (mm^2)	Perímetro de Corte (mm)	Quinagens	Esp.
47	35	1369.14	258.57	1	1.5

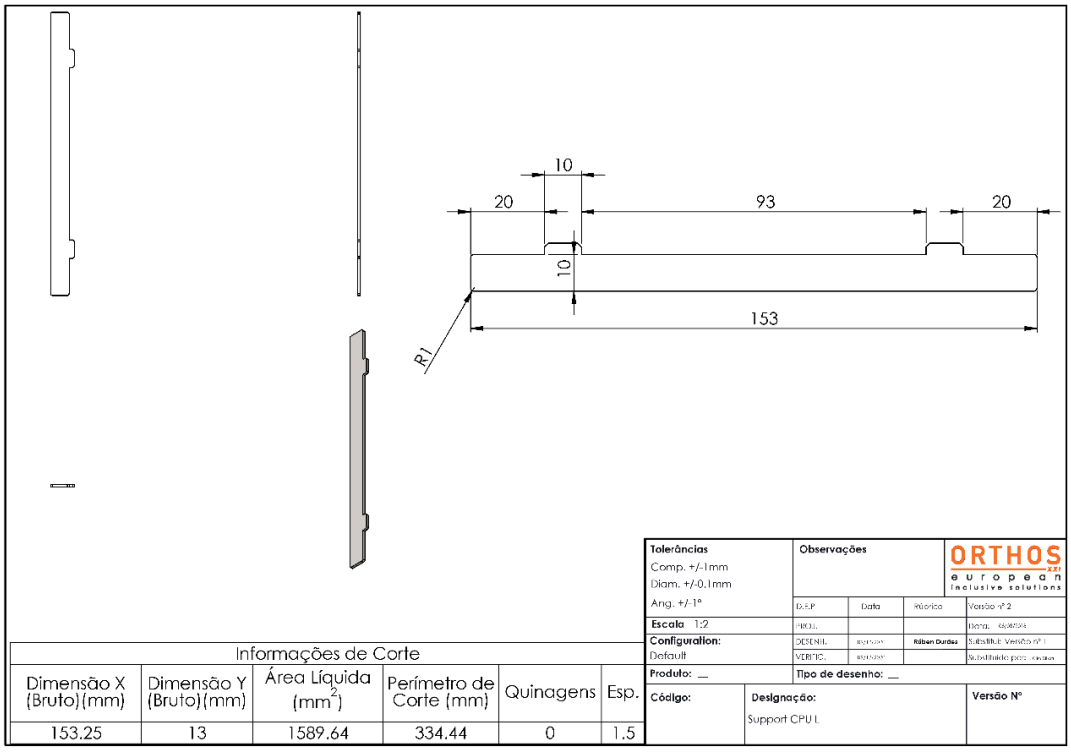
Figure 70: 2D drawing for the front sonar support, all dimensions are in millimeters. This piece can be obtained using laser cutting.



Informações de Corte

Dimensão X (Bruto) (mm)	Dimensão Y (Bruto) (mm)	Área Líquida (mm^2)	Perímetro de Corte (mm)	Quinagens	Esp.
65	35	1745.79	374.37	2	1.5

Figure 71: 2D drawing for the right sonar support, all dimensions are in millimeters. This piece can be obtained through laser cutting.



Informações de Corte

Dimensão X (Bruto) (mm)	Dimensão Y (Bruto) (mm)	Área Líquida (mm^2)	Perímetro de Corte (mm)	Quinagens	Esp.
153.25	13	1589.64	334.44	0	1.5

Figure 72: 2D drawing for the larger piece of the CPU support, all dimensions are in millimeters. This piece can be obtained through laser cutting.

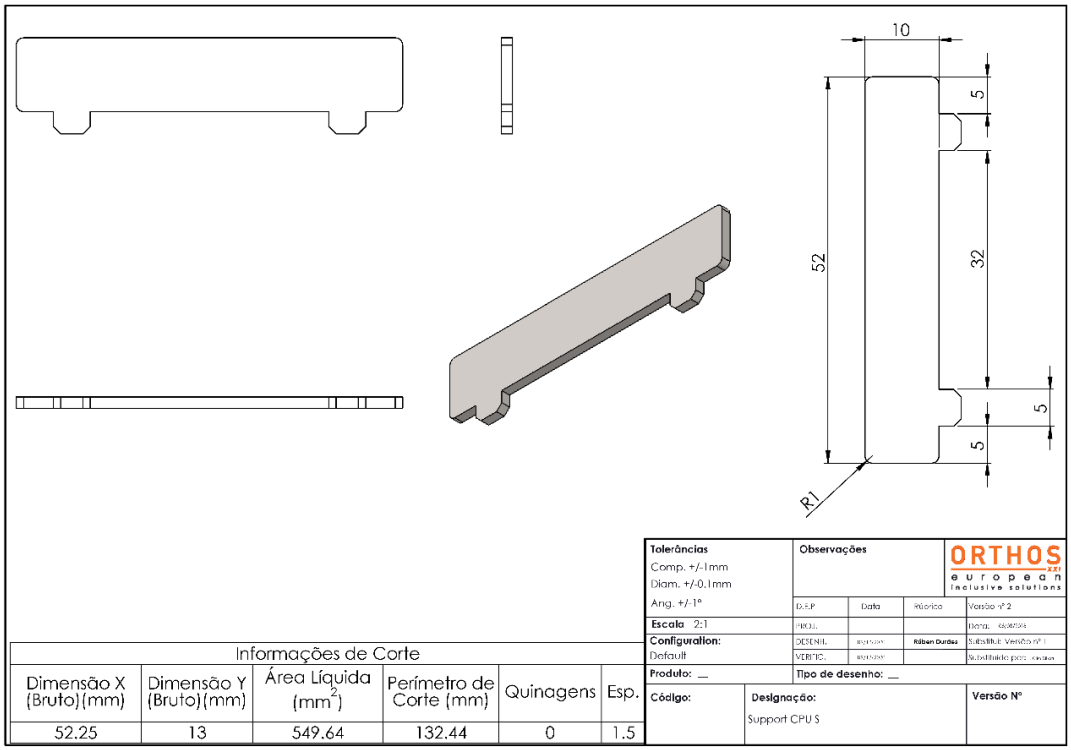


Figure 73: 2D drawing for the smaller piece of the CPU support, all dimensions are in millimeters. This piece can be obtained through laser cutting.

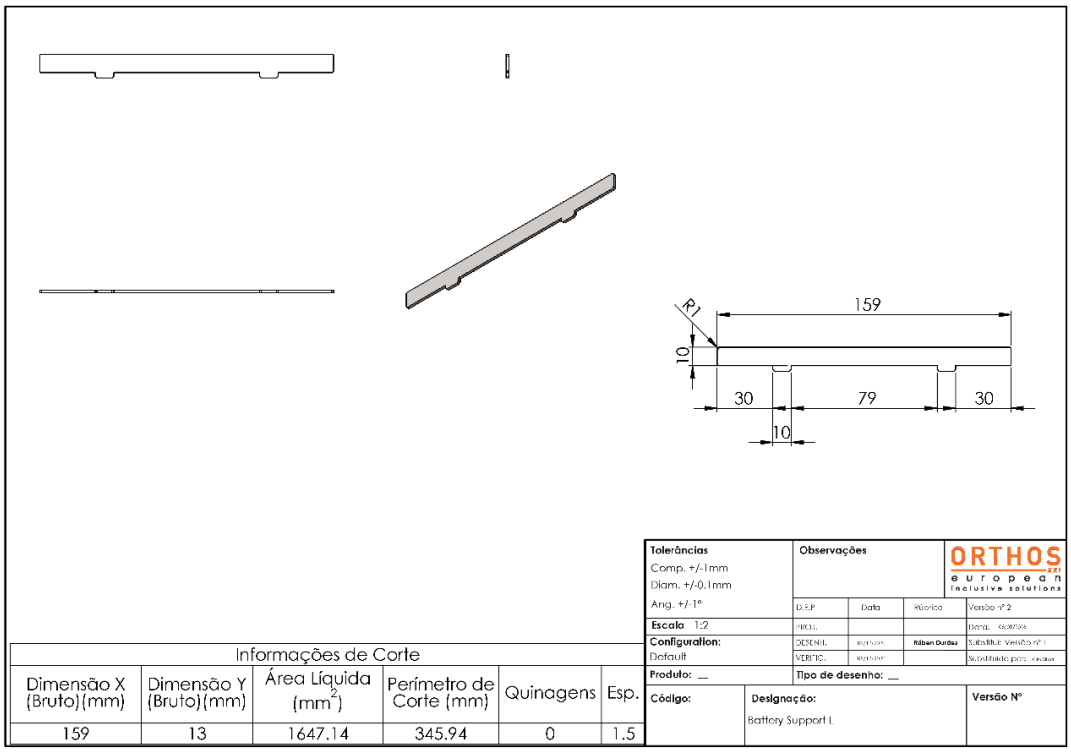


Figure 74: 2D drawing for the bigger piece of the battery support, all dimensions are in millimeters. This piece can be obtained through laser cutting.

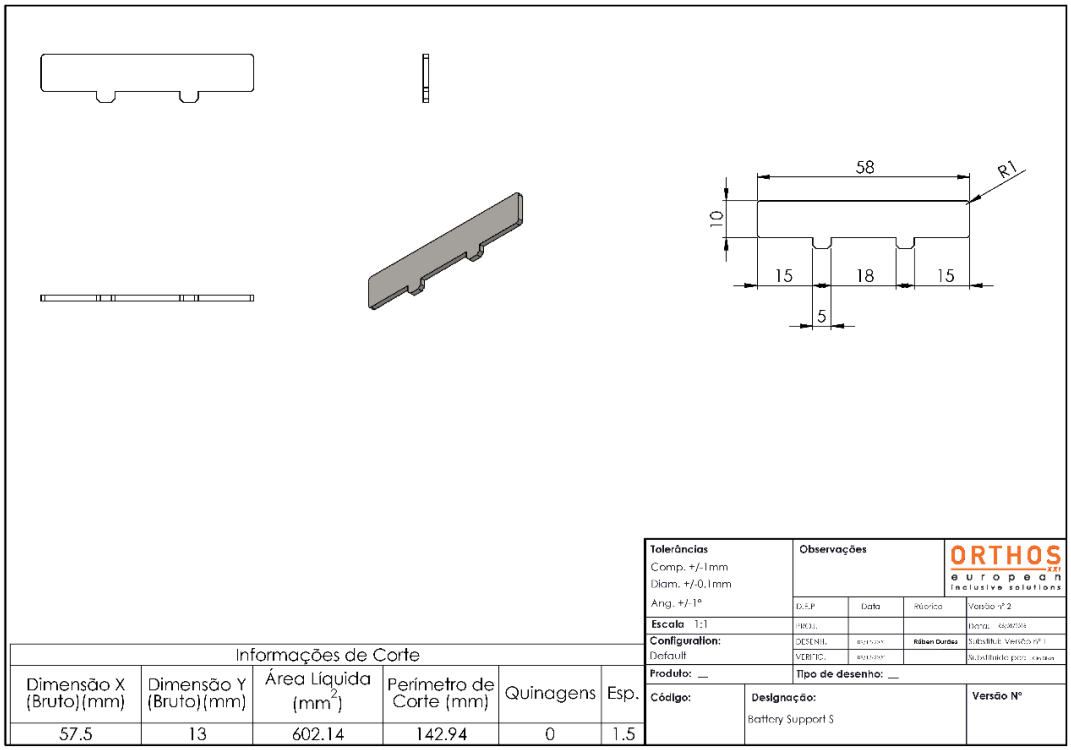


Figure 75: 2D drawing for the smaller piece of the battery support, all the dimensions are in millimeters. This piece can be obtained through laser cutting.

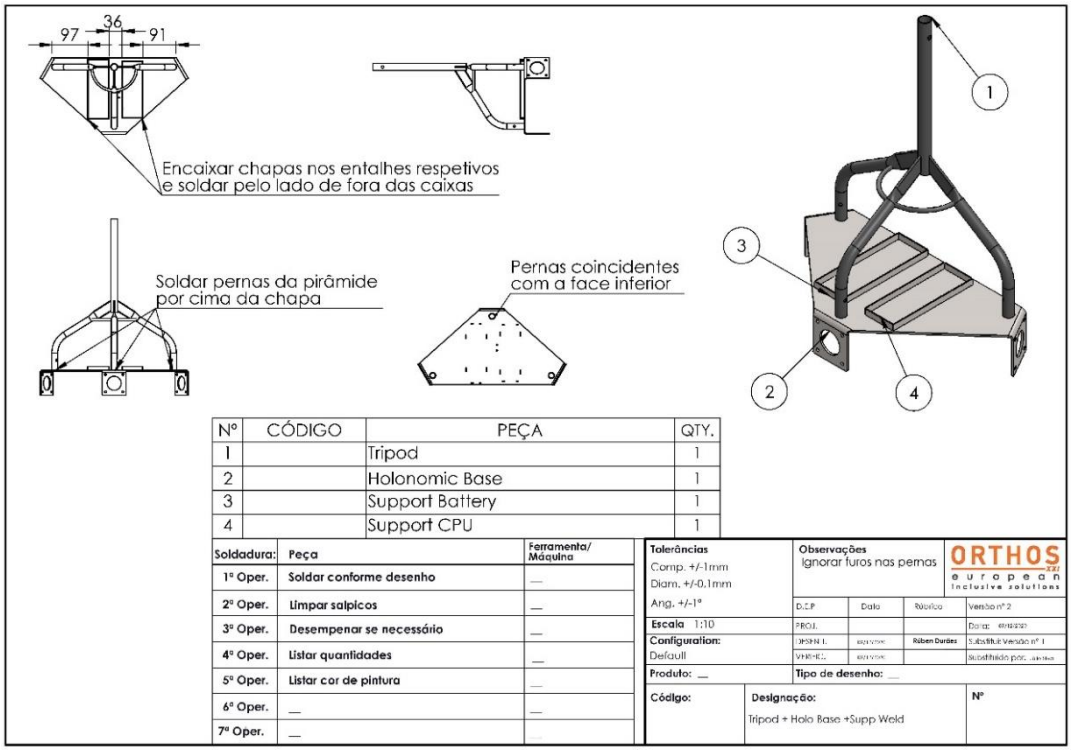


Figure 76: Welding instructions for the prototype. 1: striped down tripod from the original P1 tripod; 2: holonomic base; 3: battery support, welded in the designated groves; 4: CPU support, welded in the respective groves.

Appendix IV

This appendix contains information relevant to the analytical studies performed during the analytical validation for the anti-fall cane prototype.

All the FOS values were obtained using the FOS wizard, available within SW simulation, which divides the von Mises's maximum stress and the yield strength of the material being analysed, written as eq. IV.

$$FOS = \frac{\sigma_{VM}}{\sigma_Y} \quad \text{(IV)}$$

Table 20: Mesh information and details.

Mesher used	Standard mesh
Element size	4.77233 mm
Tolerance	0.238616 mm
Mesh quality plot	High
Total nodes	214414
Total elements	140543

Table 21: Plain carbon steel properties, information retrieved from the SW material library.

Yield strength	2.20594e+08 N/m^2
Tensile strength	3.99826e+08 N/m^2
Elastic modulus	2.1e+11 N/m^2
Poisson's ratio	0.28
Mass density	7800 Kg/m^3
Shear modulus	7.9e+10 N/m^2
Thermal expansion coeficient	1.3e-05/Kelvin

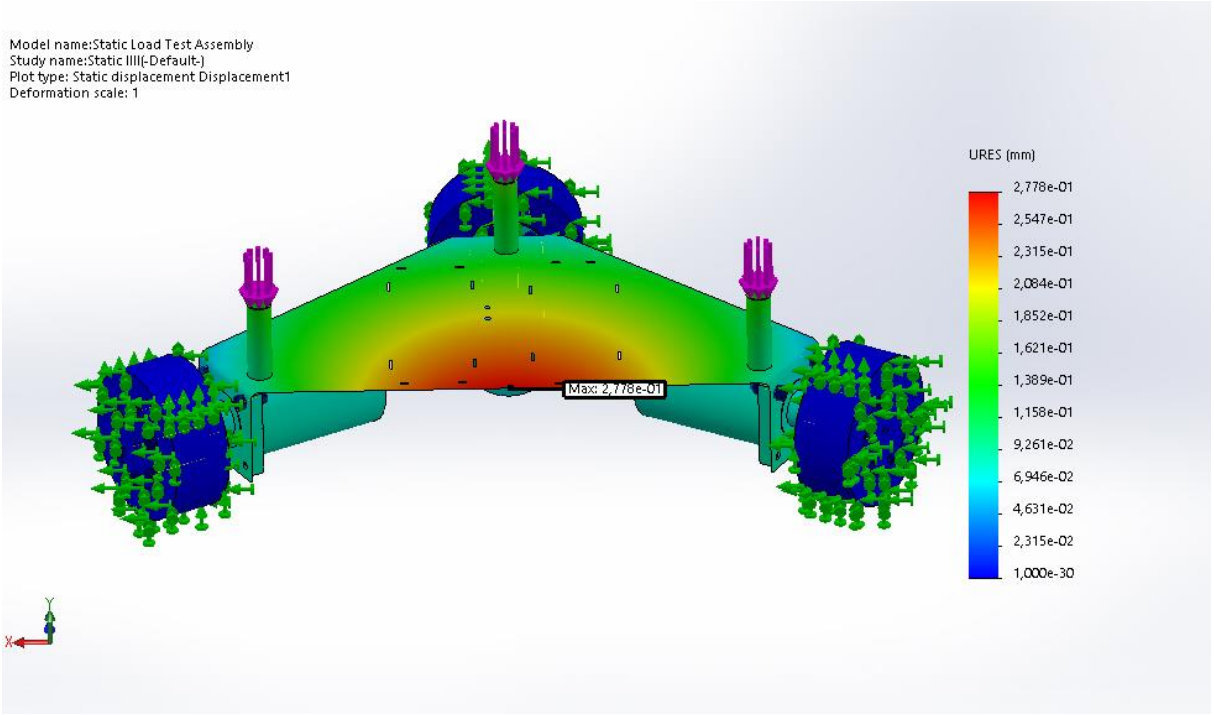


Figure 77: Resultant displacement plot obtained in the static load test simulation, where the maximum displacement is equal to 2.778e-01 mm.

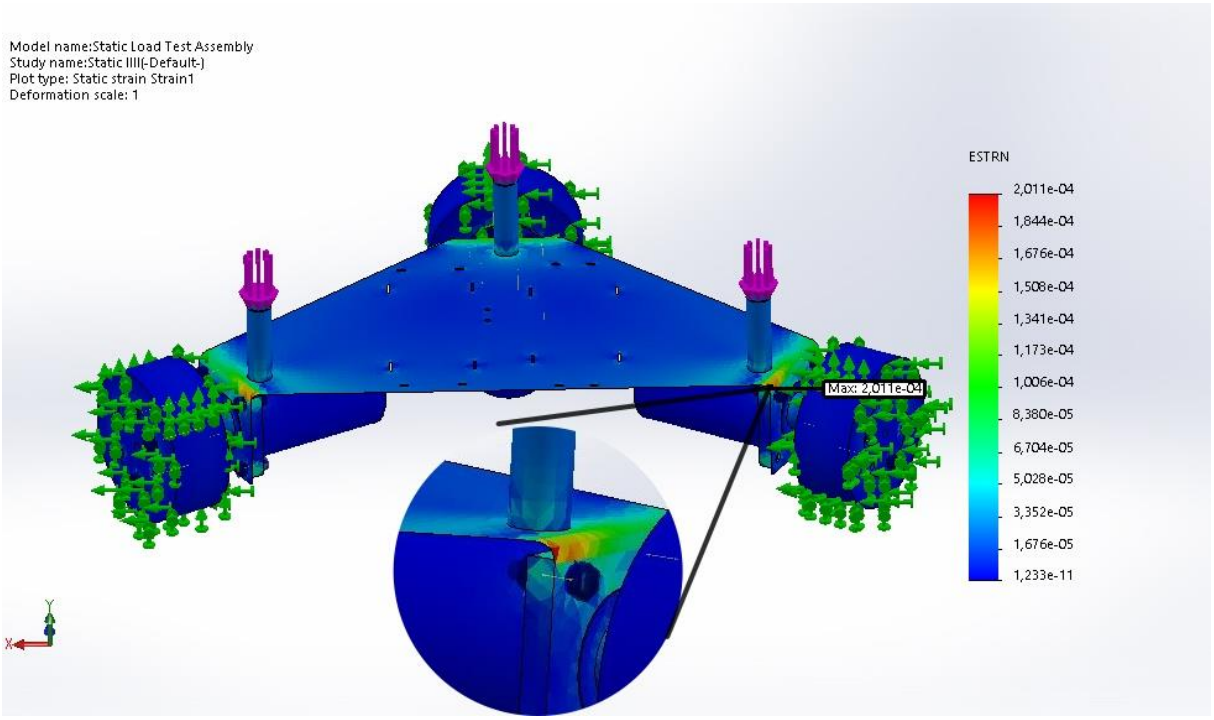


Figure 78: Strain plot obtained in the static load test simulation, where the maximum strain is equal to 2.011e-04.

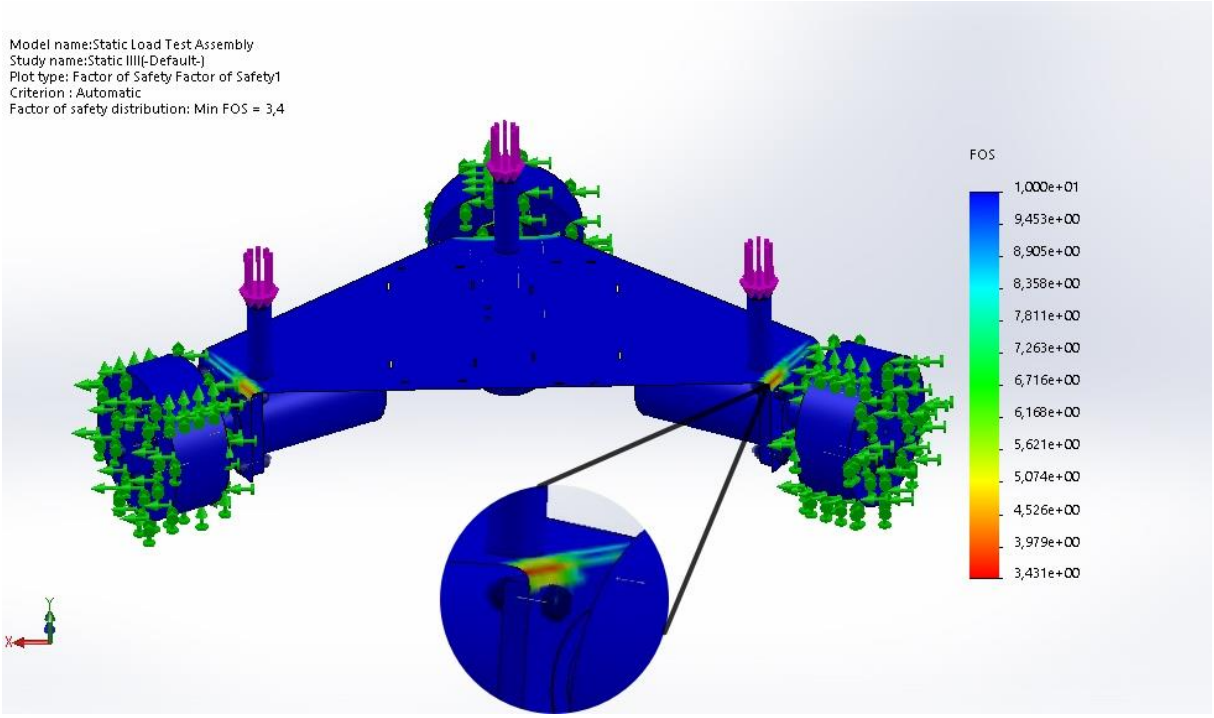


Figure 79: FOS plot obtained in the static load test simulation, where the minimum FOS is equal to 3.4.

Table 22: AISI 1045 steel properties, information retrieved from the SW material library.

Yield strength	5.3e+08 N/m^2
Tensile strength	6.25e+08 N/m^2
Elastic modulus	2.05e+11 N/m^2
Poisson's ratio	0.29
Mass density	7850 Kg/m^3
Shear modulus	8e+10 N/m^2
Thermal expansion coeficiente	1.2e-05/Kelvin

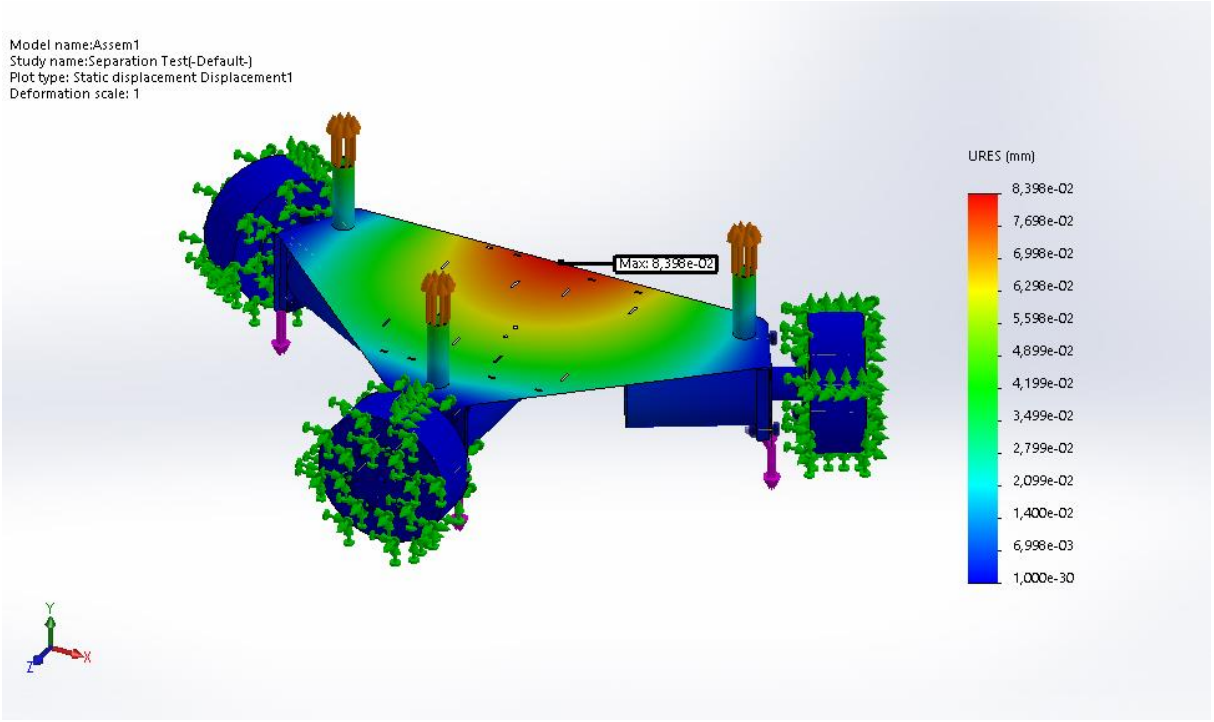


Figure 80: Resultant displacement plot obtained in the separation test simulation, where the maximum displacement is equal to 8.398e-02 mm.

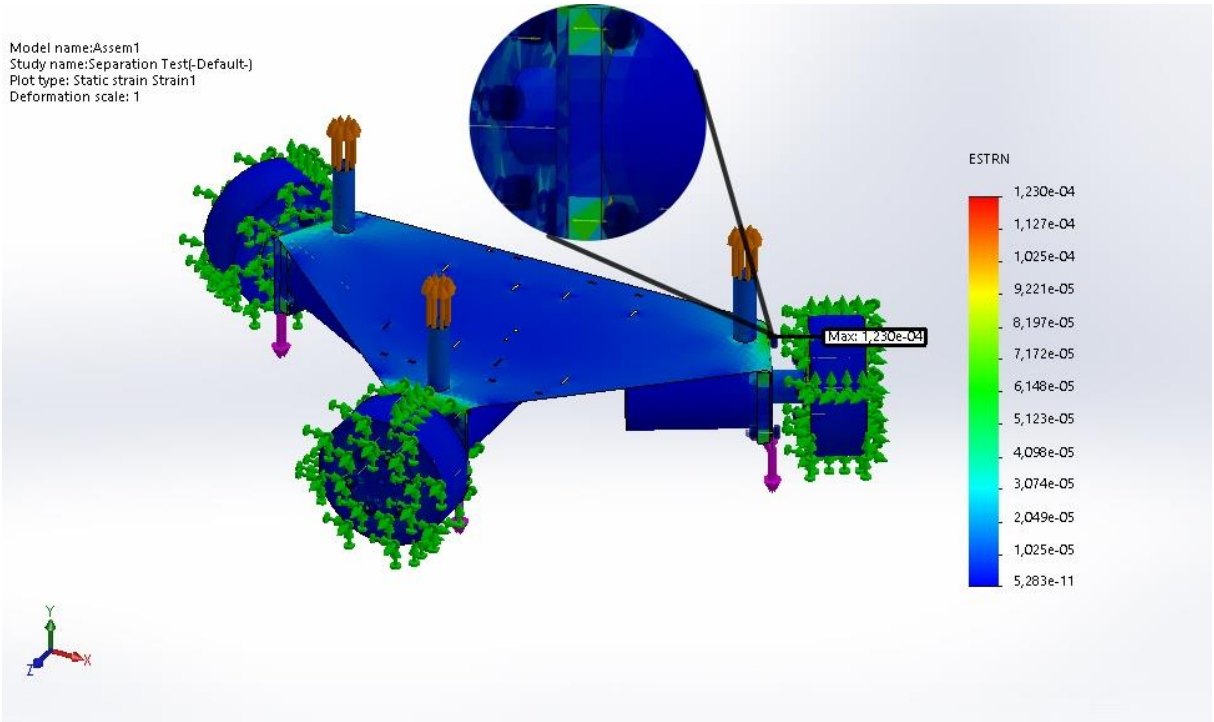


Figure 81: Strain plot obtained in the separation test simulation, where the maximum strain is equal to 1.230e-04.

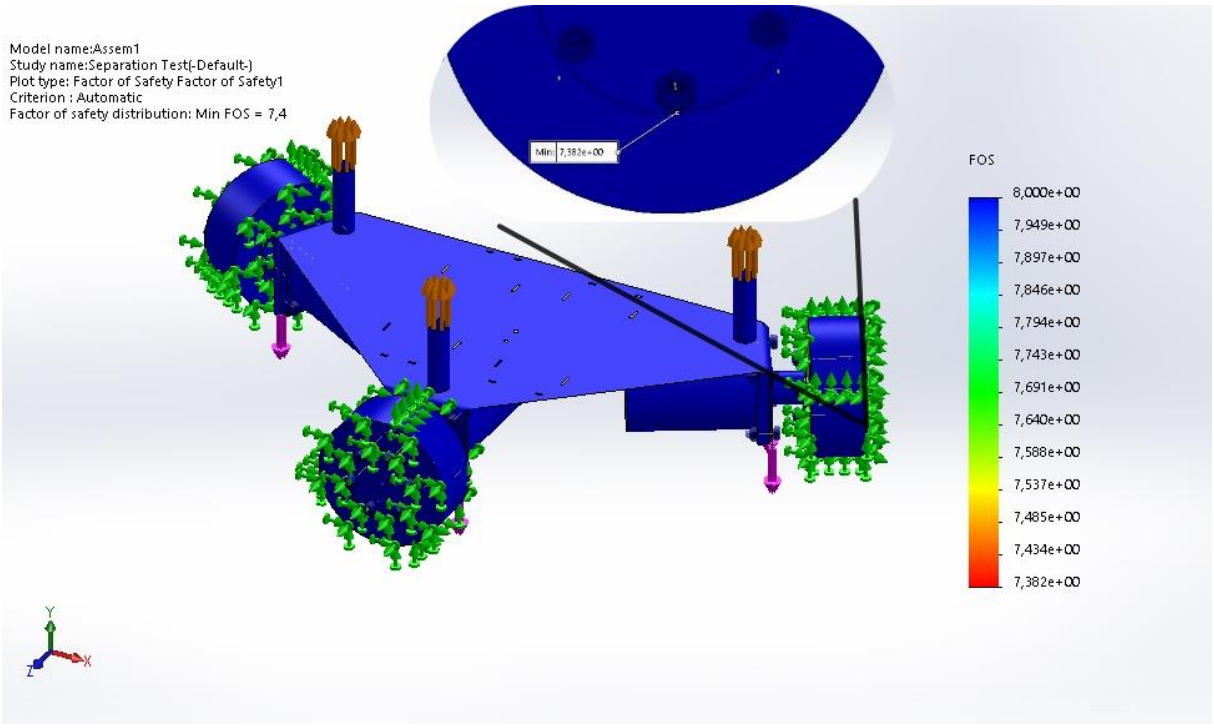


Figure 82: FOS plot obtained in the separation test simulation, where the minimum FOS is equal to 7.4.

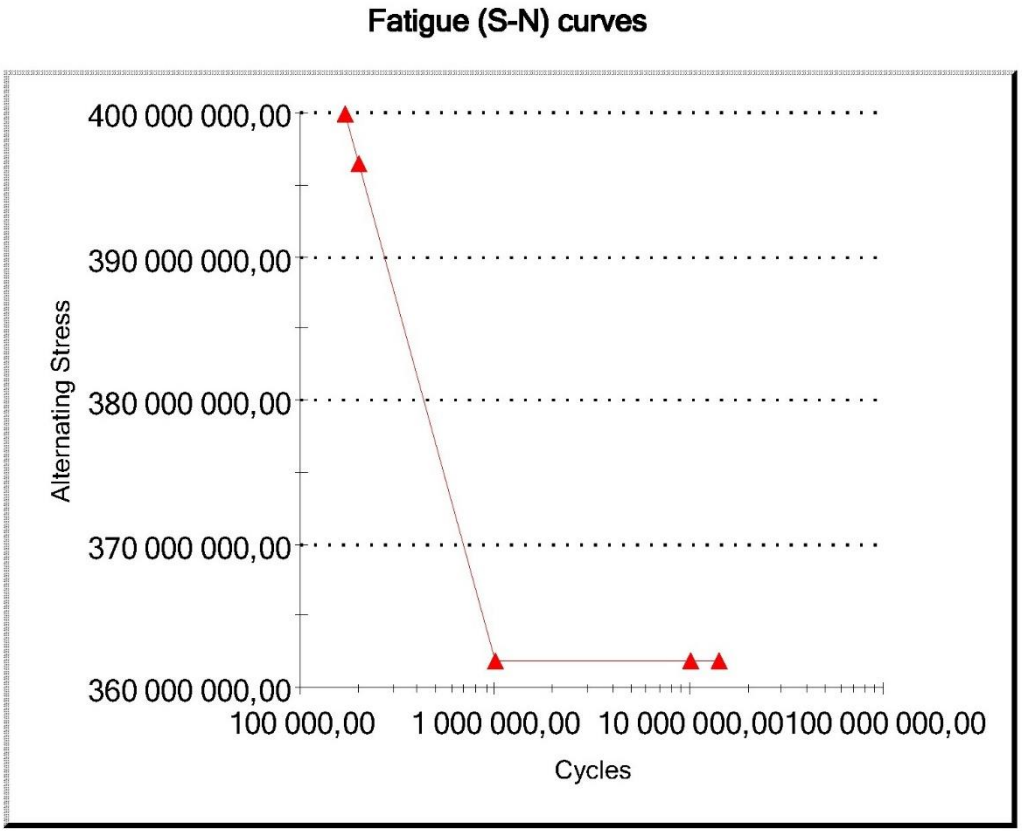


Figure 83: S-N curve for 0.53% Carbon Steel Oil quenched and drawn, obtained through the SW material library. The endurance limit is, approximately, 3.6e+08 N/m^2.

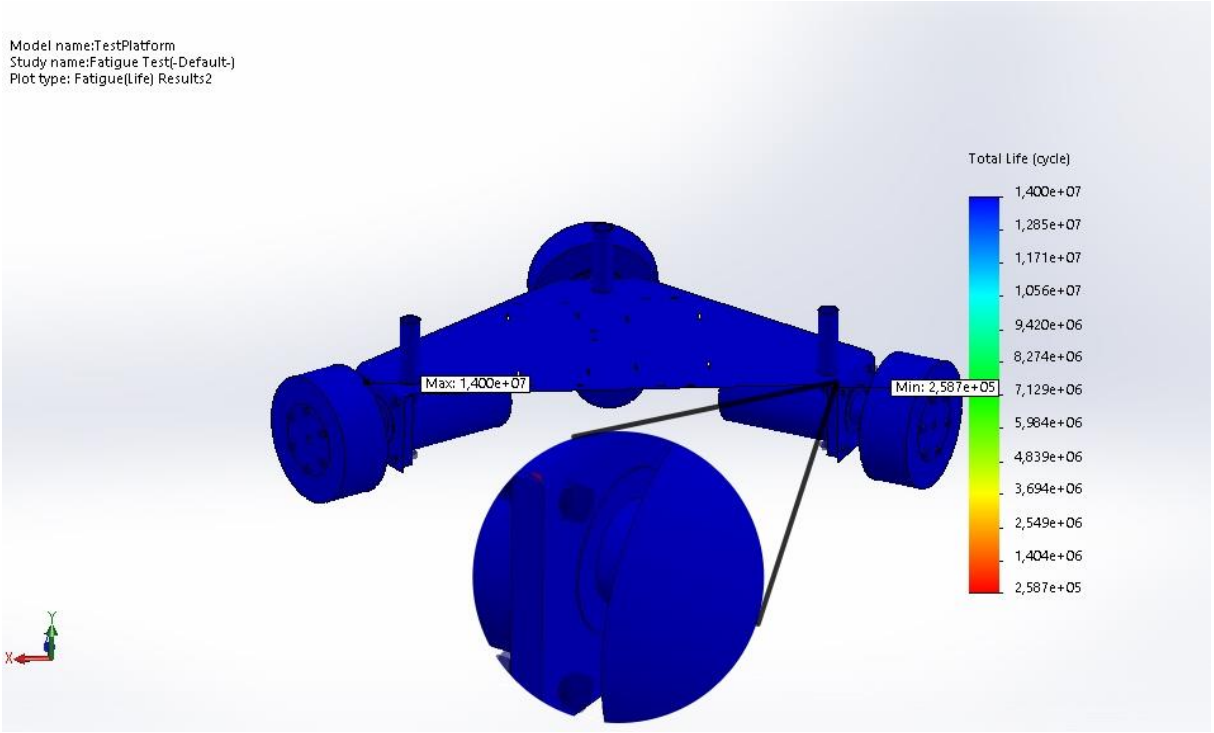


Figure 84: Total life, in cycles, obtained during the fatigue test simulation for a 6000 N fully reversed cyclical force distributed between the three legs. This shows that, approximately, 258700 cycles is the limit before fatigue failure (considering the simulation setup).