UNIVERSIDADE D
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Facial Paralysis Rehabilitation at home

FaceRehab

Dissertation in the context of Master in Biomedical Engineering, Specialization in Biomedical Instrumentation, supervised by Doutor João Manuel Leitão Quintas and Professor Doutor Rui Pedro Duarte Cortesão and presented to the Faculty of Science and Technology

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To Luiz Carlos and Fabiana Salomão

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Nomenclature

ACM Association for Computing Machinery

AI Artificial Intelligence

BCE Before Common Era

COM Chronic Otitis Media

CSF Cerebrospinal Fluid

DTx Digital Therapeutics

EIT European Institute of Innovation and Technology

EMG Electromyography

EU European Union

FCT Fundação para Ciência e Tecnologia

FDA US Food and Drug Administration

FEUC Faculdade de Economia da Universidade de Coimbra

FP Facial Paralysis

GDPR General Data Protection Regulation

HBS House-Brackmann Scale

HC Healthcare

HC/FMUSP Hospital das Clínicas, Faculty of Medicine, University of São Paulo

HCP Healthcare Professionals

HSV Herpes Simplex Virus

HSV1 Herpes Simplex Virus Type 1

HTA Health Technology Assessment

ICT Information and communications technology

IoB Internet of Bodies

IoT Internet of Things

IPNIas Instituto Pedro Nunes - Laboratory for Automatics and Systems

ISO International Organization for Standardization

mA Milliampere

MAST Model for Assessment of Telemedicine

MBSE Model Based on System Engineering

MD Medical Devices

MRI Magnetic Resonance Imaging

NMR NeuroMuscular Reprogramming

PESTLE Political, Economic, Sociological, Technological, Legal and Environment

PICO Population, Intervention, Comparison, Outcome protocol

PRISMA Preferred Reporting Items for Systematic review and meta-analysis

QoL Quality of Life

SD standard deviation

SotA State of the Art

TRL Technology Readiness Level

UK The United Kingdom

USA United States of America

USE Usefulness, Satisfaction, and Ease of Use Questionnaire

UX User Experience

VS Vestibular Schwannoma

VZV Varicella-Zoster Virus

Abstract

This thesis addresses the problem that patients with facial paralysis encounter when reaching for an effective and reliable treatment for the condition. The rehabilitation programs frequently require patients to travel to a particular facility distance from their residences, and the treatment prescribed is not standardised, depending solely on the physician responsible for the patient's case clinical opinion. Our primary solution for this problem is FaceRehab, a telerehabilitation device that will use technology to enhance facial rehabilitation exercises, accelerating the digital transformation of facial paralysis patients' health and care. This thesis utilised the MBSE methodology to integrate the technical, regulatory and business components, connecting those systems across all relevant development domains.

The research question being addressed can be stated as follows: How can we integrate the different domains of the technological device and incorporate its information model and decision-making process to implement it on the market successfully?

To answer our research question, we conducted our study in five main phases, which include: Understanding the problem domain of Facial Paralysis, Performing a systematic review of similar technologies; Analysing the co-design and specifications of the technology; Validating the device's usability and studying its impact on the market. Finally, we concluded the study by performing an overall analysis of the results.

Our hypothesis is that we can overcome the limitations the users might express as well as the restrictions regarding its entry into the market. Our theory is that the problems can be more easily overcome if an extensive internal and external analysis of the solution is performed

in addition to a design and specification evaluation of the technology. Finally, we intend to validate the solution's usability by performing a formative evaluation.

To test our hypothesis, several well-known and reliable methodologies were applied during the development of this work, such as: PRISMA, for the systematic review; Meyer's approach for patient journey mapping; International standard IEC 62366-1 (ISO) protocol for usability validation; MAST for technology assessment; SWOT and Porter's 5 Forces analysis for external factors evaluation and Value proposition Canvas for position placement.

We expect that adopting this framework will reduce errors and flaws regarding decision-making, resulting in improved performance with the user and a more satisfactory market positioning. We believe this study will contribute to the overall internal and external analysis of other telerehabilitation and medical devices. We also expect that the structure of the thesis will serve as an example to conduct future research, ensuring that all factors related to the design, evaluation, validation, and approval of a dynamic network like FaceRehab are considered.

Resumo

Esta dissertação aborda os atuais problemas enfrentados pelos utentes com paralisia facial, os quais incluem as deslocações frequentes a clínicas de reabilitação e a falta de um padrão clínico relativamente aos diagnósticos e tratamentos. A solução sugerida para os problemas mencionados é o FaceRehab, um dispositivo de telereabilitação que oferece, através de uma tecnologia de ponta, exercícios faciais de reabilitação e um acompanhamento remoto especializado. Esta dissertação de mestrado utiliza como base estrutural a metodologia MBSE, a qual integra os componentes técnicos, regulamentares e de mercado.

A questão a abordar neste estudo, pode ser enunciada da seguinte forma: Como podemos integrar os diferentes domínios do dispositivo de telereabiliação, incorporando o seu modelo de informação e processo de tomada de decisão, por forma a implementa-lo com sucesso no mercado?

Para responder à questão referida, implementou-se o estudo em cinco fases principais, incluindo; Compreender o domínio da paralisia facial; Realizar uma revisão sistemática de tecnologias digitais para telereabilitação da paralisisa facial; Analisar os elementos de co-design e as especificações; Validar a usabilidade do dispositivo; e estudar o seu impacto no mercado. Concluí-se o estudo através da realização de uma análise global dos resultados.

A hipótese a validar é que com os resultados deste estudo, seja possível uma melhoria incremental no dispositivo de telereabilitação por forma a ultrapassar as limitações que os utilizadores possam expressar, bem como as restrições relativas à entrada da tecnologia no mercado. A teoria é que os problemas podem ser mais facilmente ultrapassados se for realizada

uma análise interna e externa extensiva da solução, para além de uma avaliação da concepção e especificação da tecnologia. Finalmente, pretendemos validar a usabilidade da solução através da realização de uma avaliação formativa.

Para testar a nossa hipótese, várias metodologias fiáveis foram aplicadas durante o desenvolvimento deste trabalho, como por exemplo: PRISMA, para a revisão sistemática; Abordagem de Meyer para o mapeamento do *patient journey*; Protocolo IEC 62366-1 (ISO) para a validação da usabilidade; MAST para a avaliação da tecnologia; SWOT e análise das 5 Forças de Porter para a avaliação de factores externos e Proposta de Valor Canvas para posicionamento no mercado.

Espera-se que a adoção deste estudo reduza erros e falhas no processo de tomada de decisão, resultando num melhor desempenho com o utilizador e num posicionamento de mercado mais satisfatório. Acredita-se que este estudo irá contribuir para a análise global interna e externa de outros dispositivos de telereabilitação. Espera-se também que a estrutura dessa dissertação sirva de exemplo para conduzir futuras investigações, assegurando que todos os factores relacionados com a concepção, avaliação, validação e aprovação de uma rede dinâmica como o FaceRehab sejam considerados.

Chapter 1

Introduction

A standard general term used to describe the medical condition in which a person loses the ability to move one or both sides of their face is "Facial Paralysis." Accordingly, the primary symptoms are facial weakness, where the muscles in the area do not respond to voluntary stimuli, resulting in difficulty eating and drinking. The documented incidence of this health illness is 20 to 30 cases per 100.000 persons per year, which indicates that it is a relatively common condition. Facial paralysis is regarded as an enigmatic disability due to the numerous etiologies that have been associated with it, and the process of identifying and treating the condition is currently problematic and ambiguous. Neither diagnosis nor treatment methods include a standard protocol to be followed by the physician and depend only on their clinical judgment. Langhals et al. [1], highlighted the need to expand digital solutions that comprehensively address facial paralysis due to the complexity and absence of mature solutions addressing all the above factors in an integrated approach.

Attending to these initial considerations, four questions are pertinent to drive this thesis: (i) What are the technological solutions available in the market; (ii) How can a digital solution for facial paralysis be modelled and implemented into the telerehabilitation market: (iii) How to validate an integrated digital solution for facial paralysis through users' perspective; and finally, (iv) What is the impact of this solution on the market?

1.1 Purpose and goals

According to Riordan in [2], although there is no established methodology for treating the condition, Neuromuscular Reprogramming (NMR) treatments, especially facial exercises, are currently widely used in the medical community. Its objective is to strengthen muscles and reestablish face coordination and expression. The exercises recommended are not standardised, and their selection depends solely on the therapeutic or physician responsible for the patient's case.

Rehabilitation programs frequently require patients to travel to a special facility distanT from their residences, which can be difficult for certain people, particularly those with poor mobility, lack of access to proper transportation, and informal carers. In the case of facial paralysis, patients commonly encounter this difficulty since they must visit the medical facility frequently. As a result, some patients fail to finish the rehabilitation program, and their recovery is less than ideal as they are unable to continue to the supplementary exercise therapy that supports the rehabilitation progress.

New disruptive technologies, including virtual and augmented reality, depth cameras, sensors, the internet of things (IoT), and artificial intelligence, have made it possible to create gadgets and software to assist people in rehabilitation. These technologies usually suggest exercises in virtual environments, monitor how they are carried out, give the patient feedback, and motivate them. FaceRehab's technological solution aims to fully utilise these advancements for the benefit of patients, enabling them to receive rehabilitation services and lengthen the period of their recovery through the extensive use of these disruptive technologies in conjunction with the oversight and assistance of their care team members.

In conclusion, FaceRehab is working on a device that will use technology to enhance facial rehabilitation exercises, accelerating the digital transformation of facial paralysis patients' health and care. The primary goal and technological advancement will be developing new software associated with a digital application designed and monitored by therapists to improve the facial rehabilitation process for users. By bringing rehabilitation programs currently carried out in

hospitals or clinical settings into the domestic environment, FaceRehab's novel solution will help integrate the actions of professional and informal caregivers utilising a common ICT-based approach. The solution will impact healthcare systems by offering a new service model that can lower the price of healthcare for individuals with facial paralysis (FP) while maintaining performance.

This study focuses on the co-creation and co-design of the solution (identification of user needs, value-proposition, and definition of user stories), design and specification of the technology (requirements and technical specifications of the hardware and face recognition algorithms), and addresses early-stage health technology assessment (HTA) to steer validation of technology processes and main document conclusions.

1.2 Challenges and obstacles

According to Gilden in [3], the prevalence of this ailment affects tens of thousands of people each year of all ages and is caused by various etiologies. The most typical kind of facial paralysis is Bell's paralysis, which accounts for 60% to 75% of all cases.

As stated in a research study by Holland [4], the author mention that, for every 100.000 people, there are 20 to 30 occurrences of facial paralysis per year. Although the disease can affect anyone at any age, generally speaking, the incidence is lowest in children under the age of ten, increases from 10 to the age of 29, remains stable from 30 to the age of 69, and is highest in people over the age of 70.

Currently, there are two main obstacles to treating facial paralysis: (i) The lack of a standard evaluation methodology for diagnosing and treating the condition and (ii) The obstacles with remote therapy leading to medical complications. Both challenges are going to be discussed in the following section.

Standard evaluation of Facial Paralysis

Measurement tools are considered essential when discussing scientific research or academic reports since they make it possible to standardise variables and outcomes. Health scales, in particular, assist physicians in analysing psychological and clinical disorders that are challenging to quantify.

According to Marenda and Olsson in [5], evaluating acute facial nerve paralysis is difficult for clinicians. There are several causes for this, including the wide range of treatment choices available, the fact that patients receive various diagnoses, and the absence of a standard scale for grading the disease. Traditional classification methods are, therefore, based on the treating physician's subjective clinical observation, which might result in erroneous medical recommendations.

This difficulty inspired FaceRehab to develop a tool that will, among other things, help with the clinical evaluation of facial paralysis, supporting medical professionals in identifying the severity of the condition while enhancing the face rehabilitation of patients with facial paralysis.

Remote therapy for Facial Paralysis

According to Wernick and Baiungo in [6], frequent consultations with physiotherapists to perform facial rehabilitation exercises is one of the broadest treatment methods for facial paralysis. The study states that frequent facial motor exercises expedite and enhance the recuperation process. Therefore, most doctors advise patients to perform a set of prescribed exercises at home, to continue activating their muscles in addition to these consultations.

Even though performing regular exercises at home is an essential component of treatment, doing them incorrectly can result in complications such as synkinesis, excessive lacrimation when eating, or an increase in inappropriate muscle activity. Therapists have no control over the movements or the outcomes due to the lack of actual interaction or visual biofeedback of the exercises' efficient implementation. This is solved with FaceRehab by giving the therapist

the ability to observe, track, and analyse the exercise set performed at home.

Methodology

This work uses a Model-Based System Engineering (MBSE) to design, implement, and sustain complex systems, such as FaceRehab, over its life cycles, ensuring that along the development of the medical device, all potential project components are taken into account and integrated into the overall project. Using this concept as a guide, a clinical and technical study has been performed, along with regulatory and business components, in order to comprehend the overall picture of how the device will be implemented, identify inefficiencies, recommend improvements, and resolve issues.

Several other well-known and trustworthy methodologies were used as guidelines, including PRISMA for the systematic review, Stakeholder Analysis, Meyer's approach for mapping patient journeys, International Standard IEC 62366-1 (ISO) protocol for usability validation, MAST for health technology assessment, SWOT and Porter's Five Forces analysis for evaluating external factors, and Value Proposition Canvas to set positions.

Project scope

This master thesis was submitted to the University of Coimbra in partial fulfilment of the requirements for the degree of Master in Biomedical Engineering. It was developed within the scope of research and innovation projects that were being developed at IPNIas during 2021/2022.

Mainly, this work was motivated by the challenges addressed by the European project FaceRehab, which is being led by IPNIas and involves four additional European partners from Portugal, Spain and Luxembourg. Hence, it provided a direct contribution to the weekly discussions involving the key stakeholders: ThinkDigital, a Portuguese SME and healthcare organizations Fisioermesinde in Portugal, Parc Sanitari San Joan de Deu in Spain and Rehazenter in Luxembourg. FaceRehab project, is being funded by the European Union's under the AAL programme

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Additionally, a complimentary action within the EIT Health Education activities allowed a collaboration concentrated on business-related themes, such as measuring health outcomes, decision-making on health expenditures, and managing health innovation.

Structure of the document

Overall, this paper has seven global sections that aim to study the impact and implementation strategy for the FaceRehab medical device. This work began by describing the project and contextualising the study, including establishing the technology's purpose and goals, challenges, the methodologies used as guidelines, and the project scope. Following this introductory section, a brief contextualisation about understanding the condition domain was be provided. It is followed by a systematic review aiming at analysing the pre-existing solutions for telerehabilitation for facial paralysis.

The implementation strategies and analysis of the solution in the market can be found in section 4, including the users' and developers' perspectives of the device and the technology's technical elements. A formative usability evaluation was also performed to identify and minimise user errors and reduce use-associated risks. This research was based on the "International standard IEC 62366-1 - Part 1: Application of usability engineering to medical devices" and can be found in section 5.

The impact of the device on the market and external analysis of the solution can be found in section 6, which includes a MAST Assessment, SWOT Analysis, Porter's 5 Forces and a Valuation Proposition Canvas. This work reaches the end with the presentation of the results obtained, their interpretation and a note of the future work to be developed.

Chapter 2

Understanding the problem domain of Facial Paralysis

This chapter focus on the understanding of the problem domain of facial paralysis. Its objective is to clarify essential factors regarding facial paralysis to introduce the medical condition and facilitate the understanding of the following chapters. To reach this goal, an anatomic explanation, its aetiology, signs and symptoms, diagnosis process, treatment methods, grading and prognosis are superficially explained. A detailed explanation can be found in Appendix A through Appendix E, including its medical history.

2.1 Anatomy

Facial muscles, also known as mimic muscles, are directly responsible for facial expressions, according to Izard [7]. The facial nerve, designated as the seventh cranial nerve, is in charge of controlling these muscles. The nervous system mediates the intracorporeal relationship between a person's activities and feelings or emotions.

Consequently, the seventh cranial nerve is what is damaged in cases of facial palsy [8]. Two categories of the disability can be made out:

- Central facial palsy: Due to damage above the facial nucleus
- Peripheral facial palsy: Due to damage at or below the facial nucleus

A deepen explanation of the nerve system and the facial nerve can be found in Appendix B.

As mentioned, facial paralysis is mainly caused by damage to the facial nerve (the seventh cranial nerve). It contains the motor, sensory, and parasympathetic nerve fibres, which provide innervation to several areas of the head and neck region. A Schematic diagram of the motor innervation of the facial nerve and a diagram of the parasympathetic innervation of the facial nerve can be found on figure 2.1

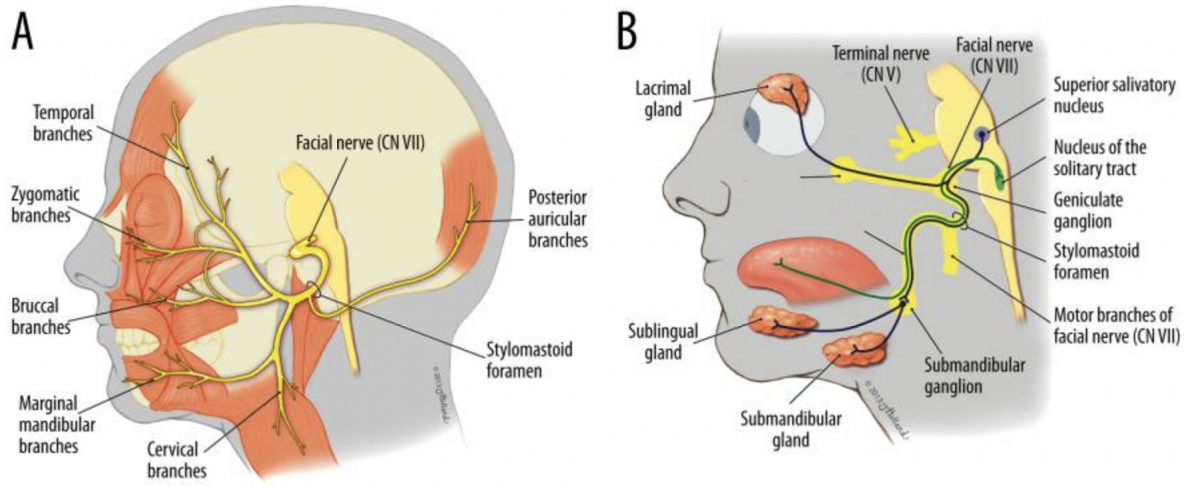

Figure 2.1: Schematic diagram of the motor innervation of the facial nerve and a Schematic diagram of the parasympathetic innervation of the facial nerve, respectively [9]

As mentioned in Westersson's work on the risks of damage to the facial nerve [10], injury to the facial nerve can result in malformation on several levels, depending on where it occurs. As a result, identifying the location of the damage is essential for developing a diagnosis and course of action.

According to May and Klein in [11], Central facial palsy, also referred to as supranuclear lesion, is a symptom or finding characterized by palsy of the lower half of one side of the face. It usually results from a unilateral upper motor neuron lesion between the cortex and

corticobulbar tract. As a result, the lower portion of the face (such as the lips and cheeks) has its movements impacted. However, the higher portion (e.g. eyelids and forehead) continues to receive input from the opposite side, maintaining the function.

When the contrary happens, it is called peripheral facial palsy [11]. It comes from a lower lesion between the nuclei and muscles rather than a unilateral higher motor neuron lesion between the cortex and corticobulbar tract. The upper and lower faces are both paralyzed in sequences, and all the muscles on that side get weaken. Figure 2.2 compares the damage's location and the following physical characteristics.

That being said, most cases of facial paralysis are considered acute peripheral facial nerve palsy of unknown aetiology, causing rapid onset of facial weakness. According to Holland and Weiner in [4], this condition is also the most common known cause of facial nerve injury.

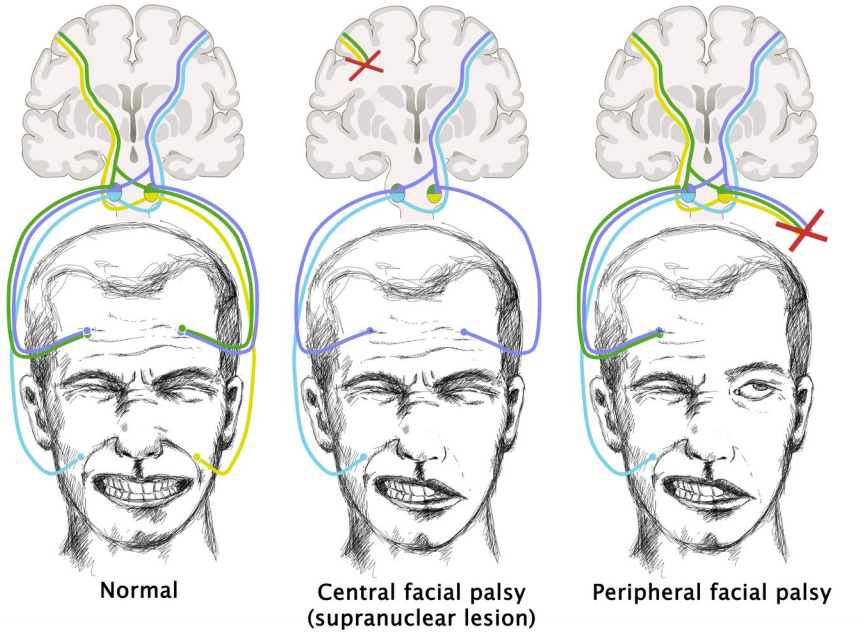

Figure 2.2: Pathway of the facial nerve [12]

2.2 Aetiology

According to Melvin et al. in [13], facial paralysis is currently considered an enigmatic disability due to the different etiologies linked to the condition. Currently, the scientific community reported 31 known causes that can be categorized into 6 sections: Infectious, Neoplastic, Trauma, Neurological, Congenital and Systemic. The list of the categories and causes of FP can be found in Table 2.1.

The most common causes identified are Herpes Simplex Virus type 1, Varicella-zoster virus, Ramsey-Hunt syndrome, Complications of Otitis Media, Lyme Disease, Neoplasms and Trauma. A deepen explanation of each of them can be found in Appendix C

Table 2.1: Causes of Facial Paralysis

Causes of Facial Paralysis		
Infectious	**Neoplastic**	**Trauma**
Herpes Simplex	Chloresteatoma	Iatrogenic
Ramsey-Hunt S.	Vestib. Schwann	P. wound
Otitis Media	Facial Neuroma	Birth trauma
Mastoiditis	Carcinoma	Fractures
Lyme	Glomus Jug.	
HIV	Histiocytosis	
Tuberculosis	Rhabdomyosarcoma	
Mumps virus	Osteopetrosis	
Rubella virus	Hemangioblastoma	
Influenza virus	Leukaemia	
Mononucleosis		
Neurological	**Congenital**	**Systemic**
Guillain-Barré	Mobius S.	Sarcoidosis
Mult. Sclerosis	Melkersson	D. Mellitus
Millard-Gubler	D. Myotonia	Hyperthyroidism
		Autoimune Disease

2.3 Signs and Symptoms

Makeham, in his work "Infective causes of facial nerve paralysis" [14], claims that the main sign of facial paralysis is facial weakness, which occurs when the muscles in the area do not contract in response to voluntary stimulation. Other signs include hyperacusis, dry eyes, decreased salivation, and taste loss. Patients with this illness typically go from mild symptoms to their most significant level of weakness in three days, nearly always in one week. Medical professionals should try to reevaluate the diagnosis if the progression lasts longer than two weeks.

According to Portelinha et al. in [15], most patients are generally uninformed of their diagnosis, and about 50% of patients think they have had a stroke, 25% are afraid of getting a tumour, and the remaining 25% are unsure of what is wrong. The aetiology of the weakness and the patient's treatment options significantly impact the prognosis and outcomes. However, generally speaking, the symptoms progressively go away in 71% of instances without medical intervention, 13% exhibited just a mild residual palsy, and the other 16% resulted in symptom persistence [15].

About 50% of patients report experiencing retro auricular discomfort, which is a pain similar to a headache that lasts for a few days and typically needs analgesics. In half of these patients, symptoms starts two to three days before paralysis sets in, but in the other half, it starts right when paralysis starts.

In 30% and 5% of instances, respectively, decreased taste sensitivity and tear production are observed. During acute facial palsy, the parasympathetic preganglionic fibres that migrate into the submandibular ganglion may retract and link to the larger surface petrosal nerve. Crocodile tear syndrome is a tearing phenomenon that can result from this regeneration following a salivary stimulation. Up to 70% of patients with facial paralysis exhibit this condition.

The absence of the stapedial reflex results from the stapes muscle becoming paralyzed. Therefore, about 15% of patients with FP are found to have hyperacusis (increased sensitivity to sound).

2.4 Diagnosis

There is currently no established method for diagnosing facial paralysis since the causes are diverse. However, clinicians should conduct the procedure by exclusion, ideally with the assistance of a neurologist. Early detection of FP (Facial Paralysis) can significantly increase the likelihood that muscle functioning can be recovered.

According to Pulec in [16], doctors often begin by performing a physical examination and asking the patient to contract a particular facial muscle. By doing so, they identify the symptoms and determine whether the paralysis is central or peripheral.

The cranial nerve examination and an otoscopy, a clinical procedure used to evaluate ear structures, should be performed simultaneously with the physical examinations. Such procedures ought to be performed since several etiologies that result in facial paralysis (e.g. Lyme disease, stroke, and tumours) are more lethal than the palsy itself and can be diagnosed by the exams mentioned. These abnormalities should be diagnosed as soon as possible due to their detrimental implications on health.

Based on the results of the initial tests, the clinical specialists might then decide if a further assessment is necessary. These include a standard blood test, an electromyogram, an electroneurography, a Stapedius reflex test, and an MRI scan.

A short description of the diagnosis methods can be found in Table 2.2. In contrast, a more detailed description and explanation of each of the diagnosis methods mentioned above can be found in Appendix D.

Diagnosis Method	Description
Physical Examination	Physicians may ask the patient to complete specific facial movements while also performing an auricular examination.
MRI Scan	The doctors can examine the facial nerve's injury and spot swelling and unexpected growth thanks to the MRI scans, which are typically detailed and three-dimensional (3D)
Topographic Testing	Tests such as topographic examinations should be used to assess the location of the lesion on the facial nerve. The Schirmer's and Stapedial Reflex tests are the two most often used methods.
Electroneurography	Electroneurography is a test used to assess facial nerves and other peripheral nerves' functionality. This test should ideally be done within 14 days of the paralysis's beginning.

Table 2.2: Diagnosis Methods

2.5 Grading

In the therapeutic process, looking for evidence-based practice has become crucial. Methods to assess FP clinically have been developed in response to the need to predict how the condition would progress and to aid in therapeutic planning.

Clinical observations made by the therapist, both objective and subjective, serve as the foundation of traditional classification systems. Subjective and objective techniques, including the House Brackmann scale, the Index of Facial Function, Moiré topography, three-dimensional analysis of facial movements, electroneuromyography, and anthropometric measurements, were developed to clinically quantify the effects of facial paralysis on facial mimicry as well as the results of intervention processes [17].

The most common method used and accepted by the American Academy of Otorhinolaryngology Head and Neck Surgery is the House-Brackmann Scale (HBS) [18]. The scale is based upon functional impairment, varying between I (normal) and VI (no movement).

The score is defined by calculating:

- The midpoint of the top of the eyebrow moving upward

- The outwards movement of the oral commissure

1 point is given for every 0.25 cm of motion, up to a maximum of 1 cm, for the brow and oral commissure movements. The House-Brackmann score is calculated by adding the scores for each structure. If both structures move a total of 1 cm, the highest possible score is 8. Figure 2.3 represent the House-Brackmann scale grading system.

Grade	Description	Measurement	Function %	Estimated Function %
I	Normal	8/8	100	100
II	Slight	7/8	76 - 99	80
III	Moderate	5/8 - 6/8	51 - 75	60
IV	Moderately Severe	3/8 - 4/8	26 - 50	40
V	Severe	1/8 - 2/8	1 - 25	20
VI	Total	0/8	0	0

Figure 2.3: House-Brackmann Facial Nerve Grading system [18]

2.6 Treatment

Up to this point, there have been several conventional therapeutic approaches, such as therapist supervised facial exercises, certain medications, steroids, vitamin treatments like B12, and other forms of rehabilitation.

According to Riordan in [2], multiple intervention techniques have been shown to be ineffective in enhancing facial symmetry and functionality over time, at least when used alone. However, it has been shown that using different techniques alongside the motor exercises provided by the therapist can speed up the healing process after an accident.

A short description of the treatment methods can be found in Table 2.3, while a more detailed description and explanation of each of the treatment methods mentioned can be found in Appendix E.

Its important to highlight the Digital Therapeutics (DTx) treatment methods, since its the one used by FaceRehab. Digital Therapeutics is a way of treatment used to diagnose, moni-

tor, or heal a health condition. DTx, then, are software programs developed for patients with a demonstrated therapeutic advantage that assist patients in the management, prevention, or treatment of a disease. For instance, Digital Therapeutics can help patients manage their symptoms independently, enhancing their quality of life and other therapeutic goals. DTx employs virtual resources, including smartphones, applications, sensors, virtual reality, IoT, and other technologies, to encourage patients to change their behaviour.

Diagnosis Method	Description
Motor exercises	The most popular kind of physical therapy for Bell's palsy is facial exercises. Its objective is to strengthen muscles so that the face can once again move together and form expressions.
Steroids and antivirals	Since corticosteroids have a strong anti-inflammatory effect, they are suggested as a treatment method for FP when it is an inflammatory aetiology
Acupuncture	By creating a collateral innervation, acupuncture improves neuron excitability and encourages the regeneration of nerve fibres (which increases vascularization and muscle contraction)
Medical Surgery	Medical surgeries may be an option to release pressure from the facial nerve. Decompression procedures only work for a short period of time, in the case of FP, they must be carried out by the 12th day.
Biofeedback and EMG	This method is used as treatment support since the data picked up by the electrodes are amplified and then transformed into graphs that show the muscle movements. This approach gives the patient real-time visual or audio feedback
Eletrostimulation	Galvanic current and high voltage electrical stimulation are cited as ways to hasten the recovery of muscle contraction.
Digital Therapeutics (DTx)	Digital Therapeutics (DTx) are evidence-based therapeutic interventions driven by software to prevent, manage, or treat a medical disorder or disease

Table 2.3: Treatment methods

2.7 Prognosis

Melvin and Limb [13] claim that between 70% and 85% of Bell's palsy patients who start to recover by the second week make a complete recovery on their own within 3 months. When

symptom remission occurs after 2 weeks, the chance of full recovery reduces to 61%.

Only 50% of people experience good improvements in their facial function when 90% of their face is immobile. In this case, 5% to 20% of people will face severe, long-lasting sequelae. Patients will experience mild to intense sequelae if the first month's improvements are unsatisfactory, according to Peitersen [19]. Poor prognosis signs include total paralysis, lack of nerve excitability, Ramsay-Hunt syndrome, retro auricular irritation, hyperglycemia, secondary-cause FP, and lack of recovery after three months.

Eviston et al. reported a similar conclusion in [20]. He mentioned that natural history investigations have shown that within the first three weeks, almost 85% of patients begin to recover. Severe facial palsy, the amount of time before recovery began, and ongoing pain are all indicators of incomplete recovery. Complete facial palsy (House-Brackman grades 5-6) patients are more likely to have incomplete recovery of facial function, with or without spasm and synkinesis, if they have not shown signs of improvement in the first three to four months after on set. Additionally, persistent pain indicates a worse prognosis.

Chapter 3

Systematic review of digital solutions for telerehabilitation of facial paralysis

The market is currently dealing with other FP applications for telerehabilitation. However, none of them permits simultaneously:

- Assisted execution of exercises for recovery.
- Live biofeedback for the proper execution of the exercises.
- Evaluation of the user's progress.
- Measurement of the degree of nerve involvement.
- Associates functionality, which is primarily compromised in these patients.

The FaceRehab solution aspires to stand out from competing products by pursuing superior technology while focusing on straightforward and user-friendly solutions. It seeks to impact the health market and quality of life significantly. In this context, the product to be developed and the generated scientific evidence have added value in the rehabilitation field, assisting in lowering costs associated with lengthy intervention times and frequently inadequate success, as well as a significant business potential for the company's economy on a national and international level.

This section aims to analyse the existing cutting-edge telemedicine technology regarding facial paralysis. The authors use the reporting items for systematic review and meta-analysis

protocols (PRISMA) guidelines for reporting the protocol. Finally, this systematic review will provide a valuable summary of Telerehabilitation Solutions for Facial Paralysis and the strengths and limitations of each approach.

This systematic review relies on one main activity: Desktop exercises based on PRISMA - Preferred Reporting Items for Systematic review and meta-analysis.

The main systematic reviews have followed elements of the Cochrane Handbook for Systematic Reviews. They have used the preferred reporting items for the literature review and meta-analysis (PRISMA) framework to build and implement the literature search strategy. By following this framework, five stages have been included in this systematic review:

- Literature search.
- Article selection.
- Data extraction.
- Data analysis.
- Data synthesis.

A detailed explanation of the methodology can be found in Appendix F

3.1 Implementation

The following sections describe the systematic reviews based on the methodology explained during Appendix F on Technology for Telerehabilitation of Facial Paralysis. According to EU best practices, only open sources were used.

Literature Search

In this first stage, a search objective was built to identify appropriate search keywords based on the PICO protocol, which is explicated in Table 3.1:

Description of the search question	
Question Type	Enabling tech environment
Patient Problem or Population	Integrated TeleRehabilitation solution for people with facial paralysis
Intervention or Exposure	Technology for Telerehabilitation of Facial Paralysis
Comparison or Control	Not applicable
Example Outcome Measures	Integrated and interoperable ecosystem of technological solutions

Table 3.1: Description of the search question through a PICO protocol table for Technology for Telerehabilitation of Facial Paralysis.

Based on the description of the search defined in Table 3.1, the following objective of the study was defined:

Objective
"In the context of developing integrated telerehabilitation and at-home rehabilitation solutions for people with facial paralysis, what are the components for building a technology for telerehabilitation of facial paralysis, using an integrated approach and following a clear interoperability framework".

Table 3.2: The objective of study

Table 3.3 presents a summary of the search parameters/restrictions for the present systematic review.

Boolean queries were prepared to include all articles published before 31 December 2022 that had in their titles, abstract, or keywords at least one of the following expressions "face" or "facial, "rehab", and "paraly."

The resources searched were two Technological specific databases, IEEExplorer and ACM Digital Library, and one specific medical database, Pubmed. Other sources were considered, but they had to be discarded due to several issues reported on Table 3.3. The literature search was performed in March 2022.

Systematic review criteria summary for Digital Open Platforms		
Common	Scope	Title, Abstract and Keywords
	Query	("face"OR"facial")AND("rehab*")AND("paraly*")
	Language	English
	Years considered	2010 - 2022
	Geographic Coverage	Not Applicable
	Target Populations	FP Patients
	TRL	3 to 5 (defined by evidence of validation work)
	Sources (scientific and tech papers)	"two technological specific databases: IEEExplore (export RIS), ACM Digital Library (https://dl.acm.org/) (export BIB), one medical specific database: Pubmed (Medline) (export PubMed)"s
	Sources (notes)	Excluded Web of Science and Scopus because they are not open platforms for searching (you need to have an institutional account); Excluded Research Gate because it does not allow export search results; Excluded Google Scholar because search results are affected by Google ranking algorithms, which does not guarantee transparent results for the search query; Excluded Springer(https://link.springer.com/) because could not replicate the search protocol Excluded IET (https://digital-library.theiet.org/) because redundant results with IEEExplore")
Technology	Other sources	AAL public documents, EC reports, European projects reports, EPO (for patents search)
	Excluding criteria	Not written in EN, Not open access,Not testing in relevant environment, Articles that reported on overviews, reviews, Articles not relevant for the specific objective of this deliverable, Articles focusing on digital hardware solutions.

Table 3.3: Systematic review criteria summary for Technology for Telerehabilitation of Facial Paralysis

As inclusion criteria, the objective was to include:

- Articles published in scientific journals or in conference proceedings reported on any independent digital solution being used as an integration platform for tele/self-rehabilitation solutions.
- Articles were screened to present a technology validation method, either in-lab or in the relevant context.
- Articles were screened for presenting a linkage to relevant standards regarding data sharing in the Healthcare sector and the inclusion of interoperability frameworks (e.g. ontologies)

As exclusion criteria, the objective was to exclude:

- Articles not published in English, without abstracts or access to the full text.
- Articles that reported on overviews, reviews.
- Articles not relevant for the specific objective of this deliverable.
- Articles that report any solution being used as an integration platform for tele/self-rehabilitation, which was not compared against a reference standard.

Article selection

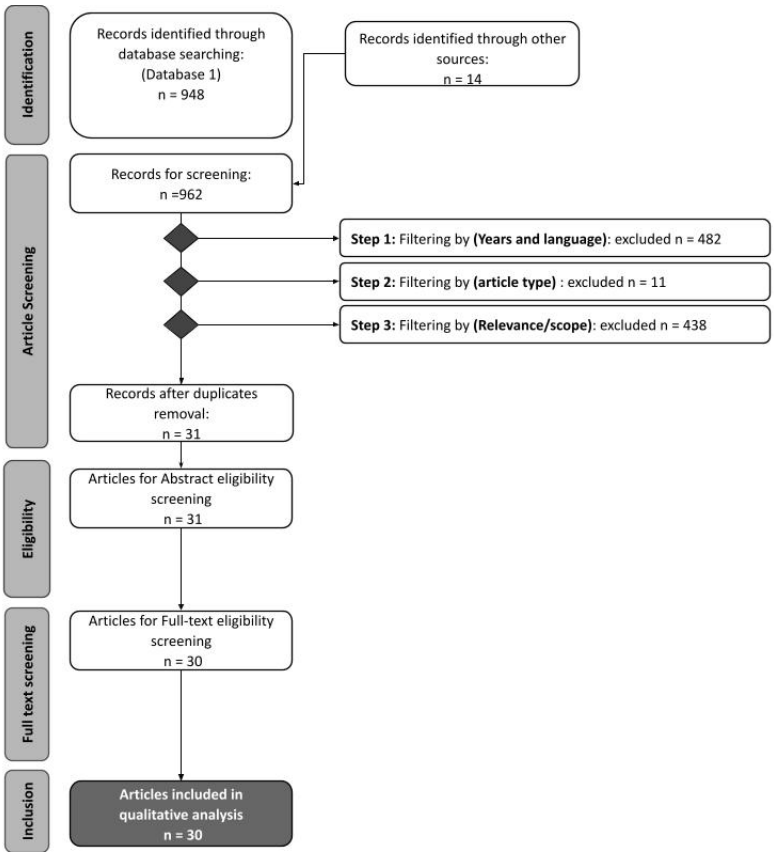

Figure 3.1: Flowchart of the systematic review for Technology for Telerehabilitation of Facial Paralysis

A total of 962 records were retrieved from the initial search on the identified sources. 948 academical ones were identified through database searching, and 14 were identified through other sources. This subsection will detail the academic article selection, while the following will detail the external sources.

The initial step of the screening phase – Figure 3.1 - Flowchart of the systematic review for Technology for Telerehabilitation of Facial Paralysis- step 1 – removed 482 records that were not published in English or were not published between the year of 2010-2022. In Step 2 of the current phase, 11 records were discarded because they were overviews, reviews or studies; In Step 3, 438 articles were removed because they were published outside of this work's scope. Finally, A total of 31 records were then screened for eligibility based on their abstracts.

Before the eligibility check, these articles were imported into the Mendeley Desktop tool, which enabled the management of citations. They were further listed in a dedicated spreadsheet within the FaceRehab project repository.

Following this first eligibility check — Figure 3.1 - Flowchart of the systematic review for Technology for Telerehabilitation of Facial Paralysis - Eligibility — 0 records were removed from the preliminary article list since they all contained open access to the abstract.

Finally, 31 records were screened for eligibility based on their full-text content. This eligibility check followed the same fundamental aspects as the eligibility check conducted for abstract content. Of these, 1 record was removed from the preliminary article list since it did not comply with the previously stated inclusion and exclusion criteria and was considered outside the scope of this deliverable, meaning works not referring to telerehabilitation of facial paralysis or frameworks to enable the remote rehabilitation.

The list of records identified as "Academic Articles" (n=16) selected to be included in this review is presented in Table 3.4. The records identified through other sources (n=14) are listed in section "Other sources".

Article citation	
Number	**Article reference**
1	A. M. Ridha et al. "Smart Prediction System for Facial Paralysis", [21]
2	Y. Liu et al. "Automatic Assessment of Facial Paralysis Based on Facial Landmarks", [22]
3	Z. Jiang et al. "A Cloud-Based Training And Evaluation System For Facial Paralysis Rehabilitation" [23]

Table 3.4 continued from previous page

	Article citation
4	T. Tasneem, A. Shome and S. K. A. Hossain, "A gaming approach in physical therapy for facial nerve paralysis patient" [24]
5	J. R. Delannoy and T. E. Ward, "A preliminary investigation into the use of machine vision techniques for automating facial paralysis rehabilitation therapy," [25]
6	C. Dittmar, J. Denzler and H. Gross, "A Feedback Estimation Approach for Therapeutic Facial Training," [26]
7	T. C. ten Harkel, S. Vinayahalingam and K. J. A. O. Ingels, "Reliability and Agreement of 3D Anthropometric Measurements in Facial Palsy Patients Using a Low-Cost 4D Imaging System," [27]
8	A. M. N. Taufique, A. Savakis and J. Leckenby, "Automatic Quantification of Facial Asymmetry Using Facial Landmarks," [28]
9	T, Cardarola et al. "Give me a kiss! An integrative rehabilitative training program with motor imagery and mirror therapy for recovery of facial palsy. [29]
10	Z. Zhang et al. "A Hybrid Evaluation System for Facial Paralysis Rehabilitation based on Machine Learning and Doctor Experience," [30]
11	Z. Guo et al. "An Unobtrusive Computerized Assessment Framework for Unilateral Peripheral Facial Paralysis," [31]
12	Wahed et al. "Quantifying facial paralysis using the kinect v2," [32]
13	T. D. Pham et al. "Region Based Parallel Hierarchy Convolutional Neural Network for Automatic Facial Nerve Paralysis Evaluation," [33]
14	Guarin DL et al. "Toward an Automatic System for Computer-Aided Assessment" [34]
15	T. N. Nguyen et al. "Real-time Subject-specific Head and Facial Mimic Animation System using a Contactless Kinect Sensor and System of Systems Approach." [35]
16	D. Jayatilake et al. "Robot Assisted Physiotherapy to Support Rehabilitation of Facial Paralysis,"[36]

Table 3.4: List of selected academic articles

Data Extraction

After the article selection procedures, all full-text articles were reviewed, and data that is relevant to the study question proposed in this work was extracted from them according to the data points that are defined in Table

3.5

Publication Information	Article title
	Author name(s)
	Author affiliation
	Publication year
	Country of origin
Technological characteristics	Technology Readiness Level
	Technological Framework
	Integration Framework
Validation characteristics	Type of validation
	Validation method
	Validation Conclusion

Table 3.5: Data Extraction Table for digital solutions for telerehabilitation of facial paralysis

The results produced in this data extraction phase were all organised in the form of a data table for more intuitive management of data and further ease in extracting views from data during the data analysis phase.

Data analysis and Data synthesis

Publication Year

From the data collected, a quantitative analysis was performed to obtain a high-level overview of the distribution of articles along the publication dates (Figure 3.2) and the distribution of topics around the technological, integration and interoperability aspects described in the included articles.

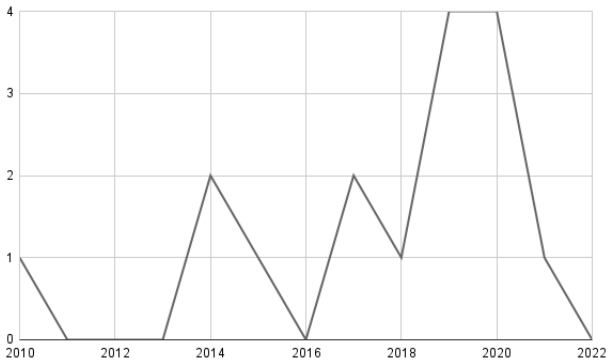

Figure 3.2: Number of articles published per year for Technology for Telerehabilitation of Facial Paralysis

From a simple analysis of publications per publication year (Figure 3.2), all included articles were published

within the defined year range interval. The articles on this topic show a rising tendency, especially during 2019 and 2020, which could demonstrate rising interest in implementing telerehabilitation for FP.

Geographical Aspects

From the geographical distribution of the articles (Figure 3.3) included in this study around the world, it can be observed that the interest for developing these kinds of solutions springs forth in great population regions, as is the case of the EU. Articles describing telerehabilitation options implemented in countries like the USA, China and Canada were also included.

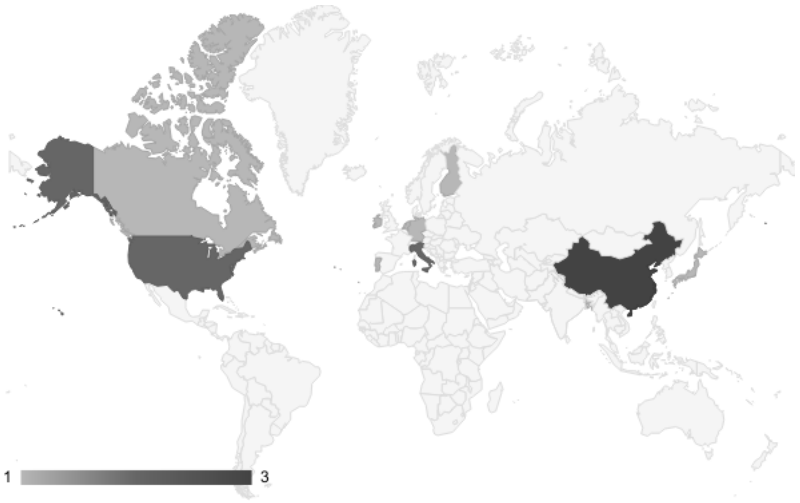

Figure 3.3: Geographical distribution of articles

Technological Topics

The objective of this review is to identify which technologies, integration and interoperability frameworks are being used and adhered currently in the scope of technologies for telerehabilitation of facial paralysis. Hence, the following analysis focuses on the distribution of topics regarding the previously mentioned research goals. The distribution of topics is visualized in the graphs from Figure 3.4 to 3.6.

From the graphic presented in Figure 3.4, it can be observed that the three most common topics referred to in the included articles within the context of integration frameworks deployed in the development of the technologies are Data Analysis, Artificial Intelligence(AI) and Internet of Bodies (IoB).

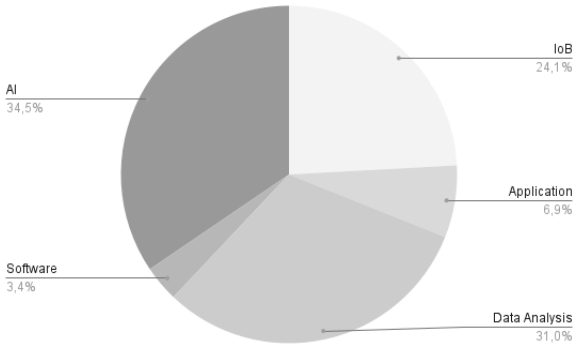

Figure 3.4: Distribution of topics regarding the aspect of Integration Frameworks.

From the graphic presented in Figure 3.5, it can be observed that the three most common topics referred to in the included articles within the context of Device Frameworks deployed in the development of the technologies are Visual Sensors, Analytical Models and Medical Devices.

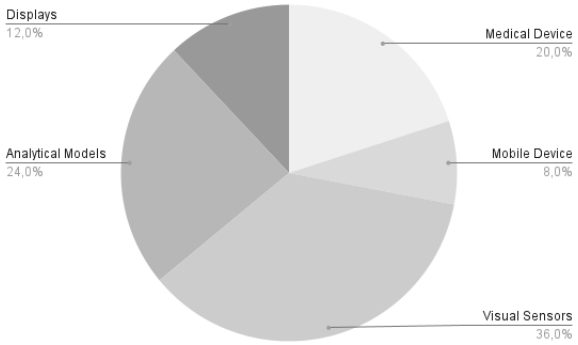

Figure 3.5: Distribution of topics regarding the aspect of Device Frameworks.

From the graphic presented in Figure 3.6, it can be observed that the three most common topics referred to in the included articles within the context of Approach on Rehabilitation deployed in the development of technologies are Automatic Assessment, Grading, and Serious Games and Exergames (equal).

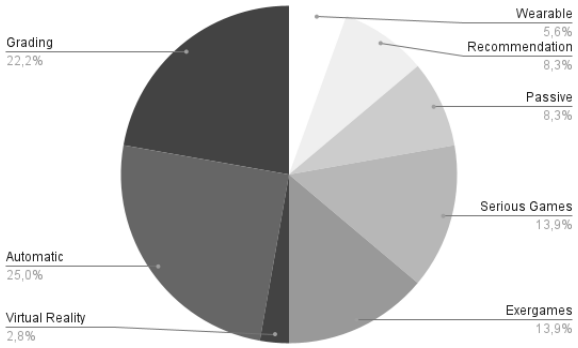

Figure 3.6: Distribution of topics regarding the aspect of Approach on Rehabilitation

Finally, from the graphic presented in Figure 3.7, it can be observed that the three most common topics referred to in the included articles within the context of the Type of Validation deployed in the development of technologies are Data Accuracy, Performance, and Proof of Concept and Data Analysis (equal).

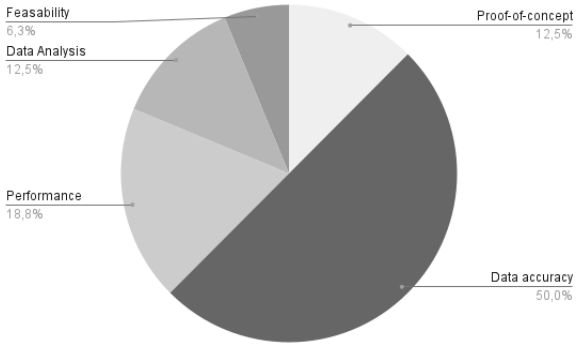

Figure 3.7: Distribution of topics regarding the aspect of: Type of Validation

Other sources

This subsection presents the records identified as "External Records" (n=14) on the topic of technologies for telerehabilitation in the scope of FP that were not identified through database searching (i.e. in Figure 1 ", Records identified through other sources").

Paralisís Facial: Developed by Familia C.V, the mobile application contains educational information on possible causes of facial paralysis and how to prevent them for future people. In addition, it offers extensive information on treatments for people suffering from this condition and examples of exercises to return the facial muscles to a normal state gradually. [37].

Parálisis Facial de Bell: Developed by Acamue, it contains general information on facial paralysis, such as

common symptoms, different causes, diagnosis and treatment options. The application also offers recommended exercises, access to specialists and testimonies of people with facial paralysis. [38].

Gimnasia facial – Tips: Developed by Things To Do, the application serves educational purposes and contains a list of articles with academic research. Among those, it offers educational information on facial paralysis causes and treatment. [39].

Parálisis Facial: Developed by Carmen Gómez Lescano, it contains possible causes of Facial Paralysis and how to prevent it. It also offers extensive information about treatments for people who suffer from FP and suggest exercises to perform at home. The application also helps prevent and rehabilitate FP [40].

Paralisia Facial: Offered by Luís Ramalho, the application contains information that helps treat facial paralysis and offers facial exercises that can be performed in a home environment [41].

FaCiPa: Facial Paralysis: Offered by FaCiPa, the mobile application has image processing software and uses the camera to capture face pictures, offering the option to diagnose facial paralysis and its stages [42].

Facial Nerve Grading: Offered by Jorge Pierre, the application contains information that helps treat facial paralysis. This is due to the academic information provided in the app that helps with the characterisation and analysis of the degree of facial nerve [43].

FNPEval: Offered by Rachelle Eljazzar, the mobile application is designated for facial rehabilitation treatment. It tracks patients' progress with FP by measuring and logging facial angles, making it possible for physicians to follow the patient progress [44].

The eFace: Offered by the Massachusetts Eye and Ear Infirmary, the application is one of the most respected in the market. It is designed to analyse the stages of FP by providing scores using visual analogue scales. The application can be used during patient evaluation by the physician or after the appointment by sending videos. In addition to that, the app provided education information and prescribed exercises to be performed at home [45].

Face It! Bell's Paralysis-Training: Offered by Ergonomhuset AB, the mobile application contains a page to provide questions and answers about Facial paralysis. In addition, it offers educational information on how to do the training and recommends therapy exercises to be performed at home [46].

BAPRAS AEC in Plastic Surgery 3.8: Offered by The British Association of Plastic, the mobile app is destined for the medical community. It keeps physicians updated on the most current discoveries and treatment options for facial paralysis. The application also offers an educational course to the professionals [47].

Face2Face Facial Paralysis: Offered by Kapios LLC, the app is designed for FP patients and provides remote mirror therapy. Mirror biofeedback therapy has been linked to positive results in treating facial paralysis. Therefore, the app uses the mobile camera to reflect the healthy side of the face, allowing the patient to perform rehabilitation exercises while seeing their faces without flaws [48].

MIRROR facial rehabilitation app: Mirrors the healthy side of the face on the unhealthy side, allowing

patients to exercise their facial muscles while seeing their faces fully healthy. Mirror biofeedback therapy has been associated with positive results in treating idiopathic facial paralysis. Unfortunately this application is no longer available.

FaceRehab: The digital application is offered by Inovuj and allows the patient to perform facial rehabilitation exercises in a home environment. the app offers treatment exercises prescribed by a specialist, muscle movement tracking software, and progress tracking [49].

3.2 Conclusion

This systematic review aimed to create an overview of the implementation of technologies for the telerehabilitation of facial paralysis. The focus of this review was to identify the types of frameworks currently being used and deployed from the technological, integration and interoperability perspectives. In addition, this review also identified the most common types and methods used to validate these rehabilitation options. Finally, through external resources, this review also identified some notable instances of digital applications and platforms currently being developed and deployed in the context of Global Innovation and Research Programs, applied to Telerehabilitation for Facial Paralysis and the Telemedicine Healthcare Sector.

This review has followed the specifications of the PRISMA protocol to produce a review based on 16 academic articles and 14 external sources, which were selected according to the predefined eligibility criteria and workflow proposed in Table 3.5 and Figure 1 - Flowchart of the systematic review for Technology for Telerehabilitation of Facial Paralysis. Following the extraction strategy, a statistical analysis of the data was produced from the data extracted from these articles.

The main results of our systematic analysis suggest that the current technology available does not provide a complete treatment option for the patient nor solve the overall issues healthcare professionals face. Most of the technology extracted from academic sources is still in development and is not yet ready to face the market or the goal is mainly academic achievements not commercial. In addition, the majority of mentioned solutions are software that uses machine learning and image processing techniques to help diagnose and evaluate the facial paralysis condition.

As for the external sources, most of these competitors offer a set of features designed to cover some aspects involved in FP. FaceRehab will be the only solution that will provide functionality for complete facial rehabilitation with monitoring, feedback, remote tracking and dedicated devices that can be extended with other exercises. In addition, current competitors mainly focus on direct selling to patients, while the FaceRehab strategy is to leverage distribution channels within institutions (target buyers). This strategy will allow FaceRehab to reach many

users while providing benefits to other stakeholders, such as doctors, physiologists, healthcare systems, insurance companies and government authorities.

Chapter 4

FaceRehab - Facial Paralysis Rehabilitation at Home

This chapter focuses on applying seven different approaches for the development of co-design and specification of FaceRehab solution. The following section will address a Stakeholder Analysis, Patient Journey, User Needs, User Stories, Use cases, Requirements and Technical Approach. It is expected to enable the development team to deliver value more efficiently with improved quality. We also expect that by performing the following analysis, the development team will be able to adapt easily to market change and obstacles.

4.1 Stakeholders Analysis

Any individual, team, or organisation interested in the project is considered a stakeholder. Identifying all stakeholders early on in the project and analysing their interests, expectations, importance, and level of influence is essential to its success. Therefore, the goal of performing this analysis is to:

- Identify actual and potential conflicts of interest
- Draw out the interests of stakeholders concerning the project's objectives
- Provide an overall picture of the consortium and partners involved as well as the relationships between different stakeholders
- Identifies viability other than in purely financial terms (e.g. includes social factors)

After being identified, they should be categorised based on their engagement, impact, and interest in the project. This classification enables the project manager to concentrate on developing connections and ensure

project success. The methodology to perform a stakeholder analysis followed in this section was provided by FEUC in collaboration with the EIT Health program. It states three steps:

- Step 1: Identify the stakeholders
- Step 2: Create a Stakeholder Map
- Step 3: Identify Stakeholder Allegiance

Identifying Stakeholders

PESTLE (Political, Economic, Sociological, Technological, Legal and Environmental) is used to identify the stakeholders. Analysing the primary outside forces that affect an organisation makes it possible to have a bigger picture of the environment, identify stakeholders, and understand how they relate to the project. A short briefing of each of the factors mentioned above can be found in chapter 5, where the impact of FaceRehab on the market is analysed.

The stakeholders in the FaceRehab value-chain are people with facial paralysis, public/private organisations of care, regulatory organisations, technology developers, informal caregivers, insurance companies and delivery partners.

Those can then be divided into 3 different categories: People with Facial Paralysis (primary end-users), caregivers and healthcare professionals (secondary end-users) and associated networks (tertiary end-users).

The group that would directly benefit from the solution is the individuals with facial paralysis, hence the term "end user." This group benefits from a more effective, convenient, and accessible therapy (instead of simply receiving it in a care facility, they can continue receiving it at home), quicker recovery of functionality, and the encouragement of independence and social integration. This stakeholder's primary responsibility in the project is to determine and confirm the demand for the solution and evaluate the product's success and quality. As a result, they are required to participate in user acceptance testing by the developers.

Healthcare institutions and professionals are also called the secondary end-user. It benefits from a unique service to evaluate, monitor and provide rehabilitation at patients' homes and in a clinic setting. Using the product, they could provide a quality service to residents (home care and care homes) with facial paralysis, extending their current services without increasing the internal resources. The product will have a positive effect on the quality of the service. Promoting user independence also reduces resources and costs for the clinics, ultimately maximising the installed capacity. The primary role of this stakeholder is to recruit and engage with the primary end-users and moderate the communication between the developers and the primary end-users.

Finally, the last stakeholder comprises the associated networks, which include the technology developers, integrators, insurance companies and delivery partners. This group mainly benefits from developing new technology and its positive consequences, such as financial feedback, better reputation in the market, and increased

networking and development of the company.

Table 4.1 shows a summary of all the stakeholders, their roles, perceived attitudes, risks and finally, the management strategy.

Create a Stakeholder Map

At this step, the stakeholders should be organised on a "stakeholder matrix" based on how much the change would affect them and how crucial they are to the project's success. The matrix correlates the power of the stakeholder and their interest in the project. Based on their place on the grid, it is possible to analyse how active they should be during the development of the device and define the hierarchy position between the parties involved.

Based on the first stakeholder analysis, it was possible to decide which part of the grid each stakeholder fits into and follow the relevant management strategy.

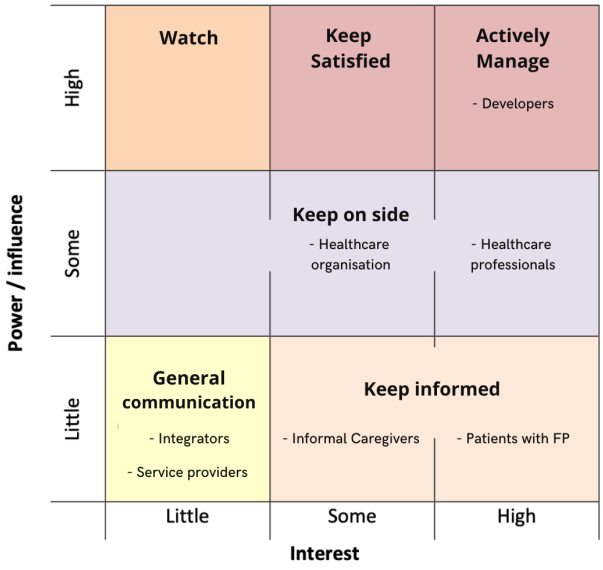

Figure 4.1: Stakeholders Matrix

The distribution of the stakeholders and their places has been decided based on the project's current stage. However, it is essential to mention that during the project development, their positions can change based on their interests and influence over time.

It is possible to conclude based on this matrix that at this moment, the developers are the ones with more interest and influence, followed by the healthcare professionals and organisations. Therefore, at this moment, they are crucial to FaceRehab's solution and its success. The other parties involved should maintain regular communication and keep informed of the updates.

Stakeholder	Stake in the project	Impact	What is needed from them?	Risks	Management Strategy
Patients with Facial Paralysis	Use the new technology to treat FP	High	- Test the technology - Validate efficacy and quality	- Lack of clarity - Lack of confidence - Inadequate use	- Frequently supported by specialized professional
Public/Private organizations of care	Implement the tech. in the clinical environment	High	- Buy the technology - Implement it in the clinical environment	- Lack of interest - May not contribute financially - May not have the right professionals	- Explain the benefits - Train the professionals for a high quality delivery - Show results from previous experiences
Healthcare professionals	Use the technology on their patients	High	- Assist in the development stage - Adapt to the treatment process - Utilize it on their patients	- Lack ok interest - May find it unnecessary - Hard adaptation - Lack of confidence	- Explain the benefits - Show results from previous experiences - Provide training classes - Show scientific proves of efficiency
Informal caregivers	Assist the patient during the treatment	Medium	- Learn how to use the technology	- May find it hard to adapt	- Provide training classes
Technology developers	Develop the technology	High	- Technically develop the solution - Ensure good quality - Ensure efficacy	- Too many projects being develop simultaneously - Not enough time to provide a cutting-edge technology	- Perform weekly meetings - Involve and delegate tasks - Hire service providers
Service providers	Assist in the development and implementation of the technology	Medium	- Consult if needed	- Lack of interest - Not enough time to provide a cutting-edge technology	- Explain and provide benefits
Integrators	Integrate FaceRehab's technology with others	Low	- Adapt existing technologies to be integrated with FaceRehab	- Lack of interest	- Explain and provide benefits

Table 4.1: Stakeholder Identification and pre-analysis

Identify Stakeholder Allegiance

This step aims to decide the extent to which each stakeholder (or stakeholder group) supports or opposes the project. Figure 4.2 identifies the possible allegiances.

Assessment	Definition	How to Manage
Advocates • Developers	• Only group driving the change or project • Active communications, keep regularly involved	• 'Internal' champions and sponsorship • Input to key milestones and decisions • Use for internal promotion of objectives and benefits
Followers • Patients with FP • Informal caregivers	• Have a low understanding of project aims and objectives • Increase their understanding for future benefit	• Support the project and tend to "go with the flow" • Keep informed and positive • Avoid the temptation to exploit
Indifferent • Integrators • Service providers	• Individual or groups yet to take a definitive position on the project • Identify gaps in knowledge and seek to fill them	• Seek their views on key issue and address concerns • Have a medium understanding and medium agreement • Be careful not to make them opponents
Blockers • Healthcare organizations • Healthcare professionals	Shows resistance to the project or its aims. Principally due to having a low understanding and low agreement. This can be driven by: • Proactive communication • Interview and meet • Explain and overcome fears	• Use conflict management techniques • A lack of communication • Seeks views once understanding starts to develop • A (perceived or actual) loss from project • Knowledge of error in project assumptions
Opponents	• Has high understanding but low agreement to the project • Initiate discussions and understand reasons for low acceptance	• Will potentially 'lose out' in some way from the activity • If the loss is perceived but not real, then convert using facts and data • Counter the reasons for low acceptance

Figure 4.2: Stakeholder Allegiance

In figure 4.2 there is a list of the assessments followed by their definition and suggestions on managing them. Using that information and the analysis performed before, it became possible to fit each stakeholder into one category.

- Producers: Advocates - Have the biggest power and are very interested in the project's success. Therefore, they are the only group responsible for the device's conquest and should be active and involved.
- Patients with facial paralysis and Informal caregivers: Followers - They are only the end users, not committed to developing the product. They should be the ones to identify the issues encountered and analyse if their

needs are being filled.

- Healthcare organisations and professionals: Followers - They only benefit from the product but do not have any commitment to the development of the product. Even though they might like the idea and find it useful, they might resist adapting to the treatment method or find it unnecessary at the moment.
- Integrators and Service providers: Indifferent. Their work will continue the same with or without the project.

Finally, once the stakeholder analysis is complete, it is possible to highlight the essential stakeholders and their conditions for the project. By performing this evaluation, the team can clearly understand each stakeholder and what they anticipate from the project. At the moment, it is clear to notice that the developers, healthcare professionals and patients with FP are the ones with more interest, while the developers hold the majority of the responsibility for its implementation.

4.2 Patient Journey

Patient journey maps are a visual and valuable tool that helps the improvement of care by, for example, cutting down the line waiting times and enhancing patient safety. The complexity of modern technology systems has left patients with little awareness of their utility and significance. Patient journey maps, therefore, strengthen patients' knowledge, which improves their ability to use technologies. The ability to find technical opportunities in the healthcare sector by comprehending the problems faced by the patient makes patient journey maps crucial for developers as well. The engineers can comprehend how technology is incorporated into the healthcare system thanks to the visual portrayal. In conclusion, such maps could improve health strategy planning at a policy level while allowing the enhancement of patients' knowledge.

This paper will outline a unique method for identifying areas where technology could be used to improve patient experience and health outcomes—patient journey mapping —. Furthermore, in addition to the patient path, the healthcare professionals and informal caregivers will also have their journey described and categorised.

Methods

This Patient Journey map relies on the findings reported by Meyer et al.[50]. It claims that using case studies and previous research could result in a more accurate and efficient patient experience. In addition to that, the investigators made essential observations on mapping the patient journey: (i) The patient's health goal must be evident, (ii) Patient and health professionals' interactions must be transparent, (iii) Shared decision-making is

necessary, and (iv) There is a need for closed-loop communication [50]. By following this framework, four stages have been included in this map:

- Creation of a relevant case report
- Context
- Mapping

Using Meyer's approach, it became possible to create a complete patient journey map that reports the benefits of FaceRehab's technology, patients' actions and the integration of the solution into the market.

Selection of a relevant case report

The first step of the map creation consists of identifying a relevant case report in which FaceRehab's technology could be used. That is a situation of Facial Paralysis that benefits from a telerehabilitation approach. The FaceRehab consortium had already developed a persona's case. In order to facilitate this work, the same case can be used, as it represents a good use of the technology and describes a possibility in real life.

Case Report

J. is a 70-year-old patient from Portugal who resides in a small rural city. He recently received a diagnosis of intravascular lymphoma, which caused him to experience: (i) Central facial paralysis, (ii) Hemiparesis, hemianopsia, and (iii) Paresis of the left 12th cranial nerve.

The right side of the patient's face is asymmetrical. Inability to close the eyelid due to changed salivary and lacrimal secretions and taste may harm the cornea. His attendance at the clinic is recommended for an interdisciplinary intervention. The evaluation was completed by a team composed of a doctor, a physiotherapist, and a speech therapist, who also created an intervention plan.

J., unfortunately, has trouble using public transportation, does not drive, and lives a significant distance from the clinic. He claims that his drooling and asymmetrical face make him extremely embarrassed when eating or just being in public. The wife claims that occasionally she misses meals, mainly eats at home, and even loses weight. He often goes to the treatment accompanied by his wife since hemianopsia causes him to have reading difficulties. Despite feeling at ease with the clinical-therapeutic team, he exhibits discomfort when travelling daily, financial difficulties, and some anxiety about the hospital environment. J. is aware that he must regularly follow his exercise plan in addition to his therapy. He does, however, draw attention to the challenges of recalling all the treatment instructions and the discomfort he has while practising some exercises at home without receiving immediate feedback.

J. and his wife began considering whether he could receive some of these therapies at home, in his own secure and comfortable setting. The couple also asked if they could do them more frequently and on their schedule. J.

added that his son enjoyed engaging in his therapy to aid in his recovery and give his mother time to relax. However, he cannot accompany them to the therapies in a clinical setting due to schedule conflicts.

The timing of their discussion with their clinical staff could not have been more ideal. The hospital had just recently begun collaborating with FaceRehab. This new medical solution will enable direct therapy plans for each patient, allowing the therapist to choose the most appropriate exercises for the clinical state and its development.

In this way, the patient can supplement the rehabilitation process in a clinical setting at home. The medical personnel will have access to a record of the movements' execution quality, keep track of the patient's home rehabilitation, provide correctional messages, and steer clear of any potential difficulties throughout their recuperation.

This technique enables monitoring of the patient's development and training of functioning and movement execution. The patient may complete exercises in the convenience of his own home while FaceRehab evaluates and documents the session's progress. A more natural relationship between his wife, him and the doctor is also made possible by the application subscription.

As a result, future complications in the recovery process can be avoided. The therapists and doctors will have access to the record of the quality of movement execution, evaluating the patient's progress by determining how much of the nerve is involved, training the functionality, and performing the movement in real-time from session to session. This intervention happens every other day (Monday, Wednesday and Friday). This app has a monthly subscription that has a cost connected with it but has no usage restrictions. The success and efficiency of the treatment are directly correlated with the frequency of interventions. As a result, J. started to notice improvements in the usability and range of motion of the affected muscles after some sessions. He and his family believe this strategy enhanced J's health and disease management while preserving their independence and social customs.

Context

The patient journey mapping took place in Portugal's healthcare system. The system can be described as a mix of public and private health providers that delivers primary healthcare in Portugal.

Taxes are utilised by society to pay for care in public health (i.e., citizens pay taxes which are then used to pay for healthcare services). These taxes are continuously collected by the federal government and distributed to the local healthcare facilities. State-run healthcare delivers comparatively good yet frequently inconsistent services. Long wait times caused by over-subscription are one of the drawbacks. Private facilities are an option when a patient wishes to receive superior care and frequently avoid lengthy waiting lists in the state system.

On the case report, primary care physicians initiated the patient's facial paralysis journey. At this first step, the professionals initiate diagnostic testing for FP. Referrals then follow this work to specialists such as physiotherapists

and speech therapists (often in private clinics)

The case report outlined a patient's experience who first directed himself to a public healthcare centre and was referred to a private clinic for an interdisciplinary intervention. The private clinic offers a specialised team composed of a Physician, a Physiotherapist, and a Speech Therapist, as well as provides the patient with modern solutions such as FaceRehab.

Patient Journey Map

The original case report includes aspects of which FaceRehab's technology can be used to improve patient care and support its rehabilitation process in a known and comfortable environment. The Patient journey map extends the usability and identifies potential solutions such as reducing wait time and complications and improving safety and effectiveness. Enterprise Architect was chosen as a patient journey mapping tool. Its configuration allowed visualisation of the patient path from beginning to end. The tool also allowed the visual representation of the solution benefits, patient's goals and technological opportunities.

The first step of creating the map consisted of extracting data from the case report and turning the information into a standard patient journey. The Facial Paralysis pathway includes several vital phases: Pre-diagnosis, Primary care doctor visits, Diagnostic testing, Diagnosis, Choosing a treatment, Treatment and Remission). A quick interpretation of the case report allowed the creation of a simple step-by-step list;

1. A medical conditions trigger Facial Paralysis.
2. The patient consults with a family doctor or private doctor, where he gets diagnosed with Facial Paralysis.
3. The patient is referred to a private clinic for an interdisciplinary intervention
4. After scheduling an appointment at the private clinic, the patient gets called for a consult with a specialised physician
5. After evaluation and diagnosis, the physician prescribes adequate treatment, and the patient is referred for physical and speech therapy.
6. The patient begins the treatment process. The assigned therapist begins the treatment with a functional, static and dynamic evaluation. In addition to that, the professional gives orientation and clarification of the patient's doubts
7. Patient starts treatment with passive techniques: Facial heat against lateral, Ice motor points and Relaxation massage.
8. After the steps described above, the patient starts an active methodology: Exercises aimed at rehabilitation of Facial Paralysis in the context of FaceRehab.
9. The Therapist selects the most appropriate exercises to the patient's needs (e.g. level, frequency and type of exercises) to ensure a steady and favourable progression.

10. The patient subscribes to FaceRehab's application. It allows rehabilitation in a clinical context to be performed at home. In addition, the caregiver interacts more with the treatment and the health professional. The physicians and therapists can correct exercises in real-time, give positive reinforcement, and encourage the patient, thus avoiding complications that may arise during recovery.
11. The health professional will have access to data regarding the quality of the executed movements. They will be able to evaluate the user's progress over time, train the functionality, and analyse the movements in real-time from session to session, thus avoiding future complications in user recovery.
12. This intervention occurs on alternate days (e.g. Monday, Wednesday and Friday). The subscription of this app is monthly with an associated value but without a limit of uses.

The list provided an overall process framework. Each action was categorised into the categories mentioned (Pre-diagnosis, Primary care doctor visits, Diagnostic testing, Diagnosis, Choosing a treatment, Treatment and Remission), and the patient goals and actions were extracted for each phase in the pathway. The last step consists of detecting the technological benefits of the solution for each of the stakeholders (patient, caregiver and healthcare organisation owned) that would allow the integration of FaceRehab into each phase of the FP telerehabilitation pathway. The final patient journey flow can be found in 4.2

The mapping tool focused on integrating the benefits for each stakeholder while improving communication between the patient, caregivers and healthcare providers throughout the facial paralysis rehabilitation process, as described in the case report. To this end, the map includes:

- The stages of the healthcare process from a holistic perspective (Pre-diagnosis, Primary care doctor visits, Diagnostic testing, Diagnosis, Choosing a treatment, Treatment and Remission)
- The patient's goals that describe the mission/objective of the patient when performing a particular action.
- The patient action. That row represents the patient's expected activities in that phase.
- FaceRehab's technological opportunities. It describes how the solution can improve the healthcare process for Facial Paralysis

Once the Patient Journey evaluation regarding FaceRehab's use is complete, it is possible to describe the full chain of events that the patient goes through in this specific healthcare system. It is then possible to note that the innovation significantly impacts primary care visits, treatment methods and remission stage. In conclusion, FaceRehab technology improves the standard patient journey regarding facial paralysis, and when analysing the context, it can be easily implemented and adapted by the end-user.

	1: Pre-diagnosis	2: Primary care doctor visit and testing	3: Diagnosis	4: Choosing a treatment	5: Treatment	6: Remission
Patient's Goals	- Notice symptoms - Make an appointment with their doctor	- Arrive at the office - Consult with the physician - Perform evaluation tests	- Receive results and diagnosis - Understand the diagnosis - Create a support system - Work with the primary care doctors	- Meet with the specialized physician - Consider all treatment options - Choose an ideal treatment option	- Follow treatment directions - Stay in touch with the physician	1: Perceive the progression of the condition 2: Perform continuous evaluations 3: Adjust treatment options
Patient's Actions	The patient become aware of the condition and schedule an appointment with their physician	- Patient meet with the doctor - Patient explains their symptoms - The physician evaluate the condition through exams	- Patient is diagnosed with Facial Paralysis	- The patient will be referred to a specialized professional - HC Professionals will give the patient the treatment options - The patient will choose a treatment option	- The patient will undergo the treatment in the clinic, with the assistance of the HC professional or by themselves, at home	- The patient realize some improvement - Doctor evaluate the level of FP - Treatment plans might change
Technological Opportunities	FaceRehab doesn't offer any technical opportunity at this level	FaceRehab offer measuring tools to correctly evaluate the level of facial paralysis	FaceRehab doesn't offer any technical opportunity at this level	FaceRehab doesn't offer any technical opportunity at this level	FaceRehab will connect the patient to the professional, ensuring that the exercises performed at home are done correctly and with the right frequency. Patients will be able to perform the exercises at home with the assistance of the HC professional	FaceRehab offers the HC professional and the patient to constant evaluate the progression of the condition. It will also offers the possibility to easily change treatment plans.

Table 4.2: FaceRehab Patient journey flow

4.3 User Needs

The term "user needs" refers to problems restricting users from reaching their objectives or aspirations. Other interpretations include opportunities to improve the possibility of the user to achieve their goals. It is feasible to comprehend the qualities a specific product should have to enhance a patient's access to healthcare by doing a "User needs analysis." While conducting this analysis, some elements should be considered, including the user's context, tasks, tools, and physical and social environments while utilising a product [51].

Researching the problems and complaints experienced by patients with facial paralysis and other stakeholders in the healthcare system is the first step in conducting a user needs analysis. Santos et al. [52] did a critical review of literature in the scope of interprofessional work on Facial Paralysis and reported that some of the main feedbacks encountered in the scope of Facial Paralysis are:

- A multidisciplinary team of medical specialists, including an otolaryngologist, neurosurgeons, and other healthcare providers like speech therapists and psychologists, should take care of patients with facial paralysis [53].
- Some researchers classify facial paralysis as a psychological illness. This has emotional, social, and professional repercussions because of an aesthetic and functional deformity. The positive effects of rehabilitation on user care enhance life satisfaction, and self-esteem [54].
- The patient reported symptoms of significant discomfort in situations where speech and hearing evaluation were considered mild. In contrast, the patient reported symptoms of minimal discomfort in cases the evaluation found severe [55].
- The peripheral facial paralysis patients are regularly treated by a multidisciplinary team that includes a speech therapist. They aid in providing the patient with the best practical care, enhancing their quality of life [56].
- Rehabilitative services are already in place. However, finding a proper, impartial, affordable assessment technique that speech therapists and other therapists can utilise for monitoring and determining discharge is still a challenge [57].
- The collaborative efforts of a multidisciplinary team aided in the process of treating paralysis [58].

Analysing the factors mentioned above, a list of the needs was prepared for the main stakeholders involved in the solution (Patient, Informal Caregivers, and Healthcare professionals), they being the 'users' in each case.

Patient needs

Reference	Patient's Needs
N1	Extend the clinical process of rehabilitation of FP to the home environment.
N2	Frequent and consistent myofunctional (exercise-based therapy) training.
N3	Faster and more effective rehabilitation.
N4	Home monitoring.
N5	Have visual feedback at home to correctly perform the exercises prescribed by the therapists.
N6	Avoid complications, such as synkinesis, triggering adverse outcomes in rehabilitation.
N7	Reduce the costs associated with travels.
N8	Provide guidance/strategies and support material more easily.
N9	Allow greater independence autonomy and accountability in the rehabilitation process.
N10	Integrate the FP rehabilitation process in the biopsychosocial model.
N11	Easy access to a multidisciplinary team, such as otorhinolaryngologists and speech therapists promoting the joint actions of professionals.
N12	Avoid emotional, social, and professional disruptions caused by unsuccessful treatments. [59].
N13	Long-term monitoring [60].
N14	Stable bond between healthcare team and patient [61].

Table 4.4: List of Patient's Needs

Informal Caregivers Needs

Reference	Caregiver's Needs
N15	Extend the clinical process of rehabilitation of FP to the home environment
N16	Provide guidance/strategies and support material more easily
N17	Allow greater independence autonomy and accountability in the rehabilitation process
N18	Support the role of the informal caregiver
N19	Create less burden for caregivers
N20	Integrate the FP rehabilitation process in the biopsychosocial model

N21	Reduce the costs associated with travels
N22	Informed follow-up on his relative by checking the exercises performed through the system
N23	Provide a new service model that can reduce the costs associated with health care for people with FP but maintaining or increase the performance of caregivers and therapists

Table 4.6: List of Caregivers Needs

Healthcare Professional Needs

Table 4.7: List of Caregivers Needs

Reference	Healthcare professional's Needs
N24	Extend the clinical process of rehabilitation of FP to the home
N25	Myofunctional training more often
N26	Promote faster and more effective rehabilitation
N27	Home monitoring
N28	More efficient follow up by the professional
N29	Have visual feedback at home, in order to correctly perform the exercises prescribed by the therapists
N30	Avoid complications, such as synkinesis, triggering negative outcomes in rehabilitation
N31	Remote supervision by a professional (avoid auto-prescription)
N32	Provide guidance/strategies and support material more easily
N33	Integrate the FP rehabilitation process in the biopsychosocial model
N34	Improve digital transformation of the health and care for people affected with FP
N35	Provide a new service model that can reduce the costs associated with health care for people with FP but maintaining or increase the performance of caregivers and therapists
N36	Improve the number and types of services related with FP rehabilitation
N37	Analyse the impact of the system in patients with FP
N38	More personalized intervention protocol for each recovery phase (e.g. session planning, prescription to home and decrease time spending in the session planning)
N39	Check whether the exercises trigger correct responses in home

N40	Integrate into oral rehabilitation plans functions such as speaking, chewing, swallowing, sucking and breathing
N41	Integrate more functional exercises such as chewing in the rehabilitation plan in the patient's environment
N42	Supporting the development of evidence-based practice in FP (e.g. keep up to date with most currently treatment practice)
N43	Clinical evaluation and reassessment (objective and measurable results from rehabilitation plan)
N44	Easy and secure way to log in the system
N45	Easy access to a multidisciplinary team, such as otorhinolaryngologists and speech therapists, promoting the joint actions of professionals [59].
N46	An standard evaluation method that is practical, objective and low cost [57].
N47	Allow clarity of the responsibilities and roles of each of the professionals and the recording or data.
N47	Provide interprofessional work, as it is a crucial component of sharing knowledge [62].

4.4 User stories

In business development, a User Story is defined as an informal description of the technology's features [63]. This methodology explains what users require from the system and how and when they get it. The advantages of creating a User Story are that the developers have a visual representation of the user's route and action options and can inform all stakeholders about the feature set. Evaluations, such as those on the "Value Proposition" (Chapter 6) and "User Needs," have information about these advantages. However, the unique aspect of "User Stories" is that it enables the developers to comprehend the circumstances that led to the persona doing that action and its results.

In this work, the information has been assumed due to the opinions of various stakeholders involved in the project and follows the subsequent sequence:

- As a [user type],
- I want [a certain feature]
- So that [I get some benefit]
- Given [Context for the behaviour]
- When [Action required to achieve the outcome]

- Then. [Expected output]

When looking into FaceRehab's utility path, it is notable that there are four significant cases where the persona performs an action while using FaceRehab: Authentication, Rehabilitation Program, Evaluation and Guidelines. That is the persona login into the system (Authentication), complete the program (Program), Report/Analyse Results (Evaluation) and Accesses guidelines. The following section will explain these prominent use cases in more detail. However, to facilitate this work and integrate the methods, the user stories will be divided according to them.

Note: For this section, the information provided in the previous four sections will be assumed, such as the involvement of only three personas/stakeholders (Patients, Caregivers and HC Professionals) and their respected needs and actions mentioned.

Figure 4.3: User Stories US001

US001: Login

As a: User (Therapist, Patient and Informal Caregiver)
I want to be able to: Get access to FaceRehab's System
So that: I can complement the rehabilitation carried out in a clinical context
Given: The system has authentication screen (e.g credentials/biometry login system)
When: The user login
Then: Get access to his personal area

Figure 4.4: User Stories US002

US002: Therapeutic Clinical Evaluation

As a: Therapist
I want to be able to: Get a facial analysis
So that: I can perform a static and dynamic evaluation to the patient in the first use, revaluation and final evaluation.
Given: The Therapist logged in the system
When: The system makes the metric or photographic record of the static and dynamic face of the user.
Then: The system register facial symmetry at rest, symmetry of ocular, nasal and mouth muscles in movement and therapist can plan a recovery plan.

Figure 4.5: User Stories US003

US003: Prescription

As a: Therapist
I want to be able to: Prescribe exercises according to the therapeutic evaluation
So that: The treatment plan is available in a given patient profile
Given: The therapist logged in the system and has access to a specific exercise list from which to choose
When: The therapist needs to prescribe a treatment plan to a given patient
Then: Patients can perform the exercises correctly at home

Figure 4.6: User Stories US004

US004: Clinical Rehabilitation Program

US004: Clinical Rehabilitation Program
As a: Patient
I want to be able to: Have access to specific exercises suitable for my needs
So that: I can improve my clinical condition over time
Given: The patient already has prescribed exercises
When: The patient logged in the system.
Then: A list of prescribed exercises is available and the patient can start the rehabilitation program at home
And: Perform the exercises
And: The system makes the record of the exercises, for therapist give feedback on the correct execution, evaluating the patient's progress and avoiding associated complications, such as the presence of synkinesis, hyperlacrimation during mastication or increased inappropriate muscle activity, due to incorrect performance of prescribed exercises, triggering negative outcomes in the user's rehabilitation.

Figure 4.7: User Stories US005

US005: Support performance of exercises

As a: Informal Caregiver
I want to be able to: Provide support for patient with the performance of exercises
So that: I can assist in the process and help during any inconveniences
Given: The patient already has prescribed exercises and can perform them
When: The patient logged in the system.
Then: The patient can have a better and more efficient treatment

Figure 4.8: User Stories US006

US006:Adjustment Treatment

As a: Therapist
I want to be able to: Adjust exercises according to the patient clinical condition and progress
So that: : I can improve the efficiency of the proposed rehabilitation plan, consequently, a faster recovery from patient
Given: The patient finishes the set of exercises
When: The therapist access to the patient profile and can see the recording of exercises
Then: The therapist can check how the session occurs and adjust the prescription according to the evaluation on the patient performance

Figure 4.9: User Stories US007

US007: Correction of exercises

As a: Patient
I want to be able to: Adjust exercises according to the therapist's recommendations
So that: I can improve the efficiency of the proposed rehabilitation plan, consequently, get a faster and more efficient recovery
Given: The patient finished the set of exercises
When: The therapist has access to the patient profile and can see the recording of exercises
Then: Patient can correct the exercises for future rehabilitation sessions

Figure 4.10: User Stories US008

US008: Caregiver Guidance

As a: Informal Caregiver
I want to be able to: Have access to detailed information and dedicated guidelines
So that: I can assist in the process and help during any inconveniences
Given: The system FaceRehab provides detailed information and materials dedicated to the Caregiver
When: The caregiver logged in to the system, is authenticated and accesses the caregiver's dashboard
Then: The caregiver has access to supporting guidelines and can help the patient to perform the rehabilitation exercises at home.

Figure 4.11: User Stories US009

US009: Professional Guidelines

As a: Therapist
I want to be able to: Have access to FP rehabilitation's newest best practices and guidelines dedicated to healthcare professionals
So that: I can stay updated with state-of-the-art clinical practice and prescribe better treatment
Given: The therapist is authenticated and accesses the therapist's dashboard
When: The therapist clicks the news tab
Then: The therapist can browse a catalogue of curated articles and scientific and clinical materials and visualise their contents.

Figure 4.12: User Stories US0010

US0010: Patient Therapeutic Guidelines

As a: Patient
I want to be able to: Have access to FaceRehab's guidelines
So that: I can learn how to properly execute the various recommended exercises and have access to specific care tips and recommendations related to my clinical situation
Given: The system FaceRehab provides detailed information and materials dedicated to the primary end-users
When: The patient logged in to the system, is authenticated and accesses their dashboard
Then: A "reminder" type guidelines triggering an avatar shows up to exemplify the self-massage and performance of cleaning nasal and eye hygiene prescribed by the therapist.

A comparative table between the needs listed on the previous chapter and the user stories have been developed in order to understand how FaceRehab respond to the end-users needs (Appendix G). Analysing this table, it is possible to note that FaceRehab's features is according to the needs seen on the market, which indicate the importance of its use on a daily basis.

4.5 Use cases

A use case can be defined as "A collection of possible scenarios between the system under discussion and external actors, characterised by the goal the primary actor has toward the system's declared responsibilities, showing how the actor's goal might be delivered or might fail" [64].

To put it another way, the use case is a particular study technique that investigates a topic and assists the developer in locating and organising the system requirements. It enables researchers to learn more deeply and comprehend the product's market trajectory once it is released. The approach entails creating hypothetical circumstances and interactions between product users and examining the outcomes, objectives, and settings.

A use case consists of three elements:

1. Actor: The person that utilises the system, that is, the user - It can be a single person or a group of people that interacts with the product
2. The goal: Represents the successful outcome aimed by the user while performing a certain action
3. The system: The process and steps taken by the user to reach the outcome. This element might include requirements and their anticipated behaviours.

Note: Equal to the last section, the information provided in the previous five sections will be assumed, such as the involvement of only three personas/stakeholders (Patients, Caregivers and HC Professionals) and their respected needs, actions and case stories mentioned.

The writing process follows the subsequent order:

1. Analyse and identify all systems users and create a profile. This step has been covered in the User Stories section and the systems identified were Authentication, Rehabilitation Program, Evaluation and Guidelines.
2. Determine one user and define their goal. Each of these goals later becomes a use case. This step has been covered in the "User Needs" and "User Stories" section
3. Once the goal is defined, every alternative course of events should be considered to reach this purpose. To that mean, every use case is clarified using four topics; a description, the personas involved, the subsequent cases related; the scenarios, which consist of a description of the persona's path through this case and finally, the constraints, which represent the obstacles and what the case must have to be completed

When looking into FaceRehab's utility path, there are four significant cases where the persona performs an action while using FaceRehab: Authentication, Rehabilitation Program, Evaluation and Guidelines. In this work, these are the primary use cases, and all of the other topics can be described as the following scenarios of the main ones. Figure 4.13 represent a visual analysis of the interaction of the three personas involved in the four prominent use cases.

This chapter will focus only in the description and constraints of each of the primary use cases, a deep and detailed use case including the personas, cases and scenarios can be found in Appendix H.

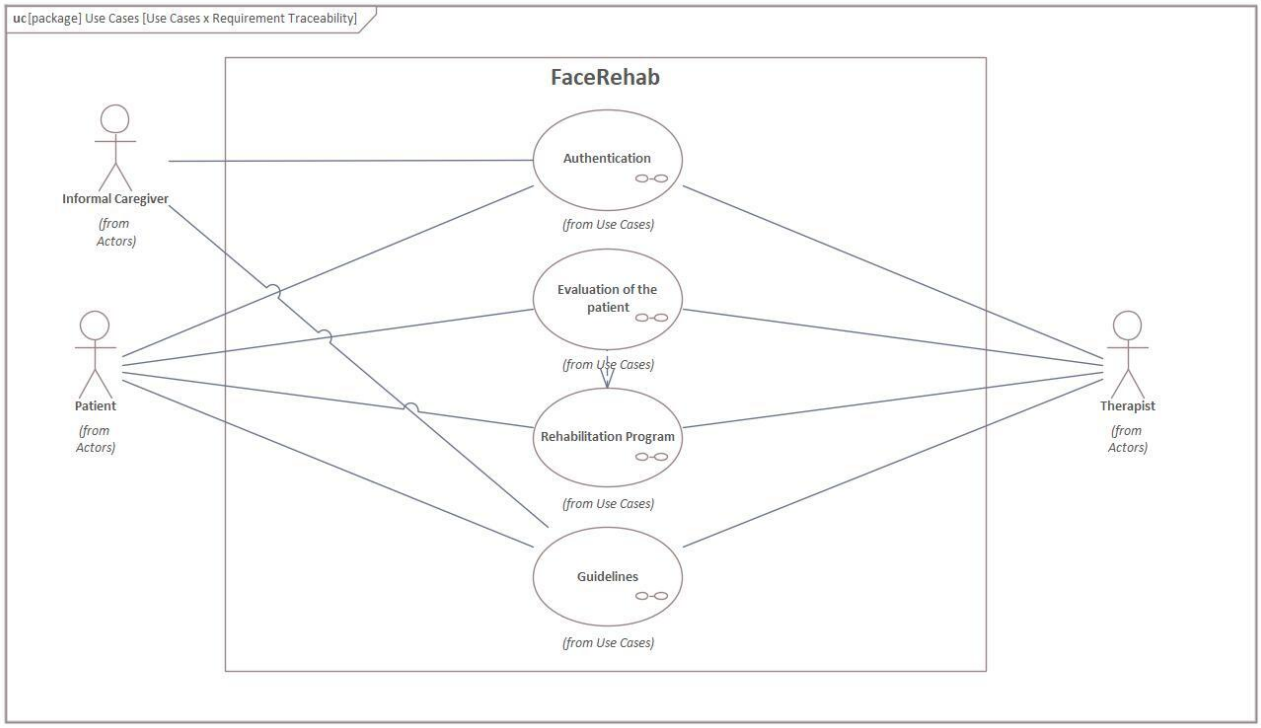

Figure 4.13: Use Cases: FaceRehab

Case 1: Authentication

Description: The Authentication's Use case represents the first step while using the FaceRehab solution for a Facial Paralysis treatment. The authentication system is described as security standards that ensure data protection by requiring inputs by the user, such as username, password, fingerprints and others. In the case of FaceRehab, the authentication system is composed of two inputs; Username and password. Another possibility would be biometric inputs, that being facial and fingerprint recognition. All three personas (patient, therapist and caregiver) will interact with this use case since they will have access to a private profile of which the entrance depends on authentication.

Personas: Patient, Healthcare Professionals, Informal Caregiver

Cases: Login that will be satisfied by Authentication with extends to username input and password input

Scenarios: There are four steps to consummation.

1. The user accesses the main screen of FaceRehab
2. Introduce a username
3. Introduce a password
4. Click the login button

Constraints: For the authentication case to be satisfied, two prerequisites should be fulfilled: the presence of a working network with a connection to the internet and the initial creation of a profile in FaceRehab's system.

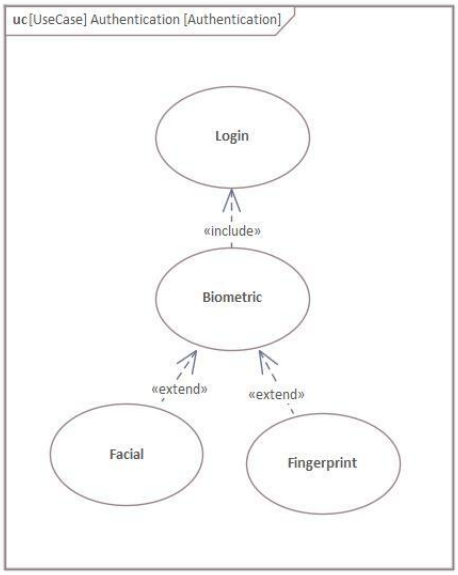

Figure 4.14: Use Cases: Authentication

Case 2: Rehabilitation Program

Description: The Rehabilitation Program represents the possible scenarios between the system under discussion and all three actor's actions during the facial paralysis treatment. It shows the path of actions through FaceRehab's features and the interactions of personas. All three personas (patient, therapist and caregiver) will interact with this use case since they will interact with the rehabilitation program.

Constraints: For the whole rehabilitation program case to be satisfied, one set should be present: A camera connected in order to start visual acquisition of the patient and a working network with a connection to the internet.

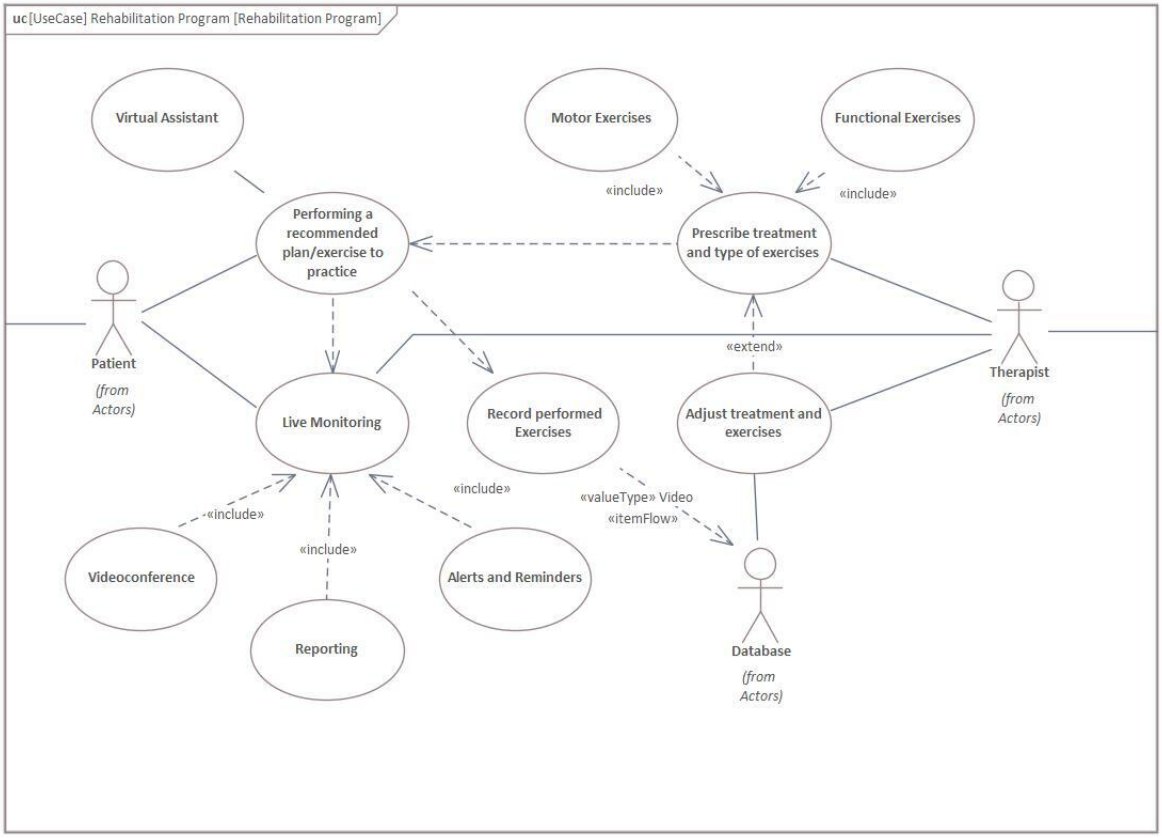

Figure 4.15: Use Cases: Rehabilitation Program

Case 3: Guidelines

Description: A guideline defines how a judgment or policy is made and intends to gather educational materials and reports. In the case of FaceRehab, the guidelines aim to inform all stakeholders of the latest updates on facial paralysis and assist practitioners in providing effective and safe services based on patients' needs, current practical evidence, and known technologies.

Constraints: For the guidelines case to be satisfied, it only needs that the platform allows material input by developers and physicians. The stakeholders can access it by connecting with a working internet connection and entering their profile on the solution.

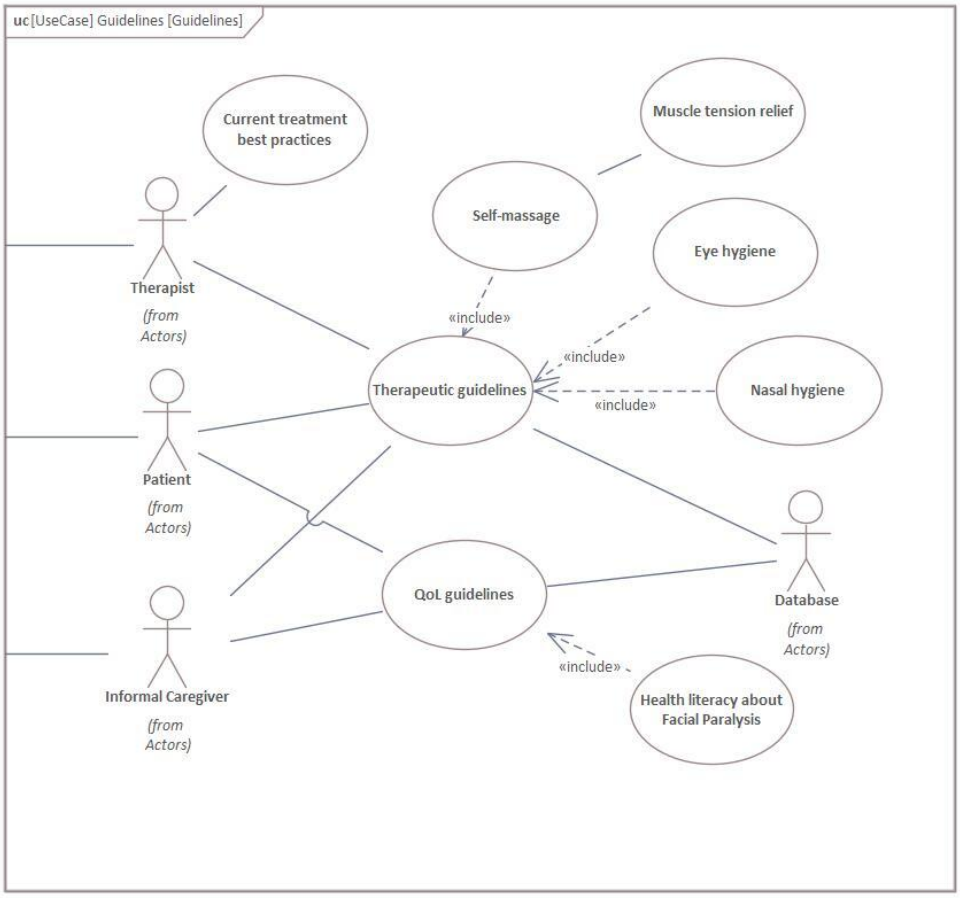

Figure 4.16: Use Cases: Guidelines

Case 4: Evaluation

Description: The evaluation case can be described as the moment in which the healthcare professional analyses the patient's condition and evaluate their progression. That is done in person during the first consult and from that point on can be performed digitally by either the registration of a video or photo to measure facial paralysis points according to the house-Brackmann scale.

Constraints: For the evaluation case to be satisfied, it needs the previous registration of the material on the platform by the patient. That is done automatically while patients perform the exercises. (Case 2.1) The healthcare professional should have access to it by connecting with a working internet connection and entering the "session" page on the patient profile.

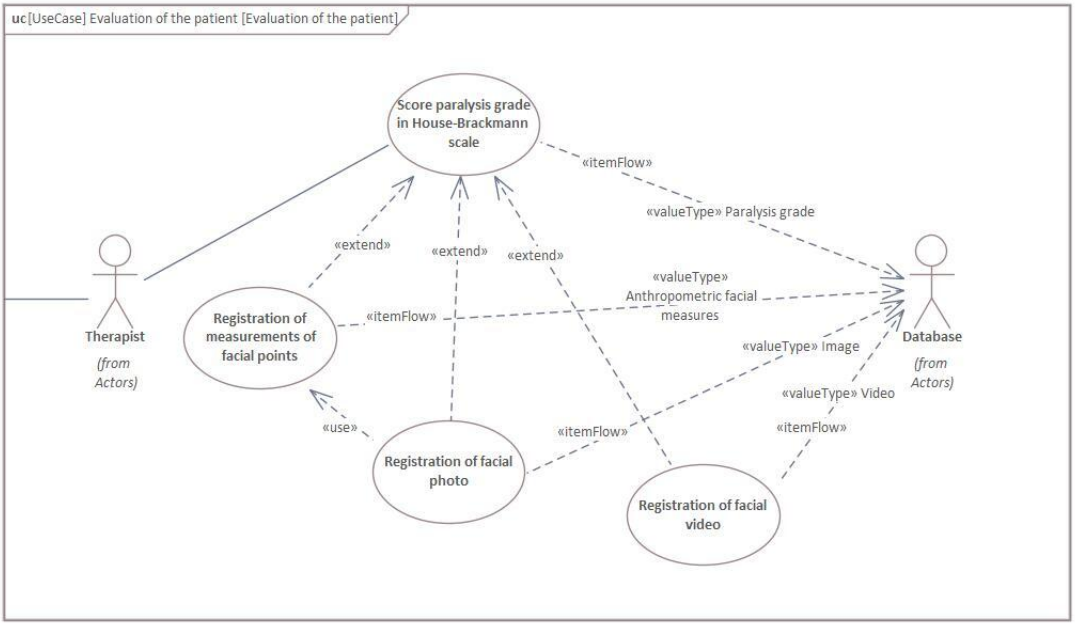

Figure 4.17: Use Cases: Evaluation

4.6 Requirements

A requirement is an expression of desired behaviour, according to one definition of a requirement by the book Software Engineering: Theory and Practice (Third Edition) [65]. A requirement concerns individuals or objects, the states they might be in, and the functions used to change those states. These specifications are detailed descriptions of features or functions that address the system's overall goal. Therefore, requirements aim to describe the link between the entities and identify critical and limited stakeholders, including the conditions put by the user to operate the solution successfully.

It is important to note that a requirement should never specify or identify the solution. That is, it does not consider how the system is to be implemented, as the purpose of a requirement is to understand the challenges and goals of customers.

Functional and non-functional requirements are the two types of system requirements according to [65]. A functional requirement is the specifications that the system should have or perform to work properly. The system will not work correctly if a functional need is not met. This is because it will not be able to complete a task necessary to function effectively. In conclusion, functional requirements outline the technology's output and how it must react to different inputs.

On the other hand, In software engineering, non-functional requirements describe the system's operation. They are related to the system's mechanism of performing a particular function. Non-functional requirements do not have an impact on functionality. However, if they are not met, users may become dissatisfied with the technology and discard the solution, replacing it with competitors.

Functional requirements

Table 4.8: Functional Requirement

Reference	**Functional Requirement**		
F1	Authentication	Login window	The authentication window shall show two input fields, one for username and the other for password
F2	Authentication	Submit Button	The login window shall include a submit button for the user to confirm the login
F3	Virtual assistant	Avatar	The system shall provide an assistive avatar

F4	Virtual assistant	Audio and subtitles	The system shall provide audio and subtitles features with the exercise description
F5	Perform exercises	Continue button	The interface shall include a continue button for the user to progress to other exercises
F6	Video conferencing	Connection	The system shall provide 1:1 video conferencing
F7	Reporting	Check patient progression:	The system shall present an overview of the patient progression in a line chart
F8	Reporting	Check patient progression:	The system shall represent measurements for each anatomical structure in a timeline.
F9	Reporting	Check Patient Scores	The system shall present an overview history of the patient scores on the House Brackmann Scale
F10	Notifications	Wrong Movement Alert	The system should alert the patient in case doing wrong the exercise
F11	Notifications	Reminder	The system should remind the patient of the next session
F12	Notifications	Guidelines input	The system should notify the users when new guidelines are available
F13	Prescribe treatment	Add patient	The system shall provide a frame with a fill form to input patient information
F14	Prescribe treatment	Start date	The system shall provide a field form to insert the start date of the therapy plan.
F15	Prescribe treatment	End date	The system shall provide a field to insert the end date of the therapy plan
F16	Prescribe treatment	Field to define time repeating series	The system shall provide a field to insert a number relative to the pretended repetitions of the current series sequence
F17	Prescribe treatment	Functional exercises	The system shall provide a field to select functional and motor exercise(s)
F18	Prescribe treatment	New plan session	The system shall provide a field form to create a new plan session

F19	Prescribe treatment	List of rehabilitation exercises:	The system shall provide a list of Rehabilitation exercises
F20	Prescribe treatment	List of patients	The system shall provide a list of the patients currently in rehabilitation
F21	Prescribe treatment	Save button	The system shall provide a button to save the current defined plan.
F22	Prescribe treatment	Selection of exercises	The system shall offer a table that shows selected exercises and allow the therapist to select the level of each exercise
F23	Registration of facial photo	Take photo button	The system shall offer in the interface of the device, a button to take photos during the Therapy Assessment.
F24	Registration of facial photo	View photo button	The system shall present in the interface a button to view the photo that was taken during the Therapy Assessment.
F25	Registration of facial video	Record Video button	The system shall present in the interface a button to record a video during the Therapy Assessment.
F26	Registration of facial video	View Video button	The system shall present in the interface a button to view the video recorded during the Therapy Assessment.
F27	Measurements of facial points	Adjustable landmarks	The system shall show landmarks with a photo.
F28	Measurements of facial points	Adjustable landmarks	The system shall include the functionality of point and click the landmark of interest as well as drag and drop.
F29	Measurements of facial points	Date form field	The system shall present a form field to insert the date of the therapeutic assessment
F30	Measurements of facial points	Edit button	The system shall present a button to edit information collected during the therapeutic assessment.
F31	Measurements of facial points	Save button:	Button to save information collected during the therapeutic assessment.
F32	Measurements of facial points	Fill form fields for measurement	The system shall show registered measurements in mm for each facial anatomical structure

F33	Measurements of facial points	Validate button	The system shall present a button to validate the measurements that appear in forms.
F34	Server	VPN Server	The system shall present a VPN Server to ensure a secure and private network.
F35	Server	Proxy Server	The system shall present a Proxy Server to prevent cyber attackers
F36	Hardware	Overall devices	The system shall present a Display, speaker, microphones and keyboard
F40	Hardware	Power Supply	The system shall present a Power Supply to supply electric power to the device
F41	Hardware	Vision processing unit	The system shall present a vision processing unit to capture face measurements during exercises

Non-Functional Requirements

Table 4.9: Functional Requirement

Reference	**Non-Functional Requirement**		
NF1	Design Constraints	Physical environment	The equipment shall be located both at the clinic and at the patient home.
NF2	Design Constraints	Physical environment	The environment shall provide a stable and strong internet connection
NF3	Design Constraints	Physical environment	The equipment shall be placed at a linear and short distance from the patient's face.
NF4	Design Constraints	Physical environment	The equipment shall be connected to a power supply.
NF5	Design Constraints	Users	The system shall be used by FP patients and healthcare professionals
NF6	Design Constraints	Users	The healthcare professionals shall undergo short classes to learn how to use the system

NF7	Design Constraints	Users	The patients shall be taught how to use the system prior to its use
NF8	Design Constraints	Users	Healthcare professionals shall have knowledge of the condition prior to using the system
NF9	Process Constraints	Resources	The developers shall have technical skills in embedded systems, electronics, software and system engineering to successfully develop the device.
NF10	Process Constraints	Documentation	The system shall provide an online and physical detailed user manual for the healthcare professionals and patients
NF11	Process Constraints	Regulatory	The device shall be following the good practices of MDCG 2019-16 Guidance on Cybersecurity for medical devices
NF12	Quality Requirements	Usability and Human Factors	End users shall be provided with training to learn how to use the device correctly.
NF13	Quality Requirements	Usability and Human Factors	The device shall be easy and logical to use for all stakeholders
NF14	Quality Requirements	Usability and Human Factors	It shall be easy to correct any mistakes made during the device use.
NF15	Quality Requirements	Security	The system's information shall be controlled by specialists
NF16	Quality Requirements	Security	User's data shall be isolated from the data of other user groups
NF17	Quality Requirements	Security	The system shall prevent synkinesis
NF18	Quality Requirements	Security	The patient's expectations shall be controlled to avoid emotional frustration
NF19	Quality Requirements	Reliability and Availability	Precaution shall be taken against water damage, fire and other incidents
NF20	Quality Requirements	Maintainability	The innovation shall undergo system improvements and maintenance often
NF21	Quality Requirements	Maintainability	The addition of new features shall be easily performed by the developers.

NF22	Quality Requirements	Maintainability	The developers shall be able to update the system of all equipment distributed
NF23	Quality Requirements	Precision and Accuracy	The facial point measurements shall be calculated precisely and undergo a scientific research
NF24	Authentication	Authentication field	The username and password field should use alphanumeric characters up to 20 chars.
NF25	Graphic	Click Buttons	The buttons in the interface shall not be smaller than 100px wide and 50px height
NF26	Graphic	Click Buttons	The buttons in the interface shall be in the colour grey.

4.7 Technical Approach

This section will include a description of the suggested technical specifications that satisfy or exceeds the technical requirements indicated in the previous section or range of activity. Overall, it builds on top of the conceptual framework and models proposed in works in [66, 67, 68, 69, 70] which proposed an integrated framework to develop interactive artificial agents for Active and Assisted Living (AAL) application domain.

To achieve this goal, a hardware and logical architecture were designed in order to define and clarify the elements of the system. The logical architecture identified and co-related the elements needed to fulfil the requirements. On the other hand, the hardware architecture went a step further and defined the actual technical components and their relationships, enabling developers to identify how the parts interact with the overall system.

The main distinction between logical and hardware architecture is that whereas logical architecture describes the system's functional components, hardware architecture specifies the essential equipment and technology the device requires.

Logical architecture

Figure 4.18 shows Facerehab's logical architecture. The solution, as explained previously, can be divided into two perspectives; one is a Health Management tool, a software destined for the therapist's use at the clinic. The other is the Artificial Agent, a hardware device mainly available at the patient's home to guide the therapy plan. In order to describe the system's functional components, both perspectives mentioned above can be divided into; the server, which represents the back office requirements and; the front-end, which includes the graphic user interface.

The Health Management Client represents the front-end part of the software. Since it is composed of a basic website, a graphic user interface is the only requirement to be fulfilled. The Health Management Server, on the other hand, represents its back office and should include what the system must deliver to function correctly. The elements included on the server are considered requirements and were previously listed and described in the last section.

The Artificial Agent Client designates the hardware device front office requirements. Apart from the patient graphic user interface, it shall also include the visual acquisition features to capture the user's expression and perform exercises. Therefore, the face metrics registration interface and video conference functionality are also listed on the Artificial Agent Client. Finally, the Server shall represent its back office and include the logger, backend interfaces, VPN and Proxy Server and Video Conference Server. The elements included on the server are considered requirements and were previously listed and described in the last section.

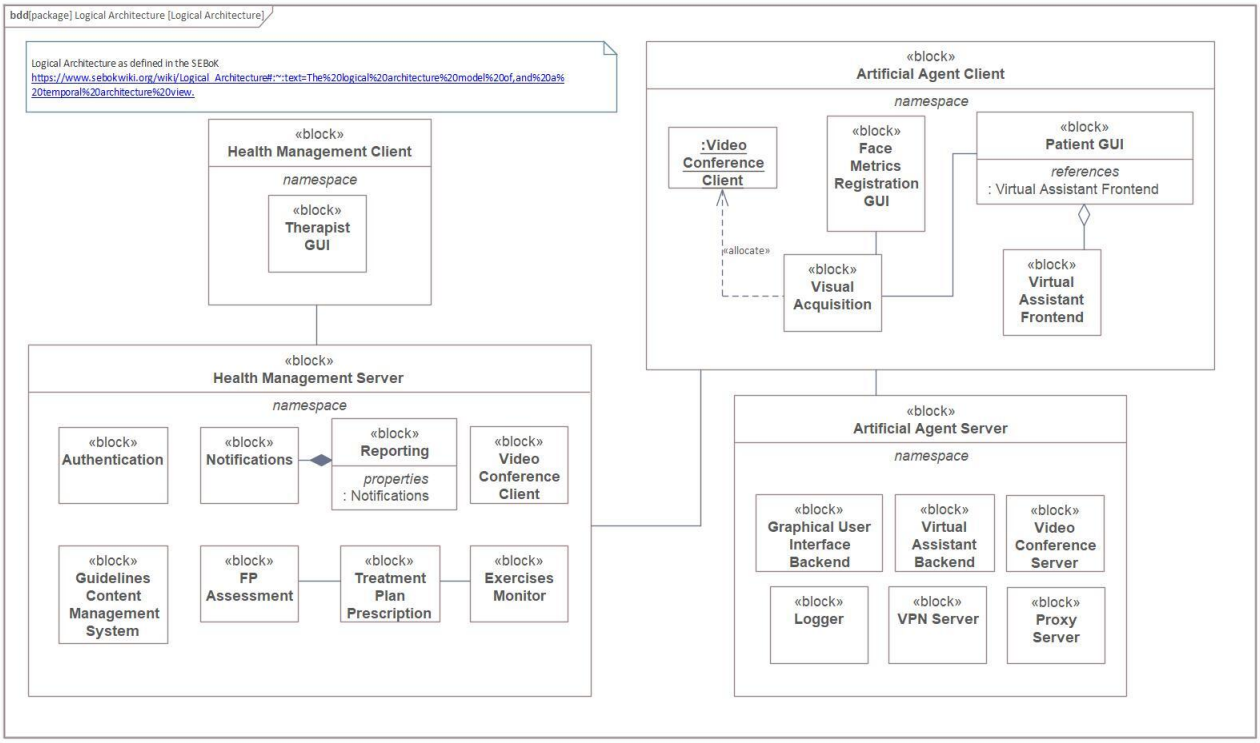

Figure 4.18: Logical Architecture

Hardware architecture

Figure 4.19 shows Facerehab's hardware architecture. In order to specify the essential equipment and technology the device requires, the framework was divided into Server and Artificial Agent Device. The server includes the Health Management System Server and the Artificial Agent Server, both already explained in the logical architecture section. The Artificial Agent Device shall include the actual technical components the system requires to work appropriately. All of those requirements have already been listed and described in the previous section and for simplification matters it will not be repeated.

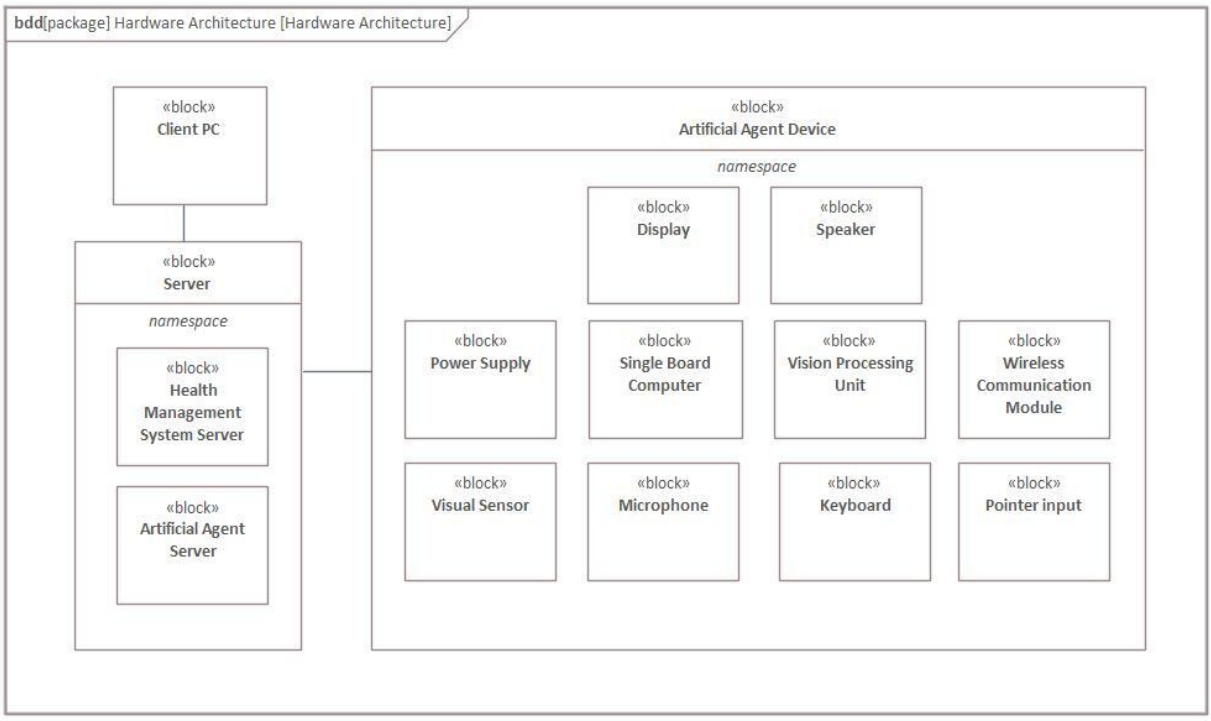

Figure 4.19: Hardware Architecture Framework

Prototype design

Based on the specifications and architecture frameworks created, a prototype was built to test concepts and refinements until it resembled the finished product. That step was also crucial to validate the architecture frameworks and provide improvements. Therefore, two user manuals has been developed and a few hardware prototypes has been produced. The software component is available and ready to use through the link: https://facerehab.thinkdigital.pt/

The design process of the enclosure was iterative and had input from therapists in co-design. Figure represent the initial idea of the hardware design. After some iterations and with the change of mind of using the previous hardware enclosure, the most recent version was designed with a slicker design seen on Figure 4.21.

Figure 4.20: Hardware Architecture

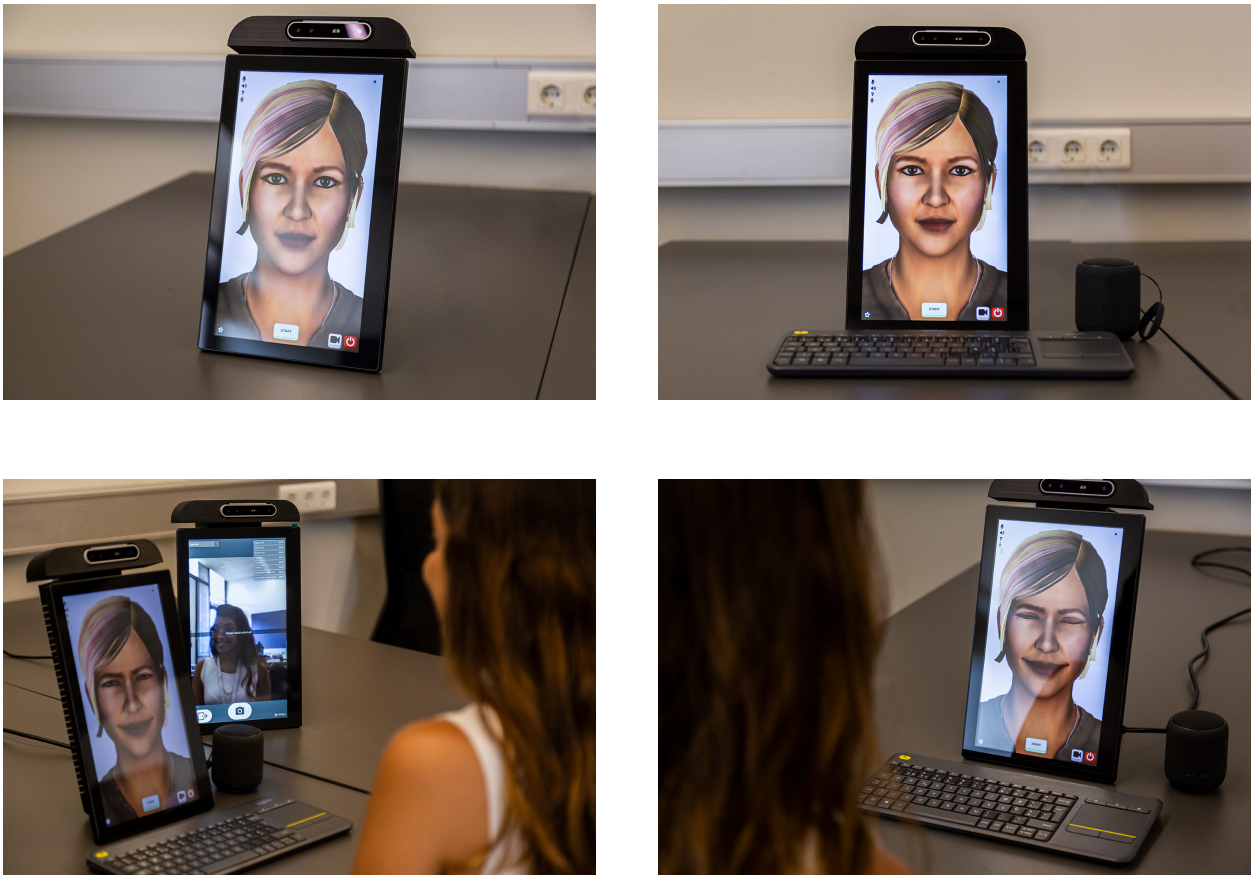

Figure 4.21: FaceRehab prototype pictures

Prototype features currently available

At the present stage, during the development phase of FaceRehab, it was possible to test the main technical features on both the Artificial Agent Device and Health Management Client. Although a few details still need to be improved, the primary features are 100% functional and achieve all expectations regarding the logical and hardware architectures. The requirements available regarding patient use are:

- **Logical Architecture features:** All servers requirements, Face Metrics GUI, Patient GUI, Virtual Assistant Frontend, Visual Acquisition
- **Functional Hardware components:** All hardware requirements are functioning.

The tasks and functionalities available to the patient in order of action are:

- Authentication: User shall enter Username and Password
- Calibrate the system: The user shall firstly start and calibrate the system following the instructions on the screen.
- Start exercises: After calibrating, the user will be redirected to the exercise plan, where he can perform the exercises previously prescribed by the therapist.
- End Exercises: After the user completes the exercise plan, he will be redirected to the menu interface.

Therefore, currently, the patient can receive an exercise plan prescribed by the physician, authenticate into the system, access the appointment, perform the exercises during a session and complete the appointment.

On the other hand, the requirements met regarding the therapist uses are:

- **Logical Architecture features:** Therapist GUI, Authentication, Notification, Reporting, FP Assessment, Treatment Plan Prescription, Exercises Monitor.
- **Functional Hardware components:** All hardware requirements are functioning.

The tasks and functionalities available to the therapist in order of action are:

1. Authentication: User shall enter Username and Password
2. Schedule an appointment
3. Check in a patient: When the session begins, the therapist shall check the patient in.
4. Initiate session: The patient should be able to initiate the session in order to measure the patient's facial points.

5. Perform evaluation on the medical device
6. Associating exercises to appointments and selecting the appropriate set of exercises.
7. Send information to the main system
8. Evaluate the level of paralysis.

Therefore, the therapist can successfully perform an initial evaluation, measure the level of facial paralysis, prescribe exercises and follow up with the treatment plan performed at home.

The task list provided was used to develop the quick guides used during the usability evaluation test (Chapter 5). Therefore, a visual representation of the patient's tasks and functionalities available can be found in the patient quick guide 4.22 while the therapist's quick guide can be found in figure 4.23 and 4.24.

Figure 4.22: Patient Quick Guide

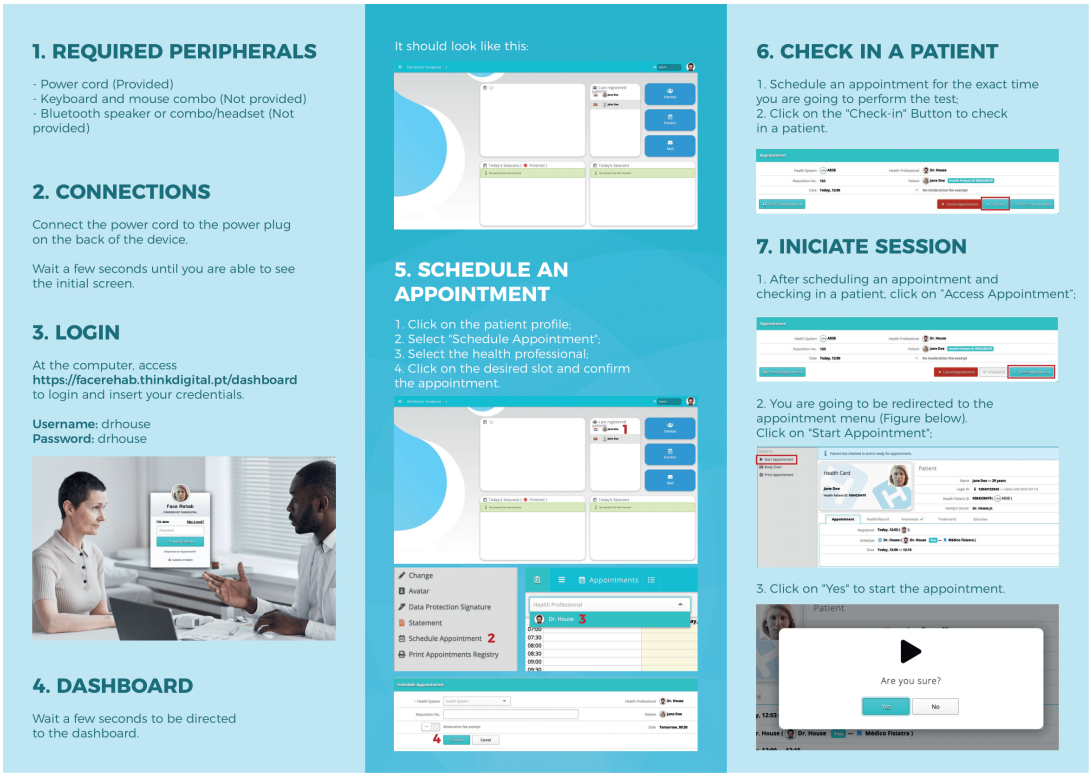

Figure 4.23: Therapist Quick Guide page 2

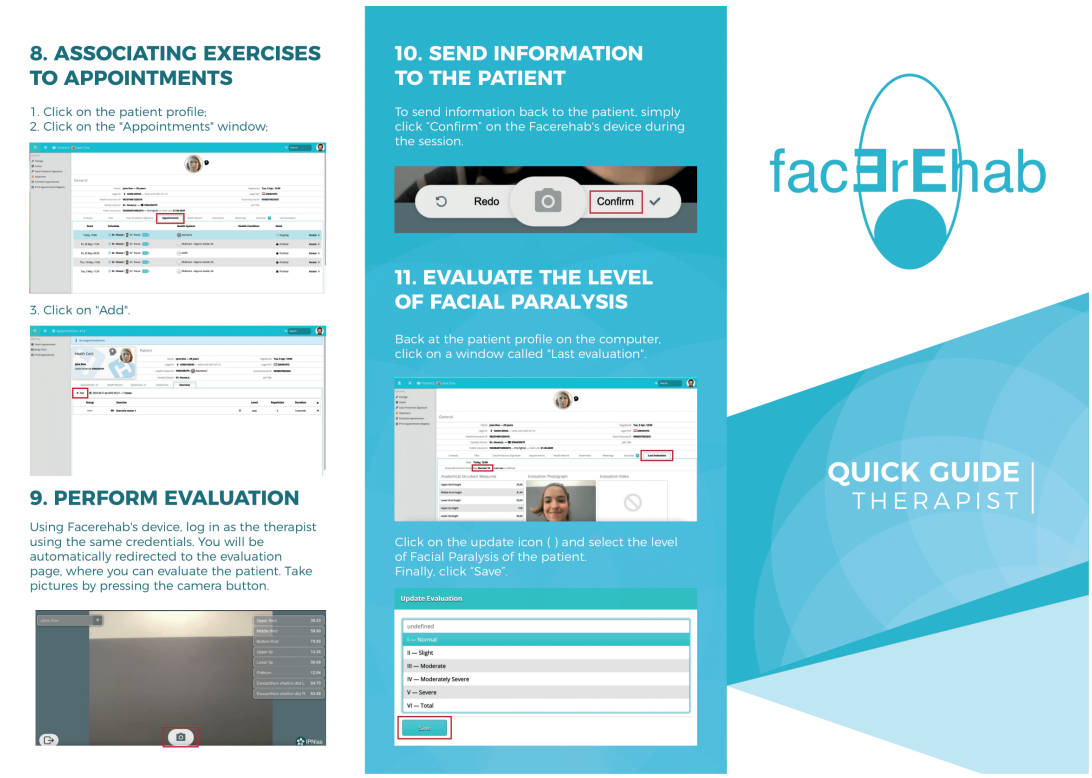

Figure 4.24: Therapist Quick Guide page 1

Chapter 5

Validation of the technology

Usability is defined by the International Organization for Standardization (ISO) as "the extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" [71]. In other words, it assesses interactive markers and analyses essential variables, such as "ease of learning, ease of use, and ease of avoiding and recovering from a user error". Therefore, performing a usability test aims to refine and validate a medical device's suggested design through an early prototype.

Such testing is essential for the regulatory process of implementing a device into the market. The authorities, such as the US Food and Drug Administration (FDA), refer to this step as "human factors validation testing," also known as summative usability testing. When the device cannot prove its usability, they can postpone their approval or reject applications.

Even though developers try to make the solution as easy and efficient as possible, sometimes the technology does not match the user's expectations and needs. Therefore, validation studies should be performed during the development phase of the solution to help determine whether a given medical solution will meet its intended users' needs and preferences. During this step, the developers should observe how easily the user interacts with the solution and how they can make the technology more efficient.

5.1 Methodology

For this work, the international standard IEC 62366-1 - Part 1: Application of usability engineering to medical devices was used as a guideline to plan and perform the usability validation. This document "specifies a process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety.

This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors" [71]. The process presented by ISO 62366-1 has eight steps, of which the first seven consist of answering questions about the technology and planning the usability evaluation methodology. In contrast, the last step consists of performing the test and documenting the results.

Step 1 - Prepare use specification

The first step consists of analysing the device specification and detailing its medical indication (i.e. intended user profile, use environments, patient population, and operating principles.)

- **Device's medical indication:** Indicated for the remote treatment of facial paralysis
- **Intended user profile:** The device has two main users: The patients (i.e. any patient with facial paralysis condition, independent of age, gender, linguistic and cultural background, level of education and professional competence) and the healthcare professionals (i.e. therapeutics, nurses, speech therapy professionals and any other healthcare professional that aid patient with facial paralysis)
- **Use environments:** Intended for a clinical or domestic environment, with good network connection and lighting.
- **Patient population:** Intended for any patients with facial paralysis, independent of ethnicity, socioeconomic status, or population density. In the development phase, it is limited to patients in Spain, Portugal and Luxembourg
- **Operating principles:** FaceRehab will develop a product that will provide a solution for supporting facial rehabilitation exercises using technology as a means to improve the digital transformation of the health and care for people affected with Facial Paralysis. The device will include user interfaces and sensors that allow human-machine interaction and remote therapy.
- **Intended part of the body or type of tissue applied to or interacted with:** Facial muscles.

Step 2- Identify user interface characteristics related to safety and potential use errors

During the second step, the developers should identify the user interface characteristics related to safety and potential use errors. That is, the user path through the device should be analysed to identify the possible human errors that can lead to hazardous occasions.

- **Whether the medical device is intended to be routinely cleaned and disinfected or cleaned and sterilised :** No. As the solution consists of a display attached to a sensor and camera, its usability features do not depend on hygiene actions.

- **Whether the medical device is interpretative:** Yes. Even though the healthcare professional will explain how to use FaceRehab correctly, the solution depends on logical thinking and interpretative use. Therefore it depends on the patient's independent actions to be successful.

- **Whether the medical device requires special training or other information for safety is provided in general:** Yes. The operating principles will be explained and demonstrated to the patient prior to domestic use. On the other hand, incorrect use does not affect the health and safety of the patient, meaning the condition can not get worst if the patient does not use the solution correctly.

- **Whether successful application of the medical device depends on human factors in general. This includes whether use errors can be caused by the user interface** Yes. The success of the solution depends on the good practices of the user. That is, as the technology consists of face motion exercises to be performed at home, the patient should be able to individually perform them correctly to achieve the expected results. If the exercises are not performed correctly, they can not harm the patient's health; the only hazard is frustration and not further improving the condition.

Step 3 - Identify known or foreseeable hazards and hazardous situations

The third step consists of identifying known or foreseeable hazards and hazardous situations. That is, the developers should list the circumstance in which people, property, or the environment are exposed to one or more hazard(s). Therefore, a list should be compiled with the anticipated hazards and hazardous situations associated with using the medical device. In the case of FaceRehab, it can be divided into clinical and usability/UX issues:

- **Clinical:** Performing too many exercises in the wrong way could lead to synkinesis, a medical condition described by the unwanted contractions of the muscles of the face during attempted movement. In addition, if the patient skips a session and performs exercises that were not recommended, it could lead to either no results or unintended ones.

- **UX/Usability:** If the patient has some difficulty using the technology or is not comfortable with the solution, the results will not be achieved, which could lead to emotional frustration

Step 4 - Identify and describe hazard-related use scenarios

Step nº 4 consists of identifying and describing hazard-related use scenarios. Consequently, it is essential to understand the meaning of the expression "hazard-related use scenario"; According to the IEC 62366-1, A hazard-related use scenario is a use scenario that could lead to a hazardous situation or harm. Therefore, the following table was created analysing the hazardous situations, their risks and the risk control measures.

Hazard	Hazard-related use scenario description	Harm	User interface risk control measure
Overuse of the solution	Patients want fasters and more efficient results. He/She thinks that by overdoing the exercises the results will be achieved faster	Synkinesis	Platform and therapist are allowed to block accounts/exercises for a specific user
Lack of commitment	The patient does not believe in the solution, is not determined to improve the condition or can become demotivated after repetitive exercises	Emotional frustation Anxiety Lack of social skills	Prior explanation of the solution Results and proof of its performance Therapist regular follow up
Lack of user interface knowledge	The patient might not be comfortable with the technology, leading to user interface issues (not sure how to use the solution, not intuitive use), resulting in the skip of sessions and underperforming the exercises.	Emotional frustation Anxiety Lack of social skills	Prior explanation of the solution Guidelines with detailed explanation Regular therapist and caregiver assistance

Table 5.1: Hazard-related use scenarios table

Step 5 - Select the hazard-related use scenarios for summative evaluation

This step consists of selecting the hazard-related use scenarios listed in the previous stage to be included in the evaluation. In case there are not several listed, the developers should select all of the hazard-related use scenarios; otherwise, it is advised to select only a few based on the severity of the potential harm.

The practical test evaluation of the solution on actual patients with facial paralysis is intended to be performed by the end of 2022. Therefore, in the scope of this study, due to the deadline issues, only formative evaluations will be accomplished, where a small number of selected people without facial paralysis will evaluate the device's usability.

The formative evaluation will be explained in more detail during steps 7 and 8. However, for contextualisation matter, it consisted of a quick (30 min) observational study to analyse and encounter technical and interpretative issues. The participants only used the devices for less than an hour and did not present themselves as patients with facial paralysis. Therefore, none of the hazard situations was considered for this stage, as they did not apply.

As for the summative evaluation, the practical test evaluation of the solution on actual patients with facial paralysis will be performed at the end of 2022. The FaceRehab solution presents only three hazard-related use scenarios; therefore, all of them were selected for the summative evaluation.

Step 6 - Establish user interface specification

The sixth step concerns analysing technical requirements to establish and maintain a user interface specification. It shall consider the user interface, the foreseeable use errors and hazard-related use scenarios previously listed.

The user interface specification should include:

- **Testable technical requirements relevant to the user interface, including the requirements for those parts of the user interface associated with the selected risk control measures:** Stable internet connection and reachable power supply.
- **An indication as to whether accompanying documentation is required:** Yes. The healthcare professional or patient might need a user manual with simple instructions during the first use.
- **An indication as to whether medical device-specific training is required:** Yes. Even though the user might not need a complex explanation of how to use the device, since it depends on interpretation, the developers decided that the operating principles would be explained and demonstrated to the patient/healthcare professional prior to its use.

Step 7 - Establish user interface evaluation plan

This stage concerns the planning of the formative evaluation. Therefore, essential questions were answered in order to maintain a user interface evaluation plan for the user interface specification. It shall include details of the methodology used, what type of participants they will have, and the test environment.

- **Document the objective and identify the method of any planned Formative evaluations:** The objective of the study reported by this article is to identify the usability issues encountered by adults while using the FaceRehab device. The method used to prove the usability validation will be an observational study followed by a user questionnaire. This method added to the formative evaluation aims to analyse a set of aspects related to the usability of a Medical Device (MD), in this case, the FaceRehab solution.
- **Participants: Document the involvement of the representative intended users to which they belong:** Since a formative evaluation is described as "A user interface evaluation conducted with the intent to explore user design strengths, weaknesses, and unanticipated use errors" clinical personnel from the manufacturing company can be used as a representative. Therefore, in this study, staff from Instituto Pedro Nunes were used as a user group.As mentioned previously, the target group is divided into two categories. Therefore, the usability tests will be performed on two distinct groups: the patients and the therapists.

Hence, the research study comprised two phases. During the first phase, an observational study was conducted, where a group of people were asked to act as patients and complete tasks while using the device. The second phase comprised a focus group to capture the therapists' perceptions regarding potential contributions to the care provision of FaceRehab in particular. A critical incident registration was implemented to capture the perceptions of both groups.

- **Participants: Document the user profile to which they belong:** Participants comprised a convenience sample of adults and were recruited either by referral from IPN colleagues or direct internal invitation by researchers. Those willing to participate were eligible if they were aged between 20-70 years and were able and willing to give their informed consent. Participants were excluded from the study if they were unable to understand the study data collection forms.

- **Document the test environment and other conditions of use, based on the use specifications:** Conditions of use include location-specific conditions, that being, the work environment with proper lighting, noise and activity levels.

- **Specify whether accompanying documentation is provided during the test:** Yes. A manual guide will be provided as well as instructions prior to the use (Available in the last section - Hardware architecture)

- **Specify whether medical device-specific training is provided prior to the test and the minimum elapsed time between the training and the beginning of the test:** A quick explanation will be provided prior to the evaluation.

In addition to the information required by IEC 62366-1, the writers found it essential to include in this chapter information on Assessment Procedures, Assessment Instruments, Critical Incident Registration, Tasks and Data Analysis.

- **Assessment Procedures:** The researchers conducted the experimental sessions with the participants on the premises of IPN LAS. The session was conducted by one of the observers and followed the steps: (i) pre-test: The observer provided a basic introduction, and the participants filled a term of compliance and completed a socio-demographic questionnaire for sample characterisation, with demographic information and information about their technical knowledge; The participants also completed a self-report file, in order to collect personal data, such as name, gender, age and technological abilities (ii) Test: the participants interacted with FaceRehab following the tasks described in the quick guide provided; simultaneously, the observer took notes about the performance of the participants and recorded the critical incidents; (iii) Post-test: Participants filled two questionnaires built to answer usability questions on FaceRehab.

- **Assessment Instruments:** The first questionnaire provided is USE [72, 73, 74]. This survey captures the participants' perceptions (i.e., it is an auto-reported questionnaire) by identifying issues that may influence and determine the frequency of use and user satisfaction. The selection of USE to determine the perception of the older adults was because the 30 items of this questionnaire were developed to assess multiple dimensions: (i) usefulness (items 1 to 7); (ii) ease of use (items 8 to 19); (iii) ease of learning (items 20 to 23), and (iv) satisfaction (items 24 to 30). Each item is scored on a seven-point Likert scale, ranging from 1 (strongly disagree) to 7 (strongly agree). The questionnaire analysis is based on the average of the users' answers, and each dimension's average can be analysed in a disaggregated way. As for the second questionnaire (Appendix I), the regulatory department of the IPN Laboratory for Automatic and Systems developed a specific survey to answer questions regarding FaceRehab's usability, named Clinical Usability Questionnaire. Two versions were developed, one for the patient's and other for the therapist's point of view. It is essential to mention that, for comparison reasons, the developers decided to use the same two questionnaires for the later summative evaluation (with actual patients with FP and clinical therapists). Therefore, for this formative evaluation, it is expected that some questions will not have an impact or will not be answered by the participants since they do not have facial paralysis and might not be familiar with the condition.

- **Critical Incident Registration:** During each experimental session, while the participant was executing the tasks, the observers recorded the critical incidents to systematically identify behaviours that contributed to the success or failure of the participants in specific tasks. In this record, some details were considered, such as easy/complex interaction with the avatar or learning ability of the sequence needed to complete a task

- **Tasks:** The following tasks served as the base for the assessment of usefulness, satisfaction, and ease of use regarding the patient as they are representative of FaceRehab's functionalities and encompass various interaction mechanisms: (i) Set up correctly (ii) Connect the device (iii) Access FaceRehab (Startup) (iv) Log in as a patient (v) Start the exercise session (vi) Continue exercises and finish it. The tasks for the therapist consisted of (i) Connect the device, (ii) Login (iii) Schedule an appointment, (iv) Check-in a patient, (v) Initiate session, (vi) Associate exercises to appointments, (vii) Perform evaluation using FaceRehab's device (viii) Send information to the system (ix) End Evaluation and define the level of Facial paralysis. The developers intent to provide the participants with a quick guide (Available in the last section - Hardware architecture) to complete the tasks accordingly.

- **Data Analysis:** Descriptive data was analysed in terms of mean ± standard deviation (SD)

Step 8 - Perform user interface design, implementation and formative evaluation

The last step consists of performing the evaluation and debating its results. To facilitate the understanding of this study, step nº 8 will be discussed in more detail during the next chapter, as it is also an analysis of the results.

5.2 Results

The observational study occurred between 24th - 29th July 2022 in the IPN LAS building.

The total sample consisted of 20 participants, 14 females (70%) and 6 (30%) males, with an average age of 34 years (SD = 9.12). Even though all the participants did not present any suspect of facial paralysis (either current or previous to the evaluation), 10 (50%) were asked to represent the patient's point of view during domestic use. The other 10 played the therapist role for facial paralysis's first clinical evaluation.

90% of the participants work at Instituto Pedro Nunes (IPN), 15% of them in an applied technology role, 50% in an administrative or financial role and 25% in biotechnology research. The other 10%, which do not work at IPN, comprises only two people, a family doctor and a biomechanical engineering student.

In terms of technical knowledge, when evaluating themselves in a score from one to ten (one being complete strange to all technological devices to ten being totally comfortable), the reported average is 7.65 (SD = 1.35), representing a good technological ability. Finally, none of them had ever used FaceRehab's medical device prior to the exam.

In each session, the participant was accompanied by either one or two observers. In the sessions in which the participant played the patient role, the experimental process lasted approximately 20-30 minutes. On average, each interacted with FaceRehab for approximately 10 minutes, varying between a minimum of 5 and a maximum of 15 minutes. On the other hand, the sessions in which the participant played the therapist role lasted approximately 30-40 minutes. On average, each interacted with FaceRehab's system for 20 minutes, varying between a minimum of 15 and a maximum of 30 minutes.

The observational notes taken during the exam can be found in the following subchapter, while USE and the Clinical Usability Questionnaire results are presented in Tables 5.2 and 5.3, respectively. As mentioned previously, it was expected that the participants would not be comfortable answering some of the questions since they are neither patients with FP nor therapists. Therefore, the questions with more than 50% "Non-Applicable (N/A) answers were excluded from the analysis.

Observational notes: Patients

- During the calibration, prior to the execution of exercises, there should be an indication of what is the appropriate speed to rotate the head
- There is a notable delay between the movement of facial muscles and the avatar replication
- It is easier to perform the exercises if the instructions are given both as subscribes and audio.
- Participants suggested the insertion of arrows on the avatar to indicate the movements
- There should be an indication of any kind of how to rotate the head for calibration. Since the calibration message appeared frequently, participants started to move their heads aggressively
- Participants agreed that the subtitles appeared too fast on the screen.
- The majority of participants forgot to press start before performing the exercise. Hence, they begin to do the movements before technically starting it.
- Participants did not immediately understand that the display was a touch screen
- During some exercises, a masculine voice gave the instructions instead of a feminine one.
- In some cases, participants did not realise the keyboard had a mouse included.
- One of the participants had hair bangs, which influenced the performance of the exercises.
- It was suggested to add other options of an avatar instead of having only a female version.

Observational notes: Therapists

- The task of adding exercises is not very logical. According to participants, they should be able to add exercises on the session page and in the profile.
- Developers should add in the quick guide the action to set up exercises. It was missing.
- The camera is not placed correctly; therefore, when the therapist is taking pictures for the first evaluation, the image is not centralised. That fact might influence the measurements taken for evaluation.
- When evaluating the level of facial paralysis, the action to click on the update icon is not intuitive. Most participants took a few minutes to find the button even when reading the instructions.
- When scheduling an appointment is not obvious that they need to select a healthcare professional to access the agenda. Some participants mentioned that selecting a profile did not make sense since they had already logged in.

- Some participants showed difficulty leaving the session page to access the patient profile. After explaining that all it takes is to click on the patient's name, they responded that it was not obvious and suggested adding a button.
- There is a bug in the system; when clicking on the "Schedule" button, an error appears on the screen.
- Some participants did not think it was logical that the blue part of the calendar represents the available slots.
- Participants suggested adding an action to print the selected exercises and set up.
- When sending the picture taken during the first evaluation back to the system, the button to select a patient should be more intuitive on the screen. Often participants tried to take a picture without selecting the patient first.
- While taking a picture of the patient, they tend to look down at the button. This movement might affect the measurements taken; therefore, moving the button up was suggested.
- One of the participants reported that the letters were small and suggested an option to zoom in on the screen. In addition to that, the combination of colours (blue and white) made it worst to read.

USE Questionnaire

From the USE Questionnaire, it is possible to conclude that, regarding the device's usability, patients found it more straightforward and intuitive to use than therapists. Of the 30 questions made, one was excluded (question 29), and only three (questions 2, 9 and 18) got a lower usability score than the therapists'. That result was expected since the therapists were asked to complete more tasks than the patients. In addition to that, the therapists' tasks were often complex and required more intuitive thinking and knowledge of the condition. Finally, during the examination, it was observed that one of the bullet points in the therapist's quick guide was incomplete and led the participant to make mistakes.

The average total score of the USE for all patient participants was 5.64 out of a maximum of 7 (SD = 0.93). The results for the four categories associated with USE, were: (i) usefulness (mean value = 5.82; SD = 0.80); (ii) ease of use (mean value = 5.32; SD = 1.02); (iii)ease of learning (mean value = 6.08; SD = 0.90); and (iv) satisfaction (mean value = 5.73; SD = 0.93). Overall, the results indicate that FaceRehab presents a reasonable degree of usefulness, satisfaction, ease of learning and ease of use.

USE	Patients (n=10) Mean Value (SD)	nº N/A	Therapist (n=10) Mean Value (SD)	nº N/A
Total Score	**5.36 (0.94)**	**37**	**5.27 (1.04)**	**57**
Usefulness	**5.82 (0.8)**	**22**	**5.64 (0.98)**	**28**
Help me to be more effective.	5.86 (0.38)	3	5.33 (1.03)	4
Help me be more productive.	5.29 (1.11)	3	5.6 (1.14)	5
It's useful.	6.33 (0.50)	1	6.22 (0.83)	1
It gives me more control over the activities of my life.	5.83 (0.98)	4	5.50 (1.05)	4
It makes the things I want to accomplish easier to get done	5.57 (0.79)	3	5.40 (0.89)	5
It saves me time when I use it.	6.00 (1.09)	4	5.83 (0.98)	4
It meets my needs.	5.83 (0.75)	4	5.60 (0.89)	5
Ease of use	**5.32 (1.03)**	**9**	**4.90 (1.05)**	**14**
Does everything I would expect it to.	5.00 (1.00)	3	4.80 (0.84)	5
It's easy to use.	5.60 (0.70)	0	5.60 (0.70)	0
It's simple to use.	5.80 (0.79)	0	5.70 (0.67)	0
It's user friendly.	5.80 (0.63)	0	4.50 (1.43)	0
It requires as few steps as possible to reach my goal when I use it.	5.70 (1.06)	0	5.11 (0.93)	1
It's flexible.	5.56 (0.88)	1	5.22 (0.97)	1
Using it its effortless	6,00 (0.47)	0	5.30 (1.16)	0
I can use it without written instructions.	5.10 (1.60)	0	3.90 (1.79)	0
I do not notice any inconsistencies as I use it.	4.30 (1.64)	0	3.89 (0.93)	1
Both occasional and regular users would like it	5.60 (0.97)	0	5.00 (0.87)	1
I can recover from mistakes quickly and easily.	4.43 (1.27)	3	4.86 (0.90)	3
I can use it successfully every time	5.00 (1.31)	2	4.88 (1.46)	2
Ease of Learning	**6.08 (0.90)**	**3**	**5.38 (1.16)**	**0**
I learned to use it quickly	6.10 (0.88)	0	5.40 (1.07)	0
I easily remember how to use it.	6.13 (0.99)	2	5.20 (1.14)	0
It's easy to learn how to use it.	6.10 (0.88)	0	5.80 (1.14)	0
I quickly became skillful with it	6.00 (0.87)	1	5.10 (1.29)	0
Satisfaction	**5,74 (0.94)**	**3**	**5,53 (1.00)**	**15**
I am satisfied with it.	6.00 (0.82)	0	5.56 (1.24)	1
I would recommend it to a friend.	6.40 (0.70)	0	5.78 (1.09)	1
It's fun to use.	6.10 (0.99)	0	5.78 (1.20)	1
It works the way I want it to work.	5.63 (0.74)	2	4.67 (0.52)	4
It is wonderful.	5.70 (0.67)	0	5.63 (1.06)	2
I feel like I need to have it.	4.44 (1.88)	1		6
It's pleasant to use.	5.90 (0.74)	0	5.80 (0.92)	0

Table 5.2: Results of the application of USE Questionnaire

Items with higher scores were related to the ease of learning and usefulness of the FaceRehab, namely, (i) "I easily remember how to use it" (mean value = 6.13; SD = 0.99); (ii) "It is useful" (mean value = 6.33; SD = 0.5) and (iii) "I would recommend it to a friend" (mean value = 6.40; SD = 0.70). On the other hand, the items that obtained lower scores were related to ease of use and satisfaction: (i) "I do not notice any inconsistencies as I use it." (mean value = 4.30; SD = 1.63); (ii) "I can recover from mistakes quickly and easily" (mean value = 4.43; SD =1.27) and (iii) "I feel like I need to have it" (mean value = 4.44; SD = 1.88).

As for the therapist questionnaire, the average total USE score for all therapist participants was 5,27 out of a maximum of 7 (SD = 1,04). The results for the four dimensions associated with USE, were: (i) usefulness (mean value = 5.64; SD = 0.98); (ii) ease of use (mean value = 4.90; SD = 1.05); (iii) ease of learning (mean value = 5.38; SD = 1.16); and (iv) satisfaction (mean value = 5.53; SD = 1.00).

Items with higher scores were related to the usefulness and satisfaction of the FaceRehab, namely, (i) "It is useful." (mean value = 6.22; SD = 0.83); (ii) "It saves me time when I use it." (mean value = 5.83; SD = 0.98); and (iii) "It is pleasant to use." (mean value = 5.80; SD = 0.92). On the other hand, the items that obtained lower scores were related to ease of use: (i) "I can use it without written instructions." (mean value = 3.90; SD = 1.8); (ii) "I do not notice any inconsistencies as I use it." (mean value = 3.89; SD =0.93). This result is consistent with the expected since, as mentioned earlier, it was observed that one of the bullet points in the therapist's quick guide was not complete, which led to mistakes. In addition, the tasks were complex; therefore, it was expected that the participants would depend more on the instruction manual (Available in the last section - Hardware architecture).

One crucial piece of information to mention is that even though no questions from the "usefulness" category were excluded, an average of 40% of participants answered the questions as "Non-Applicable (N/A)". This result was also expected since participants were not therapists and were not familiar with the daily basis of the role; consequently, they did not know how useful the technology was.

Clinical Usability Questionnaire

From the Clinical Usability Questionnaire, it is possible to conclude that, regarding the device's usability, patients also found it more straightforward and intuitive to use than therapists. Out of 24 questions, one was excluded from the patient questionnaire (question 20) and six from the therapist's (questions 11, 12, 16, 17, 21 and 22). That result is because the questions excluded required some knowledge of the FP treatments and therapists' work conduct. Since the participants did not have that information, they answered they showed themselves more comfortable answering "Non-Applicable(N/A)".

Clinical Usability Questionnaire	Patients (n=10) Mean Value (SD)	nº N/A	Therapist (n=10) Mean Value (SD)	nº N/A
Total Score	**4.09 (1.09)**	**39**	**5.18 (0.94)**	**72**
The information provided is sufficient and adequate.	6.20 (0.63)	0	5.70 (0.67)	0
The information provided is in clear and simple language.	6.20 (0.63)	0	6.20 (0.79)	0
The information provided facilitates the use of the device.	6.60 (0.52)	0	5.90 (0.74)	0
The information provided is confusing and unnecessary.	1.56 (0.53)	1	1.60 (0.70)	0
The information provided is not appropriate for the purpose of the device.	2.11 (1.45)	1	1.70 (1.06)	0
The information provided is incomplete and missing important points for using the device.	2.22 (1.56)	1	3.60 (1.26)	0
Using the device is intuitive.	6.10 (0.74)	0	4.70 (1.57)	0
The audio instructions are useful.	6.20 (1.03)	0	5.60 (0.84)	0
Captions are helpful.	4.80 (1.87)	0	5.60 (1.51)	0
The use of audio-only instructions is preferred.	3.30 (2.41)	0	6.60 (0.55)	5
The use of instructions in caption form only is preferred.	2.80 (1.93)	0		6
The use of instructions in both forms (captions and audio) is preferred.	5.90 (1.60)	0		6
The size of the monitor is adequate.	6.10 (1.29)	0	6.00 (0.71)	5
The avatar image is pleasing.	5.80 (1.23)	0	5.50 (1.18)	0
Using the avatar helps my recovery.	5.71 (0.76)	3	5.40 (0.89)	5
The use of the avatar is advantageous for the clinical purpose.	6.13 (0.64)	2		10
Using avatar is preferable to conventional therapy (mirror exercises).	5.14 (1.46)	3		10
Using avatar completely replaces conventional therapy.	2.75 (1.75)	2	5.70 (1.06)	0
The use of avatar complements conventional therapy.	6.25 (0.71)	2	6.20 (0.92)	0
I miss professional accompaniment during the therapy session.		6	5.83 (0.98)	4
With the use of this device, I can easily do therapy at home.	5.67 (0.52)	4		9
Using the avatar allows me to have insight into my difficulties.	4.67 (1.03)	4		6
Using the avatar allows me to be aware of my improvements.	5.20 (0.45)	5	5.44 (0.73)	1
The use of the device facilitates my recovery process.	5.20 (0.45)	5	6.00 (0.71)	5

Table 5.3: Results of the application of the Clinical Usability Questionnaire

The patient questionnaire results are consistent with the USE questionnaire conclusions. The answers indicate that its use is intuitive and that the information provided is sufficient to achieve the expected response. It is possible to note how easily participants understood the device's features and efficiently completed the tasks. As for the questions regarding the technical components, results indicate that participants had some difficulty when the instructions were given only through sound or subtitles; they all preferred both ways. Finally, even though they link the technology and find the avatar pleasant, they do not believe it replaces the clinical approach.

As for the therapist questionnaire, the results are also consistent with the USE questionnaire conclusions. Overall the results indicate that the participants were able to complete the task but faced some difficulties in the process. The questionnaire results indicate that the information provided during the exam was insufficient, which was expected. In addition, they found it simple to use but not immediately intuitive, meaning they relied on the quick guide to complete the tasks. Finally, most questions regarding the measurements taken during the exam and the device's usefulness were not answered due to information lack.

5.3 Discussion and Conclusions

The results collected during the observational study made it clear that although participants did not present facial paralysis, they considered the device a helpful tool. It was easy to understand the solution's goal and realise that it may represent an added value for users' daily lives, both clinical and home contexts.

Although the participants performed the evaluation using an unfinished prototype, they appreciated the available functionalities and exercises. In addition, they were satisfied with the solution and implied that they would recommend it to friends and family if needed.

Considering the results of the application of the USE questionnaire, the participants reported an overall good level of acceptance in all four categories, usefulness, ease of learning, ease of use and satisfaction. The therapist's evaluation had some negative results and issues, but the results were still satisfactory. These results were confirmed by the outcomes of the application of the second questionnaire. The positive outcomes obtained by the analysis may be a good predictor of frequent and independent use of FaceRehab by patients and clinicians.

After this formative evaluation, a summative evaluation with actual FP patients and therapists will be conducted to validate the device's usability. We intend to use the results from this first study to improve the technology and use the same questionnaires to compare the results.

Although some features need to be improved, virtual companions based on embodied conversational agents present a potential means of providing supportive care to patients with FP, including connecting them to the specialised healthcare professional, supporting the performance of the exercises and correct facial movements.

Therefore, opportunities can be envisaged for the use and commercialisation of virtual companions such as FaceRehab.

This research presents a few limitations to be considered while interpreting the results. Firstly, some participants had a technical role and were very comfortable using complex technologies, which might influence the results. Also, the 20 people sample is a good selection size for a simple formative evaluation but is not large enough to ensure the success of the device regarding its usability.

Finally, it was evident that many details need to be improved; therefore, the solution is an object of further development to solve usability and technical issues. The development focus from now on includes improving visual aspects such as lettering, the appearance of the virtual assistant and colours. As for the technical features, the developers are improving the camera display and image quality. Finally, academic research is already being conducted to prove that the measurements taken to evaluate the level of FP are reliable.

Chapter 6

Impact of FaceRehab on the market

As the market for medical devices is not stable, uniform or constant, developers that produce medical tools should seek to seize opportunities, dampen or absorb threats, or adapt to them. Looking through this perspective, this chapter consists of an internal and external analysis of the FaceRehab solution. The objective is to study the existing relationship between the device, its functionalities and its environment regarding opportunities and threats.

This study will accomplish four external analysis methods: MAST - Systematic aspects for feasibility assessment, SWOT analysis, Porter's Five Forces evaluation and Value Proposition Canvas.

6.1 Systematic aspects for feasibility assessment (MAST)

According to the European Commission [75], Health Technology Assessment (HTA) summarises information about medical, economic, social and ethical issues related to the use of a health technology [76]. The primary goal of HTA is to give decision-makers evidence-based data to create safe, efficient, patient-focused, and cost-effective health policies.

When it comes to the introduction and application of telemedicine, the Model for Assessment of Telemedicine (MAST) offers a strong foundation for decision-making. The model is the most popular framework for evaluating telemedicine in Europe, and the European Commission advises using it to analyse telemedicine initiatives. Therefore, The Model for Assessment of Telemedicine was chosen to assess the feasibility and value of the FaceRehab solution.

According to Kidholdm et al. in [77], MAST includes a "Pre-implementation assessment, followed by a multidisciplinary assessment, including a description of the patients and the application and assessment of safety, clinical effectiveness, patient perspectives, economic aspects, organisational elements and socio-cultural, legal and ethical

aspects."

The following section stages comprise the MAST: (i) preceding considerations, (ii) multidisciplinary assessment, and (iii) transferability assessment. In the main stage of the multidisciplinary assessment, the outcomes of telemedicine applications are evaluated in seven domains based on the domains in the EUnetHTA model. For practical reasons, this section will focus on the multidisciplinary assessment of the MAST Model and appraise the utility and achievability of the Facebehab using its seven domains.

Health problem and characteristics of the application

This section should include a description of the medical device, including technical characteristics, the patient's expectations towards its use, and an overview of the medical condition. All the factors mentioned have already been explained in detail in chapters 1 and chapter 4. Therefore, due to simplification matters, it will not be repeated.

Safety

According to Kidholm [76], the assessment of damages and their identification can be used to define safety. For instance, using telemedicine applications could lead to poor diagnostic and treatment choices that endanger the patient. Clinical safety and technical safety are the two categories into which safety concerns for telemedicine applications can be classified.

As mentioned in chapter 5, in the case of FaceRehab, the safety concerns can be divided into clinical (Performing too many exercises in the wrong way could lead to synkinesis) and usability/UX issues (If the results expected are not achieved, it could lead to emotional frustration). Regarding digital safety, FaceRehab has a system file in place and strictly complies with its reporting responsibilities as described by the MDCG 2019-16 Guidance on Cybersecurity for medical devices. A Risk Minimisation Plan prepared to handle and minimise the risks produced by using the device.

Clinical effectiveness

It is recommended to adhere to general rules for reporting clinical results when presenting findings from evaluations of telemedicine's therapeutic impacts, whether based on current clinical trials or a systematic review of the literature.

As mentioned in chapter 2, a systematic review of the literature comparing the FaceRehab solution to similar technologies has been presented to demonstrate that there are numerous instruments and outcome measures that are related to the unique conditions of the patients and that the description of the clinical effectiveness of telemedicine applications is highly specialised. In addition, chapter 5 reports a formative study to validate FaceRehab's usability. Later on, a summative evaluation will be performed not only to determine its usability but also its effectiveness.

Patient Perspectives

The patient perspectives will be evaluated using the participatory design study, including questionnaires and

individual interviews. The questionnaires exhibit the advantage of standardisation and can be used to measure the usability of FaceRehab as they allow for the quantification of results. On the other hand, interviews allow for deeper insights and a complete overview of each user's experience with the devices and the app. For this reason, the Project Team has chosen to deploy a combination of these two techniques in its proposed observational study. The risk of bias is inherent in both choices as the more negatively predisposed patients may refuse to provide answers.

Economic Aspects

As for the economic context, in Portugal, based on the information provided in "Código de Nomenclatura e Valor Relativo de Actos Médicos – Ordem dos Médicos", it can be estimated that the cost is between 100 to 200€ per intervention per patient (costs rationale calculated assuming one consultation with two specialists in hospital/clinic + one conference with two specialists + remote monitoring). If we consider that for a period of one year, the patient needed 2 to 3 interventions, the cost for public healthcare can be estimated at 600€ per year per patient (average cost in health care per person per year is around 821,3€, according to Eurostat). For the estimated population in the target group of around 1.111.500 people each year (in Europe), these costs reach more than 912 Million€ per year.

Assuming FaceRehab will be compared to a remote monitoring medical act contributing to adjusting, on average, the need for 0,3 interventions per year, FaceRehab provide a solution that estimates to reduce the estimated costs by 10% (reduction of 91.2 Million €/ year)

Organisational aspect

The organisational domain considers the resources that must be coordinated and mobilised to execute and implement a new telemedicine solution. This analysis should also consider the potential changes or outcomes that use may have on the organisation.

Chapter 4 describes all the steps to successfully implement the solution, along with the consequences and outcomes. Therefore, due to simplification matters, it will not be repeated.

In addition, the Project team expects that the implementation of FaceRehab will simplify and improve the delivery process. More specifically, the data exchange between patients and doctors can remarkably reduce the workload by eliminating the need for physical visits to the treating physician for regular check-ups. The possibility to provide feedback through the app will increase the flexibility of the physicians' schedules and will reduce the hours spent on patients' examinations. On the other hand, the HCPs must be trained in new procedures, and patients must be instructed in new interaction mechanisms. Both of these steps are resource-consuming.

Socio-cultural, ethical and legal aspects

Because medical technology and health care have the moral goal of helping people and enhancing health and well-being, ethics is a crucial component of introducing new technologies into the healthcare system. How-

ever, some inherent risks are associated with using medical technology that deals with sensitive personal data. The patient data in the FaceRehab situation must be collected, processed, kept securely, and protected against unauthorised use.

Patients' rights to confidentiality and privacy must be addressed in this situation since they are FaceRehab's intended users. FaceRehab is the intermediary between the patient and the doctor and an agent for the patient's private data. In this situation, the General Data Protection Regulation (GDPR) [78] policy is required to protect patient data. Patients have the following rights under the GDPR: Rights to information, access, rectification, objection, erasure, restriction on processing, data portability, and non-subjection to automated decision-making.

6.2 Analysis SWOT

SWOT Analysis is a business strategy tool to assess how an organisation compares to its competition [79]. It is a way to identify the current situation in which a company finds itself positioned and assist in defining fundamental and strategic objectives.

The tool is essential when making crucial company growth and development decisions. Its acronym refers to Strengths, Weaknesses, Opportunities and Threats. The first two - Strengths and Weaknesses - are internal analysis of the company, which helps to identify the abilities and disadvantages relative to the competition. Opportunities and Threats enable an external analysis of the environment and how this influences the company's management.

The analysis of these factors results in a 2×2 matrix, which divides the four analysis points into internal/external and positive/negative factors. Hence, it gathers a perspective of the inside and outside of the company, what is positive and negative, and finally, allows a complete picture of the factors that can determine the project's success.

Strengths

At the level of FaceRehab's medical device, the Strengths analysis was made by asking questions such as the following: (i) What makes customers choose FaceRehab, among others? (ii) What makes this solution better than others? What unique or lowest-cost services can the device provide for the main stakeholders? (iii) What differentiates the business from others?

After answering the question, the writer concluded that FaceRehab's strengths are:

- Create fewer burdens for caregivers (formal and informal) once every piece of equipment needed for the rehabilitation progress is available at home.

- The care professionals can use their time more efficiently by facilitating access to results and data. Therefore, FaceRehab provides a communication channel between patients and caregivers and optimises time.
- FaceRehab ensures integration and interoperability with other tools that may be helpful for other areas of health and care. This is an advantage for care professionals and organisations that could rely on a more integrated set of tools.
- FaceRehab will be the only solution that provides features for a complete facial rehabilitation with monitoring, feedback, remote follow-up and dedicated devices that can be extended with other exercises.
- Current competitors are mainly focused on selling directly to patients. FaceRehab strategy is to leverage distribution channels within healthcare institutions and aid facilities.
- Possibility to evaluate, monitor and provide facial rehabilitation services with greater intensity, accessibility, and quality of processes. All without increasing the costs of specialised human resources.
- Increase patient attending capacity without expanding the number of employees.
- There is no need for a significant reorganisation of the healthcare centres or patient domestic environment.

Weakness

The Weakness analysis was made by asking questions such as the following: How can the product be improved? What does the patient lose for using FaceRehab's device compared to the competition? In what field is the competition better? What features can not be accomplished in time or improved? After answering the question, the writer concluded that FaceRehab's weaknesses are:

- Price of the service can be considered too high, especially for the primary end users, meaning that sometimes the end-user is unwilling to pay for technology.
- Risk of rejection due to fear of privacy information leaks. Therefore, the end user might develop concerns regarding any data leak. If there is any doubt of confidentiality using FaceRehab, it can trigger user rejection.
- The patient can become demotivated after repetitive exercises. This fact can lead the patient to stop using the solution as the pressure is lower once they are in their homes and not in a clinic environment.
- Some of the technical features will not be implemented in time due to deadline issues. Therefore, the device will not include some expected components such as videoconferencing. This might put the device behind the competition.

Opportunities

In the opportunities section, it is possible to indicate which changes in the market are favourable for the customer, such as economic factors, emerging opportunities and market changes that may benefit the customers.

FaceRehab opportunities are:

- The number of people affected by facial paralysis in Europe (The geographic target of the project) is close to 1 million people per year. If the problem can address 0.5 percent of this market (a reasonable estimation), it will be possible to reach 5.5 thousand people. Therefore, there is ample opportunity to develop technological solutions to cover this issue.
- It is intended that care organisations will be interested in buying the FaceRehab system (as a service) and then providing a quality service to end-users with FP. That is, the product has different selling targets, becoming more profitable.
- The program partners are included in the EIT-Health network and are also big players in the health sector, which means the chances of partnerships and collaborations with other companies in the health sector and the opportunities on international land are larger.
- Thee health and social care organisation reported a strong need for monitoring, evaluation and rehabilitation tools. In addition, there is a need to decentralise and provide care systems for patients at home to restore their independence and ability to manage their health.

Threats

The threats must include the scenario in which all the unfavourable factors for the company are concentrated. In addition to the lack of control over the issues, they present themselves as significant threats to the business.

- The telemedicine market is facing a large development and increase. More and more healthcare institutions are looking for this technology. Even though that may be considered a benefit for FaceRehab, the more this need is seen in the market, probability of new competitive technologies is also increased.
- Covid-19 had a huge impact on the economy, mainly in the health sector. That means that even though the search for telemedicine solutions has increased, the healthcare institutions might be unwilling to pay for the technology as most of them show a huge increase in their debts. In conclusion, there might occur policy and legislation changes in the healthcare centres that result in the rejection of the adoption of innovative technologies.

6.3 Porter's 5 Forces

In order to properly analyse Facerehab's implementation, it is essential to define the best marketing strategies and comprehend the scenario in which the company/product is acting. In this sense, Porter's 5 Forces analysis tool helps the developers organise a strategy to know how to act in the face of opportunities and threats.

It can be divided into five categories: Competition in the industry, Entry of competitors, Threat of substitutes, Bargaining power of suppliers and Rivalry amongst the existing players.

Competition in the industry

Due to the importance of understanding the strengths of businesses that sell a comparative solution or belong to the same category, the strength is thought to be the most significant among the five divisions.

In the case of FaceRehab, the solution competes with 14 other products. Even though the competition exists, not all of them are placed in the same geographic region and do not target the exact same buyers. In addition, there is still no device that contains all of FaceRehab's features. That being said, FaceRehab has a low, competitive local rivalry and, therefore, a significant power in the market once it is released.

Entry of competitors

Costs, prices, and profit margins may be under pressure from new competitors' entry. The corporation's position may be considerably undermined by the easier and faster other competitors enter the market.

The entrance of new European rivals is expected, meaning that the FaceRehab solution can be weakened. That is mainly due to the evolution of the development of telemedicine technologies and the increase of the support of the Europe Union, which encourages the creation of innovative telemedicine solutions.

On the other hand, new entrants might be limited by the number of partnerships with existing solutions. Therefore, if FaceRehab establishes a stable partnership with a significant amount of healthcare organisations, the barriers to entering this market will get stronger.

Threat of substitutes

"Substitutes" occurs when a rival creates a product or service that can replace something that currently exists. Companies that manufacture products with no alternatives will have more freedom to raise prices. Contrarily, clients will have the choice to purchase the competing product if identical solutions are offered, which could harm

the company's position in the market. They might even be utterly distinct from a particular firm's products. However, they can nonetheless satisfy consumer demands, costing the company market share if it does not know when to act.

Therefore, the idea is to draw up a list of competitors that offer the same advantages as Facerehab and analyse the market conditions.

As mentioned earlier during the systematic review, there is no product capable of offering the same benefits as Facerehab. Therefore, there is no other equal solution to FaceRehab, that provides precisely the same benefits. Hence, it can be assumed that the product is unique and thus does not need to fear substitutes. However, healthcare organisations might set their channels for selling their solution.

Bargaining power of suppliers

According to the niche, the same provider that supplies Facerehab's development company with the necessary inputs for the production phase also supplies the competitor's product. Therefore, if the relationship between the parties is hostile, it could undermine the organisation either by leading to price rises or even a disruption in the supply of raw materials. Suppliers can also affect a company's profitability by raising prices or lowering the quality of their products.

In the case of FaceRehab, the solution only rely on easy access supplies such as robotic equipment and software programs. Therefore it can be assumed that the bargaining power of suppliers is not high, as the product can be quickly produced with other competitive suppliers.

Rivalry amongst the existing players

There is competition when multiple options are available for the same commodity. As a result, businesses compete with potential customers in various ways, relying on factors like price, customer satisfaction, interaction, connection and reliability.

As mentioned before and deeply analysed during the systematic review, the expansion of technological tools regarding telemedicine solutions in facial paralysis is increasing. A list of the competitors and the description of their features can be found in chapter 3 in the "other sources" section.

Most of these competitors offer a set of features designed to cover some aspects involved in FP. However, FaceRehab will be the only solution that will provide functionality for complete facial rehabilitation with monitoring, feedback, remote tracking and dedicated devices that can be extended with other exercises. Therefore, it can be assumed that the rivalry amongst the existing players exists, but it can not be considered a large rivalry.

6.4 Value Proposition Canvas

A value proposition design can be defined as "The benefits customers can expect from your products and services." [80]. This canvas can diverge into two sides: the Customer Profile, where the developers describe the client's understanding of the solution and the Value Map, where the value provided for the customers is clarified.

Value Map: Specify the elements that create value in the business model in detail. This section can be split into products and services (what the solution offers), pain relievers (how the solution solves customer's pains) and gain creators (how the solution provides gains for the customers)

Costumers Profile: Specify the main target group, what they expect from the solution and how it solves their needs. This section can be split into customer's jobs (the operational, social and dynamic tasks customers are trying to get done), pain (how the solution solves customer's pains) and gain (outcomes customers want to achieve)

This thesis will present a value proposition canvas for each main stakeholder (Patients with Facial Paralysis, Informal Caregivers and Healthcare Professionals). On the first side of the canvas, the Value Map remain the same for all parties involved:

FaceRehab Value Proposition Canvas

Table 6.1: FaceRehab Value Proposition Canvas

Product and Services	Gain Creators	Pain Relievers
Online medical appointments	Dedicated and detailed information easily available	Patient autonomy and independence
Physical device to deliver content and interact with the user	Communication between patients, caregivers and health professionals is facilitated (video-call)	Periodic or non-periodic therapy session options
Set of specialized exercises	Greater frequency and ease of intervention	Daily home exercises plan provided to the patient
Facial movements detection while performing exercises	Greater involvement of the patient during the rehabilitation process	Variety of exercises with different levels of difficulty
Digital platform	Automation and standardization of the treatment plans according to patient profiles	Option to add more exercises

Rehabilitation plans and therapy sessions prescription	Progress report	Exercises with different combinations of functional areas
Support the delivery of the therapeutic guidelines for the patient/caregivers/therapist	Interactive tool	Integration of new technologies in interventions (Digital transformation)
Support the delivery of care and lifestyle guidelines for the informal caregivers.	Communication between all parties involved is facilitated	Optimization of the health professional's working time
Direct contact with a multidisciplinary team	Faster rehabilitation process and saves time for all the stakeholders.	Monitor and detail reports of the accomplished therapy sessions
Real-time medical evaluation and correction of rehabilitation exercises		
Data storage of progression and assessment of patients		

Patient Value Proposition Canvas

Table 6.2: Patient Value Proposition Canvas

Costumer's jobs	**Gains**	**Pains**
Look for a rehabilitation clinic	Perform exercises in a home context	Cost associated with treatment
Find a suitable time for appointments	Personalized exercises	Travel time
Describe symptoms and be available for examination	Facilitated access to multidisciplinary and specialized team	Emotional and social disruptions caused by unsuccessful treatments
Download mobile application	Have visual feedback at home	Constant medical feedback
Subscribe to FaceRehab's app	No contamination	Lack of treatment options
Start the rehabilitation program (perform exercises)	Faster and more effective rehabilitation	Not personalized exercises
Connect to physician to evaluate the performance of exercises and evolution	Greater independence	Professional dependence to complete treatment

Access guidelines	Easy and secure way to login	
Observe results and evolution of the treatment	Access to updated materials and information	
	Decrease of time spent in therapy	
	Objective and direct goals	
	Access to treatment's evolution and results	

Informal Caregiver Value Proposition Canvas

Table 6.3: Informal Caregivers Value Proposition Canvas

Jobs	Gain Creators	Pain Relievers
Feeding (If the patient have a difficult due to mouth asymmetry)	Communication between patients,caregivers and healthprofessionals is facilitated (video-call)	Cost associated with travel
Instrumental activities of daily living	Decrease of time spent assisting therapy sessions or exercises	Access to results and evolution
Assist with the performance of prescribed exercises		Less dependency
Accompanying the patient to medical sessions and appointments		Informed follow-up on his relative by accessing the platform
In very severe cases, they are responsible for other activities of daily living		Less burden and responsibilities

Healthcare Professionals Value Proposition Canvas

Table 6.4: Healthcare Professionals Value Proposition Canvas

Jobs	Gain Creators	Pain Relievers
Facial Analysis	Increase the sense of monitoring by the patient	Avoid auto-prescription by the patients

Give feedback to the patient	Objective and measurable goals upon prescription	Cost associated with physical consumable materials
Evaluation of the therapy session reports/results	Decrease the time spent to plan therapy sessions	Little variability of tools available for the therapy
Prescribing motor exercises	Greater progress from patient	Availability from the HR to serve an increased number of patients
Prescribing miofunctional exercises	Easy and secure way to login	Not being sure about the functional exercises accomplished at home
Monitor and control the occurrence of synkinesis	Decrease the time spent in presential sessions	Negative outcomes as a result of patient performing exercises without assistance
Session Planning	Increase patient responsability	
Caregiver guidance	Receive feedback from home accomplished exercises	
Keep up to date with most current treatment practices	Greater involvement by caregiver (communication)	
Real-time medical evaluation and correction of rehabilitation exercises	Performing functional exercises in a real context (at home)	
Data storage of progression and assessment of patients	Decrease treatment cost	
Schedule Appointments	Access to information on new researchers and materials	
Subscribe to FaceRehab's App		

Chapter 7

Conclusion and future work

This work was submitted to the University of Coimbra in partial fulfilment of the requirements for the degree of Master in Biomedical Engineering. It was developed within the scope of EIT Health in collaboration with the Pedro Nunes Institute - Laboratory for Automatics and Systems (IPN LAS). The challenge was to join themes in which all the institutions actively engage and ensure that the project's components are integrated into the overall project.

The problem addressed in this thesis was regarding implementing a telerehabilitation device for facial paralysis in the market and our study was conducted in six main phases to address our research question: Introduce FaceRehab's technology, purpose and goals; Understand the Facial Paralysis problem domain, Perform a thorough analysis of related technology (Systematic Review); Analyse the users and technical components using renowned approaches; Evaluating the device's usability and; Research its market impact.

The goals and difficulties of the technology were defined in the first chapter, which also provided a general overview of the solution and project scope. The telerehabilitation solution was succinctly summarised in this section, allowing the reader to effortlessly comprehend the subsequent chapters and connect them to the scope of this thesis. The second section continues to provide the reader with helpful information on facial paralysis, which helps them comprehend the product's value and how it is needed in the market.

The third chapter aimed to analyse similar existing technologies and compare their features with FaceRehab. A deep and well-structured systematic review accomplished that goal. The primary findings of our systematic research point to the fact that neither the patient nor healthcare providers are currently being offered a full range of medical improvement options by the technology already in use. The majority of the technology listed in the academic articles is still under development and not yet ready for market adoption. Most of these competitors provide features intended to address specific FP-related issues. However, FaceRehab will be the only solution that will provide functionality for complete facial rehabilitation with monitoring, feedback, remote tracking and dedicated

devices that can be extended with other exercises. Additionally, existing rivals in the market primarily concentrate on direct patient sales, whereas FaceRehab aims to use distribution networks within institutions (target buyers).

After analysing the existing technologies, an implementation analysis and strategy was developed during chapter 4, according to the technical features and user's specifications (Patient Journey, User Needs, User Stories, Use cases and Requirements). The initial step consisted of performing stakeholder analysis, allowing us to determine roles and responsibilities. The following sections focused on understanding the importance of technology and specifying its use by the end-users. The primary findings of our analysis point to the fact that there is a clear need for this technology. In addition, this chapter allowed us to visually organise how the technology should be adapted to users' daily lives and describe each step that should be followed during the treatment. The results include a simple and transparent use by the patient and the healthcare professional, proving a relatively straightforward implementation in the market. It was possible to list the requirements the technology should have to be successfully implemented in the market. Finally, regarding the prototype developed, there are still some technical adjustments to be made but overall the results were impressive for an initial design and currently meet the needs and requirements imposed.

The following chapter validated the device's usability using a formative evaluation. That stage allowed us to list, according to the user's perspective, the technical limitations that the technology presents regarding usability (detailed in the next section, "Future Work"). The primary findings of our analysis point to the fact that even though some features still need to be improved, virtual companions based on embodied conversational agents offer a potential way to provide supportive care to patients with FP (including connecting them to the specialised healthcare professional, assisting with the performance of the exercises, and correcting facial movements). As a result, this stage contributes to the previous conclusion, as it proves that there is potential for using and commercialising virtual companions like FaceRehab.

Finally, chapter 6 focused on performing a Health Technology Assessment and external analysis of the technology. Using the MAST methodology, it was possible to co-relate the health technology features to the government requirements and interventions for their immediate and long-term effects. This stage ensured that the technology followed the necessary requirements and allowed us to develop a framework and understand the bigger picture regarding safety and economic policies. In addition, the SWOT analysis and Porter's 5 Forces allowed us to understand our strengths, weakness, threats and opportunities. The main finding point to the fact that even though the competition in the industry is growing, there is still space in the market for this innovation due to the increasing interest in telemedicine and the significant target group. This stage highlights the fact that the quality of the device and its efficiency should be impeccable to stand out in the market due to the risk of rejection and fear of adapting to the new technology. Finally, the Value Proposition Canvas allowed us to visualise what the users gain by using the innovation, which also proved the potential for using and commercialising virtual companions such

as FaceRehab.

Overall, after observing these results, we concluded that there are still some items on which the solution can be improved, especially regarding the technical components and usability issues. However, the market is open and ready for the technology's entrance, and patients' needs have been proven.

In conclusion, our initial hypothesis stated that future problems could be more easily overcame if an extensive analysis of the solution such as the one performed in this word were executed. This theory could be proved since this framework lessens mistakes and weaknesses in decision-making, improving user experience and market positioning. Finally, the intention to validate the solution's usability by performing a formative evaluation was also successfully confirmed.

Regarding the goals of this master's thesis, the primary purpose was to provide a co-creation and co-design of the solution (identification of user needs, value-proposition, and definition of user stories), a design and specification of the solution (requirements and technical specifications of hardware and face recognition algorithms) and address early-stage health technology assessment to steer validation of technology processes.

The overall work far exceeded expectations since a more thorough analysis was offered and it successfully completed and overcame the goals imposed. For example, the co-creation and co-design of the solution expand to more that only user needs, value proposition and user stories, gathering information on requirements, patient journey, use cases and performing a whole story-telling analysis. The technical specifications of hardware and face recognition algorithms were successful, and achieved a functional prototype. Finally, the impact on the market and external analysis were supposed to be studied by performing only a HTA assessment, but instead a complete analysis including SWOT, Porter's 5 Forces and MAST were accomplished. The overall result is a complete analysis on FaceRehab's implementation and strategy.

7.1 Future work

This thesis was essential to understand the technical features that still need to be improved by the development team. The usability validation was the primary source of information since the users gave direct feedback.

After reviewing this work, the team concluded that visual aspects such as lettering, the appearance of the virtual assistant and colours will be improved. In addition, some features that are not yet function will be implemented in the future, such as machine learning and artificial intelligence to train the data and construct an evaluating model. With the increasing quantity of data, the evaluating model will be continuously improved. Some other technical features, such as the guidelines and live monitoring, are not yet available, but software specialists are developing their implementation.

A summative evaluation to validate the need and usability of the device will be conducted by the end of 2022. We expect this evaluation to prove the results stated in this thesis. In addition, partnerships with healthcare facilities have already been formed, meaning that the FaceRehab telerehabilitation device will be initially tested in the market by specialised clinics.

Regarding this thesis, we also anticipate that the structure will be used as a model for future research in telemedicine devices, especially the Instituto Pedro Nunes. We also expect this research to add to the internal and external evaluation of various other telerehabilitation and medical technologies.

7.2 Contribution

This project also produced two different scientific contribution that ware submitted as articles in the MDPI Applied Science Journal under the title "Facerehab - Facial Paralysis Rehabilitation at Home: Formative Usability Test" and "Facerehab - Facial Paralysis Rehabilitation at Home: Systematic Review".

Appendix A

History of Facial Paralysis

Bell's Palsy condition was named after Sir Charles Bell in 1821 after he published a detailed description of idiopathic facial paralysis. He was not the first to be aware of the disability, despite the fact that it is now associated with his name. According to recent research, numerous Persian and Greek doctors attempted to define peripheral cranial nerve seven palsies as early as the fifth century BCE [81].

Prorrhetics II, a work written in the fifth century BCE, contains the earliest recorded description of facial paralysis. Hippocrates compares paralysis in the book to an instance of spontaneous facial deformation when it is not accompanied by other medical diseases. After that, a Greek physician named Areteaus from the first century CE goes into further medical detail about the paralysis, characterizing topics like the involvement of cranial nerves and the presence of spasms. Although other doctors have described cases of facial paralysis, the following significant study is credited to Zakariya Razi, a Persian doctor better known by his pseudonym Razi, who made his discoveries between 865 and 925 CE.

Razi is the author of a book called al-Hawi, a well-known novel destined to collect his medical notes and knowledge. His writings offer a detailed description of facial paralysis that distinguishes between spasms and serious lesions caused by palsy. In addition, Razi provided one of the earliest descriptions of bilateral facial palsy, citing numerous sources as well as outlining his own course of therapy.

Only after completing earlier work did Charles Bell, who gained recognition in the medical community and gave the illness his name, devote his career to studying face nerves in 1821. Charles was only able to accomplish that after learning about the long thoracic nerve and emphasizing the role the seventh cranial nerve plays in the regulation of the muscles of the face. He demonstrated in his work that facial paralysis arises from injury to this nerve and is intimately tied to facial expressions [82].

In conclusion, despite extensive prior work and research, facial paralysis still presents challenges and has

unknown causes. Additionally, there is still some false information spread throughout society, and Bell's Palsy and Facial Paralysis are frequently confused. Both conditions are regarded as examples of facial deformation and have been researched extensively.

Appendix B

Nervous System and Facial Nerve Anatomy

Nerve System

The central and peripheral nervous systems are the two basic divisions of the nervous system. The first is made up of the brain and spinal cord, which are both affected and guarded by three membranes referred to as meninges. The peripheral nervous system, on the other hand, is made up of nerves that come from the brain and spinal cord. The study will concentrate on this last classification since its elements are crucial to the emergence of facial paralysis.

The peripheral nervous system's job is to link the brain and the rest of the body altogether. The spinal nerves and cranial nerves fall within this category. The purpose of the 12 pairs of cranial nerves that exit the brain is to carry sensory or motor messages, particularly to the head and neck regions. 31 pairs of nerves that emerge from the spinal cord make up the spinal nerves. They are composed of motor neurons, which transmit central nervous system impulses to muscles or glands, and sensory neurons, which take in environmental stimuli.

The somatic and autonomic nervous systems are two subsets of the peripheral nervous system that are distinguished by their functions. The somatic nervous system controls our willed, voluntary movements, as well as the skeletal musculature of the entire body. The autonomic nervous system nevertheless functions in conjunction with the central nervous system. The sympathetic nervous system, which stimulates organ activity, and the parasympathetic nervous system, which inhibits it, are its primarily two types.

Facial paralysis is mainly caused by damage to the facial nerve(the seventh cranial nerve). It contains the

motor, sensory, and parasympathetic nerve fibres, which provide innervation to several areas of the head and neck region.

Facial Nerve

One of the cranial nerves with the most intricate anatomies is the face nerve. Since it has motor, parasympathetic, and sensory branches that innervate various parts of the head and neck, it is classified as a mixed nerve [83].

The facial nerve is composed of three nuclei:

- The main motor nucleus: The stapedius, a tiny bone in the ear, and the face muscles are innervated by the main motor nucleus, also referred to as the lower motor neurons.
- The parasympathetic nuclei: Consists of four nuclei, the oculomotor, which innervates the eye's smooth muscle; the parasympathetic nucleus of VII, which innervates nasal, lacrimal and ventral salivary glands; the parasympathetic nucleus of IX which innervates parotid and zygomatic salivary glands and the parasympathetic nucleus of the vagus which innervates thoracic and abdominal viscera
- The sensory nucleus: Receives information about discriminate sensation and the light touch of the face as well as conscious proprioception of the jaw

The facial nerve presents four significant functions [84]:

- General somatic efferent: Transport motor signals to the skeletal muscles.
- General visceral efferent: Conduct internal organ, gland, and blood vessel sensory signals to the central nervous system.
- Special visceral afferent: Information from the tongue's back third's taste buds should be transmitted.
- General somatic afferent: Transmit impulses to skin and other specific receptors in the muscles, joints, and ligaments.

Appendix C

Specifications of facial paralysis aetiology

Facial paralysis is currently considered an enigmatic disability due to the different etiologies linked to the condition. Currently, 31 known causes can be categorized into five sections. This study will focus mainly on the most common facial paralysis aetiology [13].

Table C.1: Causes of Facial Paralysis

Causes of Facial Paralysis		
Infectious	**Neoplastic**	**Trauma**
Herpes Simplex	Chloresteatoma	Iatrogenic
Ramsey-Hunt S.	Vestib. Schwann	P. wound
Otitis Media	Facial Neuroma	Birth trauma
Mastoiditis	Carcinoma	Fractures
Lyme	Glomus Jug.	
HIV	Histiocytosis	
Tuberculosis	Rhabdomyosarcoma	
Mumps virus	Osteopetrosis	
Rubella virus	Hemangioblastoma	
Influenza virus	Leukaemia	
Mononucleosis		
Neurological	**Congenital**	**Systemic**
Guillain-Barré	Mobius S.	Sarcoidosis
Mult. Sclerosis	Melkersson	D. Mellitus
Millard-Gubler	D. Myotonia	Hyperthyroidism
		Autoimune Disease

Infection

Herpes Simplex Virus type 1

The Herpesviridae family of viruses, which includes HSV types 1 and 2, is responsible for a number of well-known infections. Recent research has shown that HSV type 1 can also cause facial paralysis, however the underlying facts and methods are not well understood. The study's overall finding is that the reactivation of latent HSV1 infection in the geniculate ganglion is thought to be the etiology of FP [85].

Varicella-zoster virus (Ramsey-Hunt syndrome)

An acute infectious disease known as "Varicella", also referred to as chickenpox is linked to he development of FP due to the varicella-zoster virus (VZV). An damage to the seventh cranial nerve, which is now linked to the emergence of facial paralysis, is one of the direct consequences of VZV. Ramsay Hunt syndrome or Zoster sine herpete is the medical term used when this damage especially affects the face nerve [86].

Complications of Otitis Media

Otitis media is the medical term for an infection or inflammation of the middle ear. Respiratory infections, sore throats, and colds can all be linked to this condition[87].

Research from the past has shown that chronic otitis media (COM), which exposes the facial nerve to infection, can cause facial palsy. In that case, facial nerve paralysis affects 0.2% of patients with acute COM [88].

Regarding its clinical course in particular, the scientific community is still unsure of the precise relationship between otitis media and facial paralysis. Osteoitis, bone deterioration, external compression, edema, and nerve irritation are a few potential causes.

Lyme Disease

A multisystemic condition called Lyme disease is caused on by the bacteria Borrelia burgdorferi and Borrelia mayonii. It transmit to people whenever infected black-legged ticks bite humans.

Damages to the cranial nerves, which affect 5 to 10% of Lyme disease patients, are the most prevalent focal nervous system abnormalities. However, Lyme disease and facial paralysis occur more frequently in youngsters than in adults. Similar to other stated possible causes, it is still unknown how this illness is related to Bell's palsy [89].

Neoplasms

A tumour is referred to in medicine as a neoplasm, which is a lump or solid or fluid swelling. Apart from inflammation, the second most frequent cause of facial paralysis are neoplasms, with 5 to 50% of cases linked to it

[90].

Tumors can paralyze the face muscles in two different ways: Either the facial nerve is being directly contacted or the surgery to remove the tumor adjacent to the nerve may have an impact on the nerve itself.

When seen from this angle, the acoustic neuroma and vestibular schwannoma (VS), both of which are found near to the facial nerve, are the tumors that impact facial nerve function the most frequently [90].

Trauma

Trauma is also considered a frequent cause of facial paralysis. The palsy happens because the facial nerve may enlarge or become cut if the fracture involves the bone that surrounds it. There are three types of injuries in that group: Blunt force (impact to a body part), Penetrating injuries (injury brought on by an unfamiliar object piercing the skin), and Iatrogenic trauma (any adverse condition in a patient resulting from treatment by a physician or dentist).

The facial nerve is frequently traumatically injured by fractures of the temporal bone. These are typically brought on by high-speed head trauma, such as from car accidents. Iatrogenic palsy, on the other hand, is a type of palsy that is thought to be extremely rare (less than 1%) [91].

Appendix D

Specifications of facial paralysis diagnosis methods

Physical Examination

As mentioned during chapter 2, the most frequent adverse effects of facial paralysis are unintentional eye closure, the inability to smile on both sides of the lips, incomplete mouth or eye closure, the inability to lift the cheek or brow muscles, and frequently difficulties tasting. Physicians may ask the patient to complete any of these tasks while also performing auricular examination to analyze these diseases. The doctor may also address concerns like how long the paralysis lasted and when the patient first became aware of the symptoms since the typical symptoms manifest within a specified time frame.

MRI Scan

The doctors can examine the facial nerve's injury and spot swelling and unexpected growth thanks to the MRI scans, which are typically detailed and three-dimensional. The use of the contrast agent gadolinium, which goes directly to the facial nerve and highlights areas of inflammation, may improve the results of the facial nerve picture.

The facial nerve that runs from the brainstem to the fundus of the internal auditory canal can be examined using MRI technology. It can reveal whether parotid malignancies have perineural dissemination. Additionally, the MRI is useful for identifying any facial nerve enlargement (which occurs when the palsy is brought on by a neoplastic condition) and may also highlight unwanted tumors near to the nerve that may require surgical excision [92].

Topographic Testing

As mentioned in previous chapters, face-paralyzing injuries are frequently caused by trauma and brain injuries. To provide a diagnosis, several tests, such as topographic examinations, should be used to assess the lesion's location. To identify the pathology linked to face nerve damage, the primary diagnosis is therefore carried out concurrently with physical examinations. The Schirmer's and Stapedial Reflex tests are the two most often used methods [93].

The Schirmer's test, commonly known as the dry eye test, gets its name from the examination's capacity to quantify lacrimal tear production by counting the volume of tears that come into contact with a strip of paper put along the eyelid. The outcome shows if the patient generates enough tears to maintain a moist and healthy eye. This test is carried out as a facial nerve lesion frequently affects the lacrimal canal; in that scenario, a 25% drop in one eye compared to the other may indicate facial nerve involvement at the level of the geniculate ganglion.

On the other hand, the stapedial reflex, also known as the acoustic reflex, is a routine test to assess how the ear responds to various noises. The face nerve is situated adjacent to the ear muscles, as was previously noted. Consequently, the facial nerve might harm hearing. In contrast, if the response is normal, the lesions should be far from the ear nerves. The absence of the reflex implies lesions of the facial nerve in an area near to the stapedius nerve [94].

Electroneurography

Electroneurography is a test used to assess the facial nerves and other peripheral nerves' functionality. This test should ideally be done within 14 days of the paralysis's beginning. The outcomes aid medical professionals in deciding if additional testing or treatment may be necessary.

The doctor inserts many electrodes at the patient's ear base to conduct this test. The electrodes are low electrical current generators that produce flat, adhesive discs that adhere to the skin. Although it may tickle, the experience is not uncomfortable.

A doctor stimulates the facial nerves and monitors how the muscles react. The findings aid in determining whether or not the nerves can regain full functionality on their own. Less than 10% of the function that healthy muscles on the other side exhibit in paralyzed muscles may indicate that the paralysis may be permanent.

The doctor could repeat this test two or three times to determine whether nerve function improves in the weeks following diagnosis.

Digital Therapeutics (DTx)

Digital Therapeutics (DTx) is a way of treatment used to diagnose, monitor, or heal a health condition. DTx, then, are software programs developed for patients with a demonstrated therapeutic advantage that assist patients in the management, prevention, or treatment of a disease. For instance, Digital Therapeutics can help patients manage their symptoms independently, enhancing their quality of life and other therapeutic goals. DTx employs virtual resources, including smartphones, applications, sensors, virtual reality, IoT, and other technologies, to encourage patients to change their behaviour.

Due to a growing burden of chronic conditions and constrained resources, Europe's health and care systems are dealing with a dual issue of rising demand and shrinking supply. This scenario is made worse in poorly populated places, where there are frequently a lot of older people living there and various health and care services must be accessed over great distances. For many patients with specific diseases, such as facial paralysis, telerehabilitation is an essential part of care, treatment, and support.

Appendix E

Specifications of facial paralysis treatment methods

Motor exercises

Some facial paralysis patients eventually experience undesired muscle movement or no movement at all. Because there is no voluntary coordination of facial expression, there are improper reflexes and poor facial symmetry. The quality of life (QoL) may be harmed by these effects as they could affect one's ability to communicate, express oneself, and interact with others.

The most popular kind of physical therapy for Bell's palsy is facial exercises [53]. Its objective is to strengthen muscles so that the face can once again move together and form expressions. The exercises suggested are not typical, and the choice of which ones to use is entirely up to the therapist or clinician handling the patient's case. However, it is generally agreed that the majority of exercises should be done in brief sessions around three to four times a day. The fundamental idea behind face muscle exercises is therefore to gradually recreate the muscle pattern and regain the capacity to do the proper facial muscle movements voluntarily.

Steroids and antivirals

Bell's palsy can occasionally be attributed to facial nerve irritation, as was discussed in the previous chapter. Since corticosteroids have a strong anti-inflammatory effect that should reduce nerve damage, they are regarded as a disease treatment.

There has never been a single treatment for facial paralysis that has led to a complete recovery of the illness. In 1951, Rothendler [95] examined a number of studies that suggested steroids could treat idiopathic facial paralysis. Then, Stankiewicz [96] used his research to create an updated analysis of the cases, in which a second evaluation of the information published on steroids and idiopathic facial paralysis was conducted. The revision assessed 94 publications and found that while there were few unfavorable side effects, the majority of research suggested that steroid medication was not effective.

Nowadays, doctors frequently consider steroids and antiviral medications as a therapy option for idiopathic facial paralysis when it is in its early stages, but their efficacy is still unknown. Medical experts have differing viewpoints on the efficacy of corticosteroids, although the majority of studies support its use when started promptly, ideally within 72 hours after the onset of paralytic symptoms [97].

Acupuncture

By creating a collateral innervation, acupuncture improves neuron excitability and encourages the regeneration of nerve fibers (which increases vascularization and muscle contraction). In a study of acupuncture, Chen et al.[98] examined six systematic reviews with 537 patients and found that this treatment was effective in treating facial paralysis.

He et al.[99] encountered methodological issues and challenges while merging data for the meta-analysis in a different study. They came to the conclusion that the results were untrustworthy and could not demonstrate the efficacy of this treatment.On the other hand, a more recent study by Kim et al. [100] points to a 7% greater advantage in recovery from acupuncture therapy and an 11% greater benefit from combining acupuncture with pharmaceuticals. However, the positive effects of this therapy on FP were deemed inconclusive due to methodological mistakes.

Overall, the majority of the research done so far has proven that acupuncture and electrical stimulation can quickly restore peripheral facial paralysis. Due to a balance of muscle activation in response to the electrical stimulation of the acupuncture needles, the treatment can reduce the severity of the aftereffects.

Medical Surgery

Decompression procedures only work for a short period of time, and in the case of FP, they must be carried out by the 12th day. [101] Although the methods employed may vary, they all work to release pressure from the facial nerve. Given the dangers and expenses involved in such an operation, a systematic study by Somasundara, [102]

highlights the absence of benefits of decompression surgery in this location. Labyrinthine segment and geniculate ganglion decompression appears to produce better outcomes, although the hazards are higher. According to Somasundara, these risks include stroke, CSF fluid leaking, infection, facial nerve injury, temporary or permanent aphasia, seizures, and temporal lobe retractions.

Up until the 21st day of FP, Bell's palsy patients with degeneration higher than 90% can receive facial nerve decompression at the Hospital das Clínicas, Faculty of Medicine, University of São Paulo (HC/FMUSP). The labyrinthine, geniculate ganglion, and tympanic facial nerve segments can be decompressed thanks to this access. Because the transmastoid approach with decompression of the mastoid segment does not change the course of the paralysis, it is rarely utilized in conjunction with medial decompression.[58].

Despite the highly sophisticated surgical methods used in cases of this kind, the aftereffects still exist. Due to the hyperactivity of the muscles on the opposite side of the paralyzed side, the face frequently lacks the requisite symmetry in both static and dynamic positions, which causes the patient severe psychological distress. [103]

Biofeedback and EMG

For the person to monitor and comprehend their motor performance, biofeedback uses visual or auditory cues provided through EMG. Compared to other standard treatments, neuromuscular reeducation supported by mirror feedback or surface electromyogram (EMG) has greater results. [104]

The data that the electrodes picked up are amplified and then transformed into graphs that show the muscle activity in the frontal region by a computer. In order to minimize unintended muscle contraction, the approach gives the patient real-time visual or audio feedback as he attempts to relax his facial muscles. In addition to being non-invasive and painless, the technique is regarded by doctors as one of the best ways to treat neuromuscular reeducation.

The Cochrane Systematic Review by Teixeira et al. [53] and the Guideline by Baugh et al. [105] both note the absence of a recognized and uniform concept of this therapy in FP throughout the literature, despite multiple trials showing promising effects. The authors claim that this outcome may be influenced by the shortage of investigations using verifiable scientific technique. There was discussion of a number of physical therapy methods, both in combination and separately, including heat treatment, massage, breathing exercises, face imitation exercises, and biofeedback [53].

Additionally, Kim et al. [100] study have shown that physical therapy helps patients with prolonged paralysis improve to some extent. Baugh et al. [105] on the other hand, claim that this improvement may be mistaken for spontaneous recovery since there are no scientific record that contrast this type of therapy with spontaneous

recovery.

Electrostimulation

It is debatable if electrostimulation should be used for FP rehabilitation. Galvanic current and high voltage electrical stimulation are cited as ways to hasten the recovery of muscle contraction by Chevalier et. al. [106], yet animal studies have demonstrated that reinnervation damage can result from neuromuscular electrostimulation during the early stages of nerve injury recovery. That is, reinnervations will be disruptive if electrostimulation is not accurately given to the designated branch of the facial nerve. [107]

Electrical stimulation is not advised, according to some writers, unless the sequelae continue after 18 months [108]. In 2000, Targan et al. [109] conducted a research on that instance, evaluating the effects of electrical stimulation on neural delay in Bell's palsy 3.7 years after the onset of symptoms. Including Targan's research, nearly all studies failed to demonstrate a statistically significant difference in favor of treatment with electrical stimulation coupled with exercise, according to the Cochrane systematic review by Teixeira[53] and the Guideline systematic review by Baugh et al. [105].

Appendix F

Systematic Review Methodology

This systematic review relies on one main activity: Desktop exercises based on PRISMA - Preferred Reporting Items for Systematic review and meta-analysis.

The main systematic reviews have followed elements of the Cochrane Handbook for Systematic Reviews. They have used the preferred reporting items for the literature review and meta-analysis (PRISMA) framework to build and implement the literature search strategy. By following this framework, five stages have been included in this systematic review:

- Literature search.
- Article selection.
- Data extraction.
- Data analysis.
- Data synthesis.

Literature search

In this first stage, a search objective was created for the specific work objective to identify the appropriate search keywords based on the PICO protocol.

- **Patient Problem or Population:** What are the patient's demographics, such as age, gender and ethnicity? Or what is the problem type?
- **Intervention or Exposure:** What type of intervention is being considered? For example, is this a medication or some type of exercise?
- **Comparison or Control:** Is there a comparison treatment to be considered? The comparison may be with another medication, another form of treatment such as exercise, or no treatment at all.
- **Example Outcome Measures:** What would be the desired effect you would like to see? What effects are not wanted? Are there any side effects involved with this form of testing or treatment?

Using this PICO protocol makes it possible to attain a better focus on the search question addressed by this systematic review.

After defining the search question, the following table could be made (Table F.1), which presents a summary of the search parameters/restrictions for the systematic review.

Search Parameters	
Common	Domain specific (e.g. technology)
Scope	TRL
Example Query	Sources
Language	English
Years considered	Other sources
Geographic coverage	Excluding criteria
Target population of users	

Table F.1: Search parameters

Boolean queries were prepared to include all articles published before a specific date with titles, abstracts, or keyword expressions that can vary slightly according to the database source used. Inclusion and exclusion criteria were defined to help narrow down the search.

Article selection

All records identified were recorded in Google Sheets. The full text of the identified studies was then reviewed and assessed for eligibility. Disagreements were resolved by discussion or by consultation with a third reviewer.

Once the final list of studies was determined, the references for each included article were searched to identify additional studies that should be considered for inclusion.

A PRISMA flow diagram was created to document the selection process and reasons for article exclusions to ensure the repeatability of the search results. This included identification, screening, eligibility and inclusion of the literature:

- **Identification:** Records identified through database searching, additional records identified through other sources, and records after duplicates are removed;
- **Screening (by title and abstract):** Including the number of records screened and records excluded;
- **Eligibility:** Full-text articles assessed for eligibility and full-text articles excluded, with reasons;
- **Included:** Studies included in the qualitative synthesis.

Data Extraction

After the article selection procedures, all full-text manuscripts were reviewed, and data relevant to the study question proposed for this deliverable was extracted according to the data points defined in Table F.2.

Publication Information	Article title
	Author's name
	Authors affiliation
	Publication date
	Country of origin
Technological characteristics	Technology Readiness Level (TRL)
	Integration Framework
	Device Framework
	Approach on rehabilitation
Medical characteristics	Area of focus
	Target condition
	Type of rehabilitation
Validation characteristics	Type of validation
	Validation method
	Group size
	Validation conclusion
Outcome measures	Condition focused outcomes
	Other outcomes

Table F.2: Data Extraction Table

The results produced in this data extraction phase were organised in the form of a data table for more intuitive management of data and further ease in extracting views from data during the data analysis phase.

Data Analysis and Data Synthesis

The full text of the identified studies was then reviewed and assessed for eligibility. Disagreements were resolved by discussion or consultation with a third reviewer when required.

From the data collected, a quantitative analysis was obtained with a high-level overview of the distribution of articles along the publication dates and topics around the chosen domains.

Once the final list of studies was determined, the references for each included article could be searched to identify additional studies that should be considered for inclusion.

Conclusions

In the end, each systematic review provided a 'systematic and transparent review of the literature to better understand the strengths and weakness of the defined search topics according to PICO protocol, which stands for Population, Intervention, Comparison, Outcome. In this section, any researcher assumptions will be discussed, as well as the conclusiveness of the data, strengths, weaknesses and limitations of the systematic review and gaps in the current literature.

Appendix G

Comparative table between Needs and User Stories

	User			User Stories									
Need	P	CG	HCP	US1	US2	US3	US4	US5	US6	US7	US8	US9	US10
N1													
N2													
N3													
N4													
N5													
N6													
N7													
N8													
N9													
N10													
N11													
N12													
N13													
N14													
N15													
N16													
N17													
N18													
N19													

Table G.1 continued from previous page

	User			User Stories									
N20													
N21													
N22													
N23													
N24													
N25													
N26													
N27													
N28													
N29													
N30													
N31													
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N36													
N37													
N38													
N39													
N40													
N41													
N42													
N43													
N44													
N45													
N46													
N47													
N48													

Table G.1: Comparative table between Needs and User Stories

Appendix H

Use Cases

Case 1: Authentication

Description: The Authentication's Use case represents the first step while using the Facerehab solution for a Facial Paralysis treatment. The authentication system is described as security standards that ensure data protection by requiring inputs by the user, such as username, password, fingerprints and others. In the case of Facerehab, the authentication system is composed of two inputs; Username and password. Another possibility would be biometric inputs, that being facial and fingerprint recognition. All three personas (patient, therapist and caregiver) will interact with this use case since they will have access to a private profile of which the entrance depends on authentication.

Personas: Patient, Healthcare Professionals, Informal Caregiver

Cases: Login that will be satisfied by Authentication with extends to username input and password input

Scenarios: There are four steps to consummation.

1. The user accesses the main screen of Facerehab
2. Introduce a username
3. Introduce a password
4. Click the login button

Constraints: For the authentication case to be satisfied, two prerequisites should be fulfilled: the presence of a working network with a connection to the internet and the initial creation of a profile in Facerehab's system.

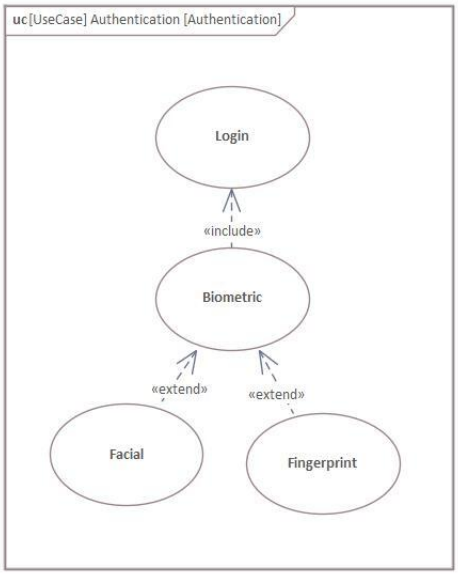

Figure H.1: Use Cases: Authentication

Case 2: Rehabilitation Program

Description: The Rehabilitation Program represents the possible scenarios between the system under discussion and all three actor's actions during the facial paralysis treatment. It shows the path of actions through Facerehab's features and the interactions of personas. All three personas (patient, therapist and caregiver) will interact with this use case since they will interact with the rehabilitation program.

Constraints: For the whole rehabilitation program case to be satisfied, one set should be present: A camera connected in order to start visual acquisition of the patient and a working network with a connection to the internet.

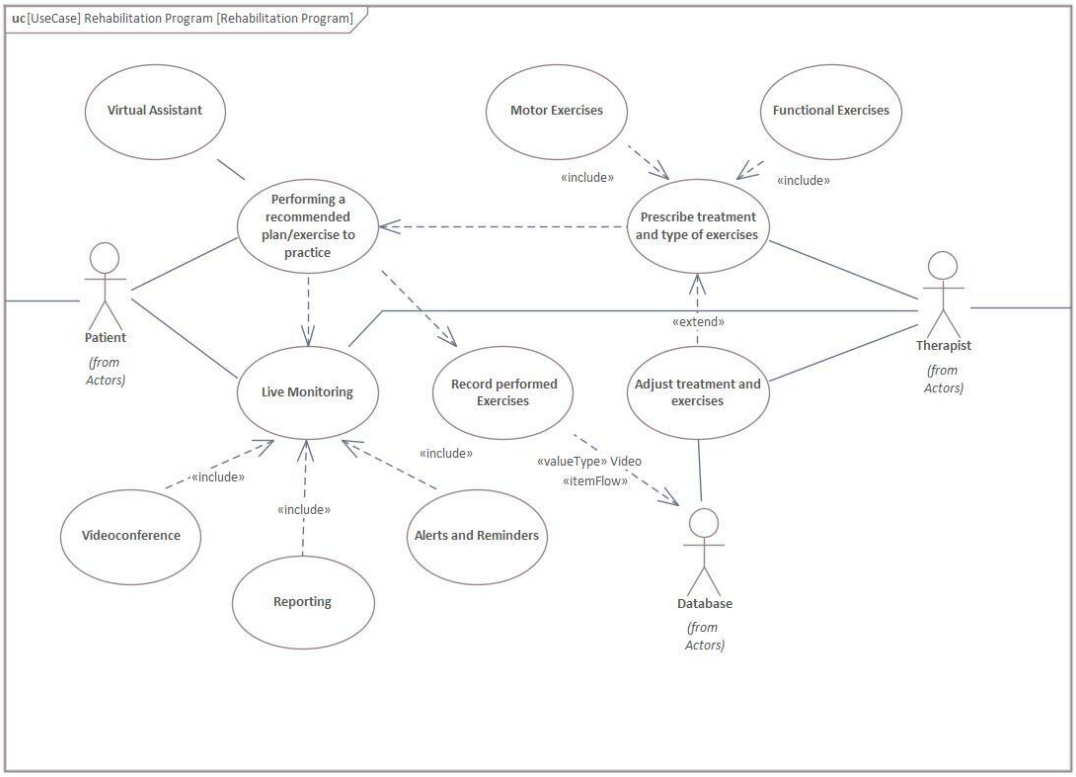

Figure H.2: Use Cases: Rehabilitation Program

Case 2.1: Performing a recommended plan/exercise to practice

Personas: Patient

Case Description: The patient takes action to perform the exercises prescribed independently. This action utilises a Virtual Assistant as an interactive program to improve the execution of the movements.

Prerequisites: This case depends on the previous prescription of treatment and type of exercises by the healthcare professional. (Case 2.7)

Dependency: Only by performing the exercises is it possible to utilise the "Live monitoring" features (Case 2.2) and record the sessions. (Case 2.6)

Scenarios: There are five steps included on the basic path:

1. Patient access the planned session
2. The patient will see an option to select the FaceRehab virtual assistant for guiding.
3. FaceRehab starts visual acquisition of the patient.
4. FaceRehab tracks key point in the face and compare to the expected exercise pattern
5. FaceRehab follows the execution of exercises during the session mimicking the patient's facial expressions on the virtual assistant face

Besides that, there is an alternative path:

1. The patient will see an option to select the video of him/herself performing the exercise (i.e. video stream mirroring the facial expressions)
2. The virtual assistant is shown in an overlay in a smaller format to still guide and motivate the patient at the bottom corner of the screen

Case 2.2: Live Monitoring

Personas: Patient. Healthcare Professional

Case Description: Being capable of simultaneously following the patient's execution of the planned session. That is, it represents the interaction of both personas, where the therapist assists the patient through videoconferencing and reporting exercises and alerts to achieve a greater telerehabilitation result.

Prerequisites: This case depends on the previous performance of the exercises by the patient (Case 2.1)

Dependency: The live monitoring case includes three other cases; videoconferencing (Case 2.3), where patients connect live with the therapist; reporting (Case 2.4), where the therapist generates a report about the patient's progress and alerts/reminders (Case 2.5), where the system should alert the patient in case of doing wrong the exercise. Either of these three cases represents a way of simultaneously following the patient's execution of the planned session (Live monitoring).

Scenarios: There are three steps included on the basic path:

1. Therapist receives notification that patient is having problem in performing exercises
2. Therapist manually triggers option for feedback to the patient during exercise execution, either choosing to do a videoconference, provide a report on exercises or send an alert. A conjoint option is also possible
3. FaceRehab provides supervised feedback to the patient during exercise execution based on therapist indication

Case 2.3: Videoconference

Personas: Patient. Healthcare Professional

Case Description: Connection of the patient to the therapist through a video conference for the patient to clarify some doubts. The therapist makes exercise corrections, advises the patient, and sets follow-up meetings regularly.

Prerequisites: The patient can connect with the therapist regarding any prerequisites.

Dependency: Even though the videoconferences help with the interpersonal connection between the personas, the therapy and other use cases do not rely on having them. Therefore, no other matter depends on having a videoconference to be successful.

Scenarios: There are five steps included on the basic path to set a date for a videoconference:

1. The user selects the video conference option
2. Set the date for the video conference call
3. Set the Time for the video conference call
4. Save
5. The appointment is added to the prescription plan available for the proposed date

Besides that, there is the path to actually performing the call:

1. The user access the video conference option
2. A video stream of the remote side is shown
3. A video stream of him/herself is shown
4. The control buttons for the video conference are displayed for the mic on/off, the camera on/off
5. If available, show an option for share screen
6. If available, show an option for the chat window

Case 2.4: Reporting

Personas: Healthcare Professional

Case Description: After following either the patient's progression, the performance of exercises or watching the recorded session, the therapist can prepare a report to state the progressions and give the patient feedback. It is essential to mention that the treatment adjustment is not given to the patient through reports. Therefore both use cases are not connected.

Prerequisites: In order for the therapist to give the patient feedback, he/she needs previous information obtained through videoconferencing (Case 2.3) or recorded sessions (Case 2.6)

Dependency: Even though the reports are extremely helpful to the improvement of the therapy, no other case relies on the reports themselves to be performed or successful. That is since adjustments are not given to the patient through reports.

Scenarios: There are three steps included on the basic path to providing a report:

1. Therapist generates every Monday a report about the patient's progress over the previous week
2. Include information on which sessions were performed and missed according to the prescription plan
3. Include a progression indicator (e.g. amplitude of movements, results from exercises performed)

Case 2.5: Alerts and Reminders

Personas: Healthcare Professional

Case Description: Alerts and reminders are a system set up to help the patient complete the telerehabilitation program. The alerts aim to make patients aware of any changes, addition of new exercises and other updates that might become available. On the other hand, reminders have to literally remind the patient of an event such as a rehabilitation program that should be completed or a meeting with the healthcare professional.

Prerequisites: The patient can receive an alert/reminder regarding any previous use case.

Dependency: Even though the alerts and reminders are extremely helpful to notify the patient and improve the therapy program, no other use case relies on the notifications to be performed or successful.

Scenarios: There are three steps included on the basic path to Alerts for the therapist that the patient missed a session:

1. An alert/notification is sent to the therapist if a patient misses a planned session
2. A note about the missing session is added to the patient's profile
3. The event is added to the weekly report for the therapist

There is also the path to send a reminder for the patient to perform the session.

1. An alarm is set for the day planned for the prescription to be performed
2. At the planned date, the patient receives a notification that a session should be performed
3. The patient can snooze the notification if she/he is not available to perform the session
4. A new schedule is set with a new date/time as selected by the patient
5. Save

In addition, the patient could be notified of any changes in the application.

1. The therapist updates the therapy program and changes the dynamics of exercises
2. A new therapy plan is set and stored on the database
3. The patient receives a notification of the modifications.

Case 2.6: Record Performed Exercises

Personas: Patient

Case Description: Once a rehabilitation plan is set for the patient, they should be able to perform the exercises with the help of a virtual assistant. Those sessions can be recorded for the following evaluation by the therapist.

Prerequisites: This case depends on the previous performance of the exercises by the patient (Case 2.1)

Dependency: When the therapist does not assist the session through live sessions, the therapist relies on the recordings to adjust the exercise and monitor the performance. Therefore, the treatment adjustment can depend on the recording of the sessions.

Scenarios: There are four steps included on the basic path to recording a therapy session:

1. Patient click on the "Start Recording" button
2. Patient starts the telerehabilitation exercises
3. Once the exercise cycle is finished, the patient stops the recording
4. Patient agrees to send the video to the therapist, which will send immediately through Facerehab's platform

Case 2.7: Prescribe Treatment and any type of exercise

Personas: Healthcare Professional

Case Description: Once the therapist has physically analysed the patient at the clinic, a treatment plan will be prescribed to be accomplished remotely with Facerehab's solution. This treatment and exercise plan should be added to the patient profile.

Prerequisites: This case depends on the previous evaluation of the patient by the Therapist (Case 4.1)

Dependency: The success and performance of the exercises by the patient depend on the previous plan prescription by the therapist. (Case 2.1)

Scenarios: There are eight steps included on the basic path to prescribe treatment and any type of exercise

1. Select the Prescription screen
2. Create a new plan
3. Add new type of exercise from Motor Exercises list
4. Select level for the type of Motor Exercises (Alternate path for Selecting the level)
5. Add a new type of exercise from the Functional Exercise list
6. Select level for the type of Functional Exercises (Alternate path for Selecting the level)
7. Insert a list of dates when the planned prescription should be performed (like a calendar appointment)
8. Save

Case 2.8: Motor Exercises

Personas: Healthcare Professional

Case Description: The Therapist can prescribe two types of exercises included in the telerehabilitation program, motor exercises or function ones. The motor exercises are the ones that use the neuromuscular system to perform specific tasks.

Prerequisites: This case depends on the creation of a therapy plan and exercises selection by the Therapist (Case 2.7)

Case 2.9: Function Exercises

Personas: Healthcare Professional

Case Description: The Therapist can prescribe two types of exercises included in the telerehabilitation program, motor exercises or function ones. Motor exercises are regular physical activities that can improve muscle strength and boost endurance.

Prerequisites: This case depends on the creation of a therapy plan and exercises selection by the Therapist (Case 2.7)

Case 2.10: Adjust Treatment

Personas: Healthcare Professional

Case Description: Once the patient has been progressing on the treatment, the therapist is allowed to adjust the treatment to continue the improvement. That can be done by selecting new exercises or changing the frequency.

Prerequisites: This case depends on the performance of the exercises plan (Case 2.1) by the patient as well as the evolution analysis by the Therapist (Case 2.4)

Scenarios: There are eight steps included on the basic path to adjust treatment:

1. Access the Exercises selection screen
2. Select existing prescription
3. Add new type of Exercises from Motor Exercises/ Functional Exercises
4. Select level for the new exercises
5. Update the previous types of exercises from Motor Exercises or Functional Exercises
6. Unlock the next level of exercises in that category
7. Automatically lock the previous level of exercises in that category
8. Remove existing exercises from Motor Exercises or Functional Exercises

Case 3: Guidelines

Description: A guideline defines how a judgment or policy is made and intends to gather educational materials and reports. In the case of Facerehab, the guidelines aim to inform all stakeholders of the latest updates on

facial paralysis and assist practitioners in providing effective and safe services based on patients' needs, current practical evidence, and known technologies.

Constraints: For the guidelines case to be satisfied, it only needs that the platform allows material input by developers and physicians. The stakeholders can access it by connecting with a working internet connection and entering their profile on the solution.

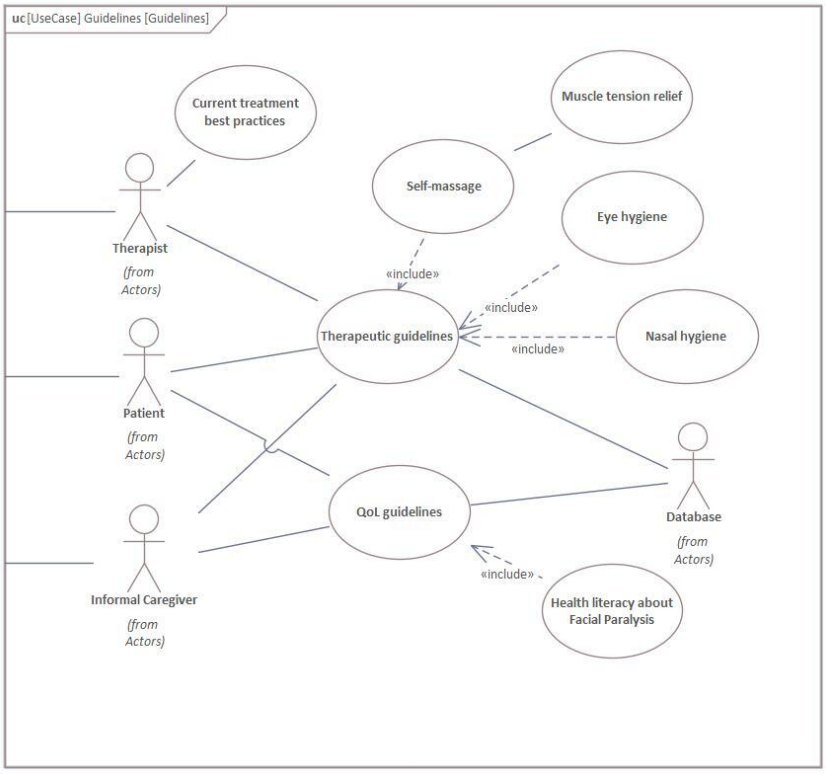

Figure H.3: Use Cases: Guidelines

Case 3.1: Current treatment best practices

Personas: Therapist

Case Description: This case defines the input of medical and educational material for healthcare professionals. It aims to keep the therapist updated on the new technologies and findings on the disease.

Prerequisites: There are no prerequisites.

Dependency: No other use cases depend on the therapist's access to the guidelines provided.

Scenarios: There are four steps included on the basic path:

1. Select the Guidelines screen
2. Select which of the material you want to access

3. You have the possibility to read it online or download the material
4. Close the guide.

Case 3.2: Therapeutic guidelines

Personas: Patient, Informal Caregiver. Therapist

Case Description: The therapeutic guidelines aim to inform the patient of his condition and alert other stakeholders of the current practices that are used in the program. In other words, it provides educational material, which can be used during his treatment to achieve a better rehabilitation result. By having a facilitated and centralised platform with access to the guidelines, the patient can better understand his treatment and follow up with the therapy. This use case includes categories of guidelines, that being:

- Self-massage: educational information on how to correctly perform the exercises.
- Eye hygiene: Information on how the patient can take care of the affected eye.
- Nasal Hygiene: Information on how the patient can perform nasal hygiene.
- Muscle tension relief: Inform the patient on how to perform movements to relieve muscle tension.

Prerequisites: This case depends on the Therapist or HCP adding the material on the platform so that the patients can access it. (case 3.1)

Dependency: The therapist can recommend reading the materials and perhaps using the information provided to guide the sessions. Therefore, the reading of the materials by the patient might influence the good performance of the rehabilitation case (Case 2)

Scenarios: There are four steps included on the basic path:

1. Select the Guidelines screen
2. Select which of the material you want to access
3. You have the possibility to read it online or download the material
4. Close the guide.

Case 3.3: QoL guidelines

Personas: Patient, Informal Caregiver

Case Description: The QoL guidelines aim to inform the patient and the informal caregivers of actions that can improve the patient's life quality. That is also done by reading in health literacy about facial paralysis, and the therapist can highlight its importance during the program.

Prerequisites: This case depends on the Therapist or HCP adding the material on the platform so that the patients can access it. (case 3.1)

Dependency: The Therapist can recommend reading the materials and perhaps using the information provided to guide the sessions. Because the information is only about the improvement of quality of life, the reading of the materials by the patient will not influence the good performance of the rehabilitation case.

Scenarios: There are four steps included on the basic path:

1. Select the Guidelines screen
2. Select which of the material you want to access
3. You have the possibility to read it online or download the material
4. Close the guide.

Case 4: Evaluation

Description: The evaluation case can be described as the moment in which the healthcare professional analyses the patient's condition and evaluate their progression. That is done in person during the first consult and from that point on can be performed digitally by either the registration of a video or photo to measure facial paralysis points according to the house-Brackmann scale.

Constraints: For the evaluation case to be satisfied, it needs the previous registration of the material on the platform by the patient. That is done automatically while patients perform the exercises. (Case 2.1) The healthcare professional should have access to it by connecting with a working internet connection and entering the "session" page on the patient profile.

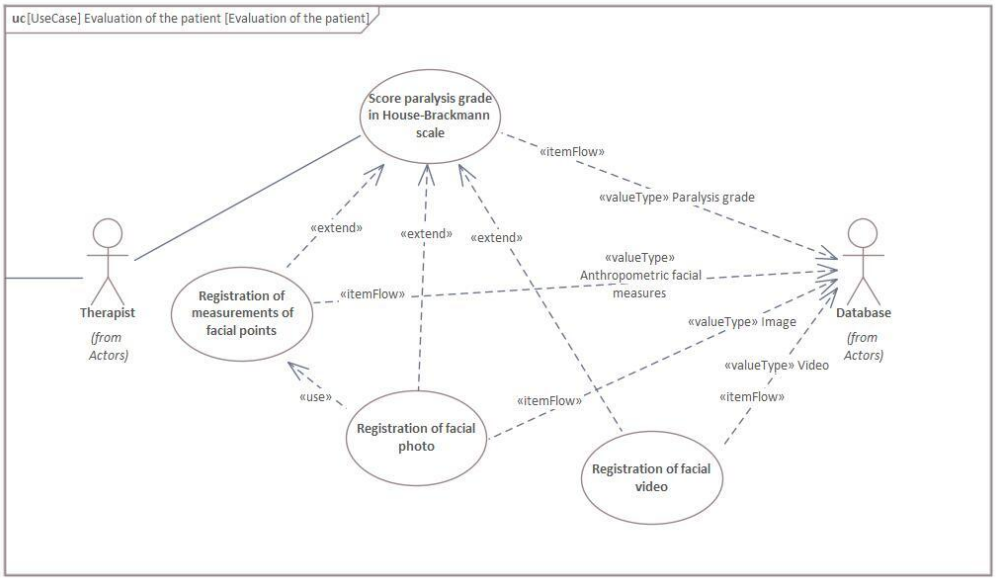

Figure H.4: Use Cases: Evaluation

Case 4.1: Registration of measurements or facial points

Description: Registration of measurements or facial points case represents the step where Facerehab's technology automatically detects the correct facial points to analyse the level of facial paralysis, according to the House-Brackmann. Later, the HCP can double-check the measurements and manually register the level of FP.

Prerequisites: For the case to be satisfied, it needs the previous registration of the material on the platform by the patient. That is done automatically while patients perform the exercises. (Case 2.1)

Personas: Healthcare Professionals and Patient

Dependency: The patient depends on the therapist's evaluation to correct the exercises that have been performed in the wrong way. (Case 4.1)

Case 4.2: Registration of facial photo and video

Description: Registration of facial photo and video case represents the step where the patient takes photos and records videos during the session for the therapist to analyse the execution of exercises and for the technology to measure facial points on the face according to the House-Brackmann.

Prerequisites: For the case to be satisfied, the patient need to input material during the execution of exercises. (Case 2.1 and case 2.6)

Personas: Healthcare Professionals and Patient

Dependency: The patient depends on the therapist's evaluation to correct the exercises that have been performed in the wrong way. (Case 4.1)

Appendix I

Clinical Usability Questionnaire

Table I.1: Clinical Usability Questionnaire

Clinical Usability Questionnaire - Patient	
Questions	**Score**
The information provided is sufficient and adequate.	1 2 3 4 5 6 7
The information provided is in clear and simple language.	1 2 3 4 5 6 7
The information provided facilitates the use of the device.	1 2 3 4 5 6 7
The information provided is confusing and unnecessary.	1 2 3 4 5 6 7
The information provided is not appropriate for the purpose of the device.	1 2 3 4 5 6 7
The information provided is incomplete and missing important points for using the device.	1 2 3 4 5 6 7
Using the device is intuitive.	1 2 3 4 5 6 7
The audio instructions are useful.	1 2 3 4 5 6 7
Captions are helpful.	1 2 3 4 5 6 7
The use of audio-only instructions is preferred.	1 2 3 4 5 6 7
The use of instructions in caption form only is preferred.	1 2 3 4 5 6 7
The use of instructions in both forms (captions and audio) is preferred.	1 2 3 4 5 6 7
The size of the monitor is adequate.	1 2 3 4 5 6 7
The avatar image is pleasing.	1 2 3 4 5 6 7
Using the avatar helps my recovery.	1 2 3 4 5 6 7
The use of the avatar is advantageous for the clinical purpose.	1 2 3 4 5 6 7
Using avatar is preferable to conventional therapy (mirror exercises).	1 2 3 4 5 6 7
Using avatar completely replaces conventional therapy.	1 2 3 4 5 6 7
The use of avatar complements conventional therapy.	1 2 3 4 5 6 7
I miss professional accompaniment during the therapy session.	1 2 3 4 5 6 7
With the use of this device, I can easily do therapy at home.	1 2 3 4 5 6 7
Using the avatar allows me to have insight into my difficulties.	1 2 3 4 5 6 7
Using the avatar allows me to be aware of my improvements.	1 2 3 4 5 6 7
The use of the device facilitates my recovery process.	1 2 3 4 5 6 7

Table I.2: Clinical Usability Questionnaire

Clinical Usability Questionnaire - Therapist	
Questions	**Score**
The information provided is sufficient and adequate.	1 2 3 4 5 6 7
The information provided is in clear and simple language.	1 2 3 4 5 6 7
The information provided facilitates the use of the device.	1 2 3 4 5 6 7
The information provided is confusing and unnecessary.	1 2 3 4 5 6 7
The information provided is not appropriate for the purpose of the device.	1 2 3 4 5 6 7
The information provided is incomplete and missing essential points for using the device.	1 2 3 4 5 6 7
The device is intuitive to use.	1 2 3 4 5 6 7
The device is simple to use.	1 2 3 4 5 6 7
Passing information between device components is easy.	1 2 3 4 5 6 7
The use of the avatar is advantageous for the clinical purpose.	1 2 3 4 5 6 7
The use of avatar is preferable to conventional therapy (mirror exercises).	1 2 3 4 5 6 7
The use of avatar completely replaces conventional therapy.	1 2 3 4 5 6 7
The use of avatar complements conventional therapy.	1 2 3 4 5 6 7
The patient's medical record is easily accessible.	1 2 3 4 5 6 7
The metrics acquired by the device are useful.	1 2 3 4 5 6 7
The metrics acquired by the device are reliable.	1 2 3 4 5 6 7
The metrics acquired by the device are sufficient.	1 2 3 4 5 6 7
It is easy to schedule an appointment.	1 2 3 4 5 6 7
It is easy to prescribe an exercise set to the patient.	1 2 3 4 5 6 7
It is easy to send the information to the patient.	1 2 3 4 5 6 7
Using the device helps me to define the patient's level of facial paralysis.	1 2 3 4 5 6 7
Using the device helps me track the patient's progress.	1 2 3 4 5 6 7
The quality of the images acquired by the device is good.	1 2 3 4 5 6 7
Using the device makes my job easier.	1 2 3 4 5 6 7

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