Expertise
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User Interface Design and Development Process for Cyber Therapy Device

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PREFACE

I want to thank Metropolia University of Applied Sciences for giving me the opportunity to upgrade my knowledge and allowing me to do this thesis, which offered me a challenge I was looking for. Special thanks to Principal Lecturer Mikael Soini for supervising this thesis, but also offering excellent guidance and support throughout the whole process of writing this thesis.

Espoo, 2 December 2020

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Based on projections of the world's population, more efficient healthcare services are needed in the future. Telemedicine has shown potential, but there are a limited number of applications available. That could create business opportunities in near future.

The challenge in telemedicine application is that it is classified as a medical device, which is obligated by legislation for demonstration of being safe to use. It can be considered that a medical device with good usability is safe to use. UI and usability has a strong connection. Hence the design and development of UI is important for telemedicine applications.

To be able to present and demonstrate a design and development process, a cyber therapy device was used as an example and the first design cycle was performed for the UI. Focus in this thesis was to study the legislation of the EU for a medical device UI point of view. Also harmonised ISO standards relevant to medical device UI was studied. In addition to legislation and harmonised standards, health conditions requiring hand rehabilitation and existing hand rehabilitation devices was studied and presented in this thesis.

First design cycle for a UI of a cyber therapy device was performed according to harmonised standards EN ISO 14971:2007 and IEC 62366-1:2015. Hence a design and development process for a UI of a medical device in accordance with regulation (EU) 2017/745 was formed and presented in this thesis. It was found during the study that user research is the most important task to perform during the development of a medical device, since the user has a strong impact on how a medical device is safely being used. Users with different backgrounds have different ways to experience a UI.

Keywords	Telemedicine, Medical Device Regulation, Medical Device, User Interface, Design and Development Process, Usability Engineering, Risk Management, Hand Rehabilitation

Contents

List of Abbreviations

AR	Augmented Reality
CEN	Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
EU	European Union
ETSI	European Telecommunications Standards Institute
FAST	Functional Analysis System Technique
FMEA	Failure Mode and Effects Analysis
FTA	Fault Tree Analysis
HACCP	Hazard Analysis and Critical Control Point
HAZOP	Hazard and Operability Study
IoT	Internet of Things
IPR	Intellectual Property Rights
ISO	International Organization for Standardization
NASA	National Aeronautics and Space Administration
PHA	Preliminary Hazard Analysis
RA	Rheumatoid Arthritis
SSa	Systemic Sclerosis
UI	User Interface
UN	United Nations
UX	User Experience
VR	Virtual Reality
WBAN	Wireless Body Area Network

1 Introduction

Convincing someone of the viability of a new business model is quite challenging so to speak. A visionary business model with balanced cost structure and promising revenue stream is a good starting point. However having a product which is regulated by legislation, for example a medical device, creation of a business model becomes even more challenging not to mention convincing someone with it. One of the challenges is related to the market area. It is crucial to adopt the legislation of the desired market area and to understand how regulations are affecting organisations like medical device manufacturers. How processes, resources, partners, vendors and customers for example are affected by legislation and what are responsibilities of an organisation. This thesis presents one of the processes regulated by the legislation. More precisely a part of a usability engineering and risk management processes, which are the foundation of a design and development process of a user interface (UI) of a medical device.

The study in this thesis is inspired by a potential business opportunity that exists even today or near future in telemedicine. Based on projections of the world's population, more efficient healthcare services are needed in the future. Telemedicine is a strong candidate to answer the predicted problem since data networks and mobile devices are commonly used today and are part of infrastructure throughout the world. There are existing applications and studies from rural areas around the world that have found telemedicine to be promising and even practical technology. The challenge in telemedicine application is to make it usable in a way that it can be considered equal or even better than traditional healthcare service. The usability in terms of a medical device is about the safety of the use of a medical device and it is required by the legislation to be proven by a manufacturer of a medical device.

The objective of this thesis is to study design and development of UI of a medical device from a legislative and methodological point of view. How legislation affects the design and development process and what are the most important methods to choose for the design and development of UI of a medical device. The goal of this study is to find out how the design and development process for medical devices look like in order

to meet requirements of legislation. How the user research should be done, how to evaluate and manage risks and how to form a conceptual model of UI.

Study in this thesis is focusing on the legislation of a medical device required by the European Union (EU) and a design and development process of a UI of a medical device that is corresponding to the legislation of the EU. Harmonised standards are European standards that are corresponding with the legislation of the EU and can be used to prove the compliance of the legislation. These harmonised standards from International Organization for Standardization (ISO) are relevant to the design and development process of a UI of a medical device and will be studied and presented in this thesis. Also health conditions related to hand rehabilitation and existing studies of hand rehabilitation devices will be studied and presented in this thesis. To demonstrate a design and development process, the first repetition of an iteration of a design and development of a cyber therapy hand rehabilitation device will be presented.

The thesis is divided into following sections. Sections are Materials and Methods, Current State Analysis, Theoretical Background, Design and Development Process, Discussion and Conclusions. The Materials and Methods section presents databases that have been used in this thesis for the search of literature, research papers, legislation and standards. The Current State Analysis section presents the background of the research problem in more detail. The Theoretical Background section presents the theory on which the research in this thesis is based on. The Design and Development Process section presents the actual outcome of this thesis which is a demonstration of the first repetition of an iteration of a design and development of a UI of a cyber therapy hand rehabilitation device. The final section presents discussion and conclusions of the research.

2 Materials and Methods

Scope of the study presented in this thesis is on the legislation of the EU of a medical device and harmonised ISO standards related to the design and development process of a medical device. Also research papers related to telemedicine, hand rehabilitation and existing studies of hand rehabilitation devices are on the scope of this study. All the materials used for this study are published in the English language.

Databases used for search of legislation of the EU and harmonised ISO standards:

- EUR-Lex
- SFS Online

EUR-Lex is a database for EU Law and SFS Online is a database of Finnish Standard Association. Also web pages of ISO and the EU were used to verify definitions.

Databases used for search of articles of telemedicine, hand rehabilitation and hand rehabilitation devices:

- Cinahl Complete EBSCOhost
- IEEE Xplore
- IntechOpen
- PubMed
- ScienceDirect

Cinahl Complete EBSCOhost, IEEE Xplore, IntechOpen, PubMed and ScienceDirect are digital libraries of published research papers relevant to scientific, technological, economical and medical research.

Library databases used for search of books of telemedicine, hand rehabilitation and hand rehabilitation devices:

- ProQuest Ebook Central
- MetCat Finna
- O'Reilly Safari Online
- SpringerLink

ProQuest Ebook Central, O'Reilly Safari Online and SpringerLink are digital libraries. MetCat Finna is a library database of Metropolia University of Applied Sciences.

3 Current State Analysis

A research problem presented briefly in the introduction will be opened up here with more details. This section discusses the development of the world population and the probable effect it has on healthcare services and a possible transformation in healthcare services that might come along.

World Population Prospects for the Next Thirty Years

According to the United Nations (UN) in publication *World Population Prospects for 2019*, it is estimated that the population of the world will grow to 9.7 billion people in 2050 from 7.7 billion people that it was in 2019. The growth is not equally divided into all areas of the world. Sub-Saharan Africa for example is estimated to double its population by 2050 while Europe and Northern America are estimated to grow only two percent. Fertility rate globally in 2019 is 2.5 births per woman and it is estimated to decline 2.2 births per woman in 2050. In 2019 half of the population of the world were living in an area where fertility rate is 2.1 births per woman while at the same time sub-Saharan Africa had fertility rate of 4.6 births per woman. Fertility rates are decreasing by 2050 in areas where they are now above average and remaining the same level in areas which are having fertility rates closer to average. Average age is estimated to increase from 72.6 years to 77.1 years by 2050 [1].

It is estimated that every sixth of people in the world are 65 years and those who reach an age of 80 years and above are expected to triple in 2050. In 2018 there were more people of 65 years old and over than people of five years old and under. A support ratio of people aged 25-64 years compared to people over 65 years is going down around the world. In Japan this ratio is 1.8, which is the lowest in the world. By 2050 Europe, Northern America and Asia are expected to have a support ratio below two. Obviously scenarios like this will put pressure on public systems like healthcare, hence new ways to produce healthcare services are needed. It is clear that more is needed than only one solution that will solve the predicted healthcare problem. Most likely many solutions will be needed and one of the many could be telemedicine [1].

Telemedicine

Telemedicine is a healthcare service provided over the network and it is used traditionally in situations where parties of healthcare service are located at far distances over each other. Hence it seems logical that roots of telemedicine are in National Aeronautics and Space Administration's (NASA) space program in the 1960's [2]. Later telemedicine became part of the solution of healthcare service problems in rural areas around the world. Telemedicine could be used for example between two hospitals, utilised from home or from an ambulance. Distance however is not a requirement for the telemedicine, it could also be useful between different units in a hospital. Infrastructure of data networks and devices capable of using them today are offering an ideal platform to utilise more and develop new applications for telemedicine. There are already some applications used in telemedicine that are successful. Telemedicine is utilised for example in eye care [3], heart monitoring [4], diabetes [5], mental health [6], cancer care [7] and rehabilitation therapy [8].

There are already existing technologies being used widely that could be useful in telemedicine, for example wearable technologies that use the Internet of Things (IoT). Rehabilitation therapy is one of the areas of telemedicine that is potentially benefiting for current developments of wearable sensors such as accelerometers and inertial measurement units, which are widely used and they are used to measure motion and performance. Since they are widely used, the development is rapid, because of the business opportunities. There are already new wearables waiting to be utilised, for example body sensor networks like Wireless Body Area Network (WBAN) [9].

Virtual Reality (VR) and Augmented Reality (AR) are also interesting technologies that have the potential to be utilized in rehabilitation therapy and telemedicine. AR headsets such as former Google Glass or Microsoft's HoloLens have already a few applications that are used by some companies. There are studies of positive rehabilitation outcomes from gaming and VR environments in rehabilitation, but those are yet with limited evidence of long term efficiency [9].

Challenges in Telemedicine

Despite the great expectations and opportunities in telemedicine, there are also challenges. Attitudes towards something new tend to always be resistive and telemedicine does not make an exception for that. Quality of telemedicine compared to traditional health care is of great concern not to forget privacy and security issues. Privacy issues are important though, especially who will see the data produced by telemedicine applications and how it will be used. Data has economic value nowadays from a commercial point of view.

The use of telemedicine application is either completely unilateral or bilateral via data network. Even with bilateral use of telemedicine applications, the user is physically alone in the location. It is essential to take that into account during the design process of the application. Research paper *Wearable technologies for active living and rehabilitation: Current research challenges and future opportunities* from 2017 suggest that human centered design is the right approach to take when telemedicine application is under development, especially those applications utilising wearable technologies. According to the paper challenge is the diverse range of user capabilities, motivations, and desired outcomes that need to be taken into consideration. There is a need for stronger human centered design approaches, developing interactive systems by focusing on user needs and requirements and applying best practices in usability and ergonomics [9].

4 Theoretical Background

This section introduces the theoretical background of subject matters needed to process this study from a medical device point of view. Those subject matters are legislation of the EU, harmonised standards related to the design and development process, conceptual design, hand rehabilitation and previous studies of hand rehabilitation devices and telemedicine.

4.1 Legislation of European Union

The rule of the EU is based on the law. The EU law is divided into primary legislation and secondary legislation. The primary legislation includes treaties which are binding agreements between the member countries of the EU. All the actions taken by the EU commission including the proposition of a new law needs to be cited as a policy area in the treaty. If the policy area does not exist in the treaty it is not possible to propose a new law. It is possible for the EU institution to adopt legislation under the treaty which is later implemented by the EU member countries. The Treaty of Lisbon is for example a treaty of the EU [10].

The secondary legislation includes regulations, directives, decisions and other acts of the EU. These are either binding or non-binding. The regulations of the EU are legislative acts that must be applied across the EU by its member countries. The regulations are binding acts of legislation that are needed to be applied in its entirety. The directives are legislative acts of the EU which are used to set goals for member countries which must be achieved, but each of the member countries are allowed to apply their own legislation in order to achieve the goals of the directives. The decisions of the EU are legal acts that are addressed to specific instances for example to a member country, an organisation or a company. They are binding only those for whom they are addressed. The recommendations are legal acts that are not binding anyone. They are aimed to improve certain issues by allowing institutions to suggest their own action to be taken without binding anyone else for whom the recommendations are addressed for. The opinions are non-binding instruments that allow institutions to make

statements that are not causing any legal obligations to anyone for whom the statements are addressed for [10].

4.2 Medical Device Regulation of European Union

Medical devices are regulated in the EU by regulation (EU) 2017/745 except for those medical devices that are excluded by the very same regulation. As a regulation of the EU it is a binding act of legislation that must be applied by its entirety. Hence it is essential to get familiar with regulation (EU) 2017/745 when starting the design and development project of a medical device, which is aimed for the market area of the EU [11].

The regulation (EU) 2017/745 sets rules about placing and making a medical device available on the market, putting medical devices into service, accessories for medical devices and clinical investigations for medical devices and their accessories. The regulation applies both for medical devices with intended medical purpose and for medical devices which have no intended medical purpose such as contact lenses for example. The regulation also applies to clinical investigations for medical devices and their accessories. The regulation oblicates medical devices both intended medical and non-medical purposes to fulfil applicable requirements of the regulation. The regulation does not apply to products that are covered in other regulation, specified in the EU directive or are excluded by the regulation (EU) 2017/745 [11].

In order to comply with the regulation (EU) 2017/745 it is needed to fulfill its requirements. For a medical device under development it is required to define intended use of a medical device and to decide which class it belongs to. It is required to define if the product is a medical device, the intended purpose and users of the medical device and classification logic to the medical device. It is required to establish processes and resources for design and manufacturing, risk management, clinical evaluation, development and maintenance of technical documentation, quality management system, post market surveillance planning, labeling development with language translations, corrective and recall, vigilance including reporting of serious incidents field safety corrective actions, regulatory authority interaction, legal liability

and damage compensation, one or more persons overseeing the regulatory compliance, access to technical, safety, clinical, quality and regulatory expertise [11].

For design and development of a medical device articles and annexes listed below are important. For intended use and classification:

- Article 2(1) definition of medical device
- Article 51 and annex VIII classification
- Article 6 devices via internet to EU citizens

It is defined in article 2(1) what a medical device. Classification of medical devices is defined in article 51 and annex VIII. Medical devices offered to EU citizens via the internet are defined in article 6. For processes needed to establish:

- Article 10,1 Design and manufacturing processes
- Article 10,2 Risk management process
- Article 10,3 Clinical evaluation process
- Article 10, 4-8 Technical documentation process
- Article 10,9 Quality management system

Article 10 defines requirements for design, manufacturing, risk management, clinical evaluation, technical documentation and quality management processes. For safety, performance and clinical requirements:

- Article 5,2 and annex I General safety and performance requirements
- Article 5,3 All devices are required to fulfill clinical requirements
- Article 61 and annex XIV part A clinical requirements

Article 5 and 61 with annexes I and XIV defines requirements for general safety of a medical device and clinical requirements a medical device is required to fulfil [11].

4.3 European Standards

A standard is a tool that can be used in a process for manufacturing, managing, delivering or supplying something in order to achieve a repeatable way of doing it. A standard is a technical document that defines requirements for products, processes, services and test methods. A standard is created by the parties acting on the field the standard is created for. The goal of a standard is to ensure interoperability and safety, reduce cost of process and facilitate integration in the value chain and trade. A standard is not an act of legislation and the use of a standard is always voluntary. A standard is typically identified with reference code, for example European Standards have reference code containing letters EN [12].

The Commission of EU uses standardization to make European policies more efficient. The main goal of the standardization in the EU is to affect areas such as trade, the EU Single Market, environment, health, innovation and Intellectual Property Rights (IPR). The main tool for the Commission of the EU are Harmonized Standards. The goal of a Harmonized Standards is to provide a solution for compliance with legal provision in other words to demonstrate that products and services comply with relevant EU legislation. Harmonized standards are developed and maintained by three recognized European Standardisation Organisations by the request of the European Commission. The three recognized European Standardisation Organisations are European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and European Telecommunications Standards Institute (ETSI). The references of harmonized standards are published in the Official Journal of the EU in order to provide access to the latest references of harmonized standards [13].

Standards for medical devices like EN ISO 14971:2012 Application of Risk Management to Medical Devices, EN ISO 13485:2016 Quality Management Systems and EN 62366-1:2015 Application of Usability Engineering to Medical Devices are all harmonized European Standards [14].

4.4 Harmonised Standards

ISO 14971:2007

For manufacturers of a medical device there is an applicable international standard for a risk management process which is in line with the regulation of the EU. The standard is ISO 14971 which defines terminology, principles and the risk management process of a medical device. The risk management process described in this standard is for risks associated with medical devices including software and in vitro diagnostic. The risks described in this standard are related to biocompatibility, data and systems security, electricity, moving parts, radiation and usability. The standard is also suitable for products that are not necessarily defined as a medical device in all aspects of the legislation. The standard does not apply to business risk management or a medical device associated with clinical procedures. The standard does not specify accepted risk levels of any risks involved with a medical device [15].

ISO 13485:2016

From a design and development point of view there is an international standard for quality management systems for organisations that are involved with a life-cycle of medical devices. Standard ISO 13485 specifies requirements for a quality management system for a medical device life-cycle processes including design and development, production, storage and distribution, installation and servicing. It also specifies requirements for final decommissioning and disposal of medical devices, design and development or provision of associated activities for example technical support. The standard can also be used by suppliers or other external parties involved with medical device life-cycle processes. Adaptation of the standard is voluntary or the adaptation of the standard can be required by a contract. For a role in a supply chain of a medical device life-cycle processes the standard expects that organisation identifies its role, regulatory requirements applicable to activities under this role and regulatory requirements applicable by that role are incorporated in the quality management system of an organisation [16].

ISO 13485:2016 is a stand-alone standard which is based on ISO 9001:2015. ISO 9001 is a general standard for a quality management system. It can be certified for organisations regardless of size or field of business [17]. Correspondence between standards from design and development point of view are presented in the table 1. Regulation (EU) 2017/745 requires organisations to establish quality management processes [16].

Table 1. Correspondence between standard ISO 13485:2016 and ISO 9001:2015 [16].

Clause in ISO 13485:2016	**Clause in ISO 9001:2015**
7.3 Design and development	8.3 Design and development of products and services
7.3.1 General	8.3.1 General
7.3.2 Design and development planning	8.3.2 Design and development planning
7.3.3 Design and development inputs	8.3.3 Design and development inputs
7.3.4 Design and development outputs	8.3.5 Design and development outputs
7.3.5 Design and development review	8.3.4 Design and development controls
7.3.6 Design and development verification	8.3.4 Design and development controls
7.3.7 Design and development validation	8.3.4 Design and development controls
7.3.8 Design and development transfer	8.3.4 Design and development controls
7.3.9 Control of design and development changes	8.3.6 Design and development changes 8.5.6 Control of changes
7.3.10 Design and development files	7.5.3 Control of documented information

IEC 62366-1:2015

For a medical device usability engineering process there is a harmonic standard IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices. Technical report IEC TR 62366-2:2016 Medical devices - Part 2: Guidance on

the application of usability engineering to medical devices which gives guidance for standard IEC 62366-1.

Figure 1 presents a usability engineering process according to standard IEC 62366-1 and its relationship with risk management standard ISO 14971. Recommended way to specify a use specification in the usability engineering process gives input to the risk management process. Letters A, B, C, D, E presents how information is recommended to move between usability engineering and risk management processes. Solid lines with letters B, D and E presents how information is required to move by standard IEC 62366-1 [18].

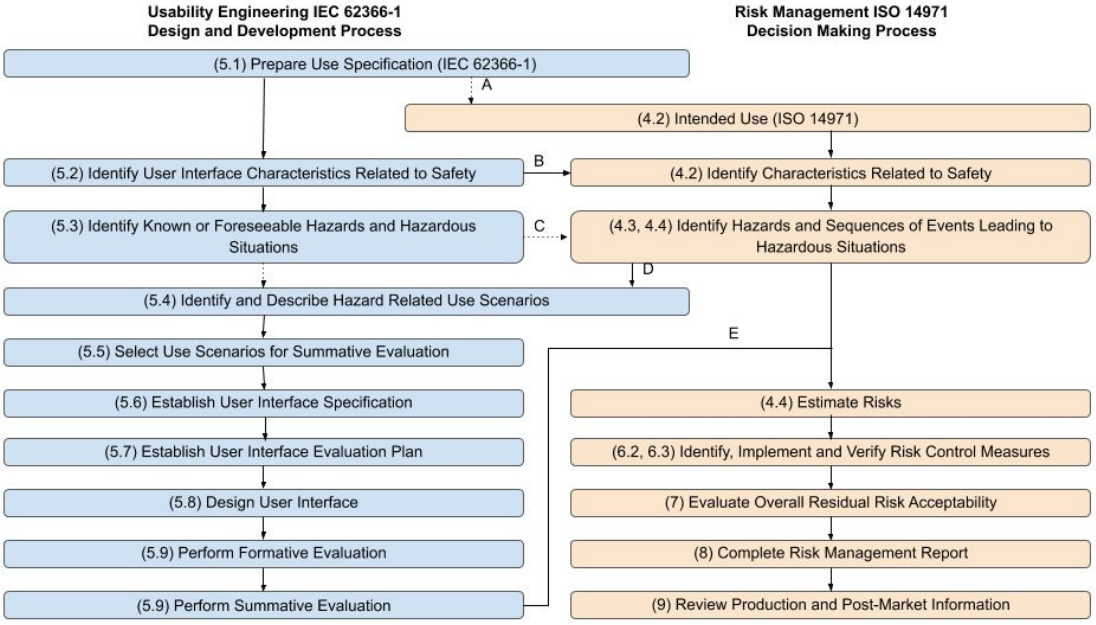


Figure 1. Relationship between usability engineering process IEC 62366-1 and risk management process ISO 14971 [18].

Usability engineering and risk management processes presented in figure 1 are for complete processes that need to be conducted in order to enter the market with a developed medical device. This thesis focuses only on the design and development process of the UI of a medical device which is presented in figure 2.

Medical device UI design and development process is presented in figure 2. It is divided into three sections according to a technical report IEC TR 62366-2. Those sections are User research, analysis and design and formative evaluation. User research section comprises specifying use specification, which includes user research, contextual inquiry and function analysis of a developed medical device. Analysis section includes risk analysis from both UI and a medical device point of view. Design and formative evaluation section includes UI specification, UI evaluation plan, design of the UI and evaluating designed UI. The design and development process of UI of the medical device is a cycle which aims to get in summative evaluation and further to the risk management process which is presented in figure 1 [19].

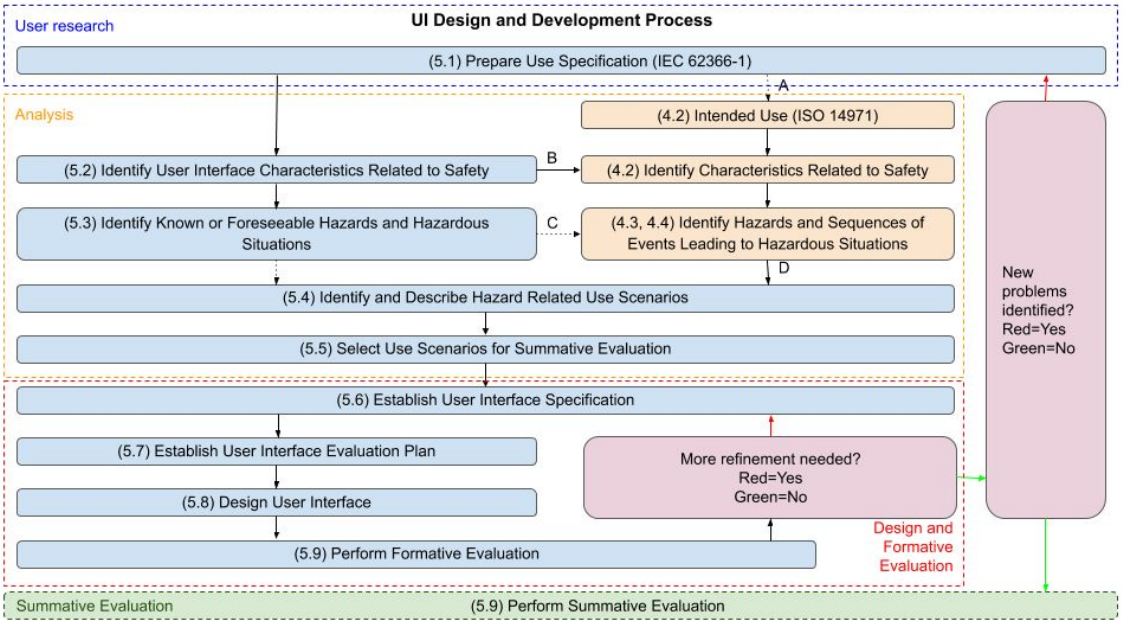


Figure 2. Medical device UI design and development process according to standards IEC 62366-1 and ISO 14971 [18].

It is presented in table 2 how to read standard IEC 62366-1 and technical report IEC TR 62366-2. Requirements and definitions are expressed with normal roman fonts. compliances with italic fonts. Notes, references, examples and other information outside of tables small fonts. For normative text on tables small fonts are used and terms which are defined in clause 3 or as noted are in small capital fonts. Asterisk references to annex A of standard IEC 62366-1. Words shall, should, may and conjunctive or as described in table 2 [19].

Table 2. Guidance to read the standard IEC 62366-1 and related technical report IEC TR 62366-2. [19].

Standard	Text in standard	Interprets
IEC 62366-1 IEC TR 62366-2	Written in "roman" font	Requirements and definitions
IEC 62366-1	Written in "*italic*" font	Compliance need to be assessed
IEC TR 62366-2	Written in "*italic*" font	Additional information about best practices
IEC 62366-1 IEC TR 62366-2	Written in "Small" font	Information outside table: notes, references, examples Normative text on table
IEC 62366-1 IEC TR 62366-2	Written in "SMALL CAPITAL" font	Terms which are defined in clause 3
IEC 62366-1	Conjunctive "or"	A statement is true if any combination of the conditions is true
IEC 62366-1	Word "shall"	Mandatory
IEC 62366-1	Word "should"	Recommended
IEC 62366-1	Word "may"	Permissible
IEC 62366-1	Asterisk (*)	Rationale provided in annex A of IEC 62366-1

4.5 Bones, Joints and Standardised Movements of Hand

The surface part of the hand covered by skin is the most visible part of the hand. The surface of the hand is divided in two parts, the palmar hand and the dorsal hand. The inner part of the hand consists of muscles, bones, joints, tendons, nerves and veins. For this study bones, joints and movement of the hand is presented in this section.

Bones of the Human Hand

The human hand consists of a total of 27 bones. Hand is divided into three parts which are carpus, metacarpus and phalanges. The bones of the human hand are presented in figure 3.

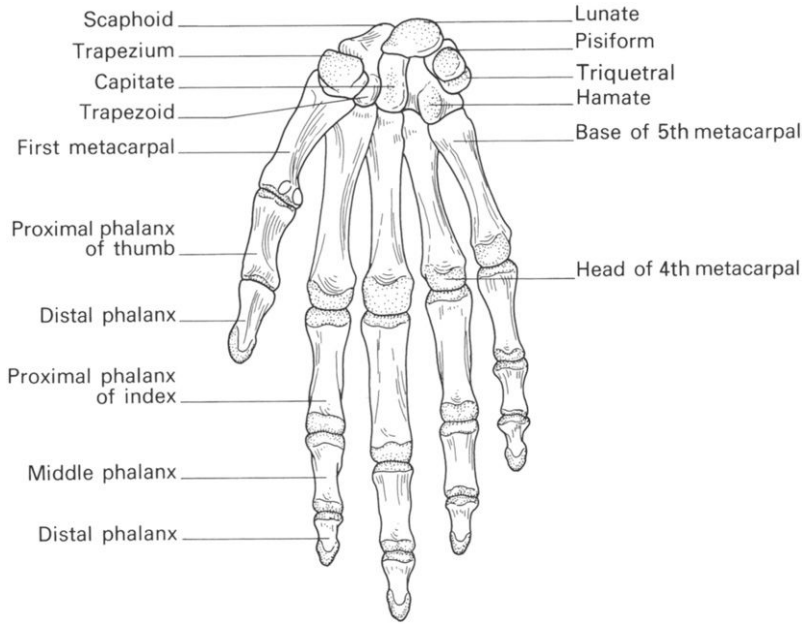


Figure 3. Bones of the human hand [20].

Bones presented in figure 6 are eight carpal bones which are Scaphoid, Trapezium, Capitate, Trapezoid, Lunate, Pisiform, Triquetral and Hamate. Five metacarpal bones starting from the first metacarpal of thumb. 14 phalanx bones which are proximal phalanx and distal phalanx of thumb, four proximal phalanges, four middle phalanges, four distal phalanges [20].

Joints of the Hand

Joints are located between the bones of the hand and are freely movable, in medical terminology they are synovial. In figure 4 joints of wrist, carpal and carpometacarpal are presented.

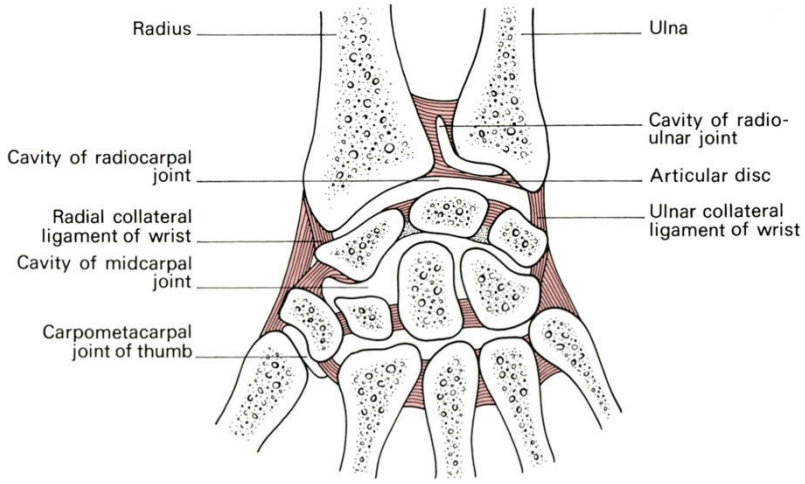


Figure 4. Wrist, carpal and carpometacarpal joint of the hand [20].

The joints between carpal bones allow gliding movement which grow the range of extension and flexion allowed at the wrist joint. Flexion and extension of a 60 degrees is possible at the metacarpophalangeal joint of the thumb. Flexion and extension of a 90 degrees is possible at the other metacarpophalangeal joints In addition to that abduction, adduction and circumduction is possible for them. The metacarpophalangeal joints of the fingers, except the thumb, prevent spreading of the palm if a firm grip is taken, but when being flexed the metacarpophalangeal joints of the fingers prevents abduction and adduction. The Interphalangeal joints are hinge joints, allowing flexion and extension only. The carpometacarpal joint located in the thumb is a unique joint. It allows movement, which is moving the tip of the thumb opposite to all other fingers. Writing with a pen for example is possible because of that. Other carpometacarpal joints allow a few degrees of gliding movement of the 2nd and 3rd metacarpals and some flexion and extension of the 4th and 5th metacarpals [20].

Movements of Hand

Knowledge of the anatomic basis for hand movement is used for a diagnosis and for locating site and level of an injury. Figure 5 presents accepted terminology used to describe movement to forearm, wrist, fingers, and thumb. These terms are used by healthcare professionals allowing better communication between each other. Diagnosing a patient and making treatment plans is easier if it is noticed that a specific movement is disabled by a patient [21].

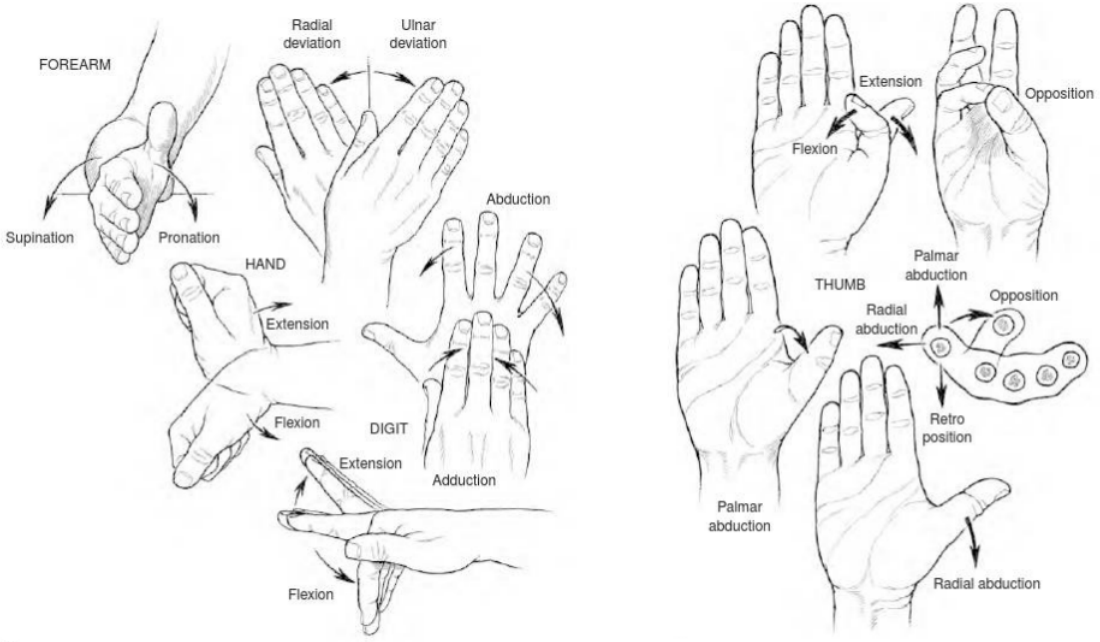


Figure 5. Terminology and movements of the forearm, wrist and fingers [21].

4.6 Disorders Requiring Hand Rehabilitation

Hand therapy as a rehabilitation method is needed when a patient suffers a condition that limits the use of a hand either partially or entirely. Such conditions typically occur due to specific disorder, injury or surgery. Hand therapy with regular exercises is needed when recovering from stroke, tendon and nerve injuries, fractures, dislocations, strains, amputations, soft tissue injuries and burns. It can also be used to ease symptoms of carpal tunnel syndrome, rheumatoid arthritis (RA) and systemic sclerosis (SSa).

Stroke

Stroke is a cardiovascular disorder and it is a major cause of disability for elderly people. Stroke is caused by an anomaly on bloodstream to a certain part of the brain. Leading to an event where brain cells start to die from lack of oxygen and nutritions. Most common types of stroke are ischemic stroke and hemorrhagic stroke. Ischemic stroke is caused by seriously reduced bloodstream by narrowed or blocked blood vessels. Hemorrhagic stroke is caused by blood vessels leaking or rupturing. Common symptom of stroke is paralysis of the other side of the body which leads to disability of the other leg or arm. Emergency procedures varying from medication and endovascular procedures to surgery are needed urgently after the stroke occurs. Rehabilitation is needed to recover from stroke. Stroke is more common in men [22].

Rehabilitation exercises for post stroke patients are done with special equipment such as a therapeutic ball or a therapeutic putty, which are developed for exercises strengthening hand and fingers. Other common objects such as bottles, pens, coins and rubber bands, which are usually found in home could be used for rehabilitation exercises. Rehabilitation exercises for post stroke patients are for example gripping of a hand, extension of a thumb, pinching of fingers, opposition of a thumb, side squeezing of fingers, extending of fingers, spreading of fingers, pressing of a thumb, pinching of a thumb, adduction of a thumb, hooking of fingers, spreading of fingers, curling a wrist and extension of wrist. In figure 6 from left to right presents gripping of a hand using a therapeutic ball, pressing of a thumb using therapeutic putty and curling of fingers using a water bottle [23].

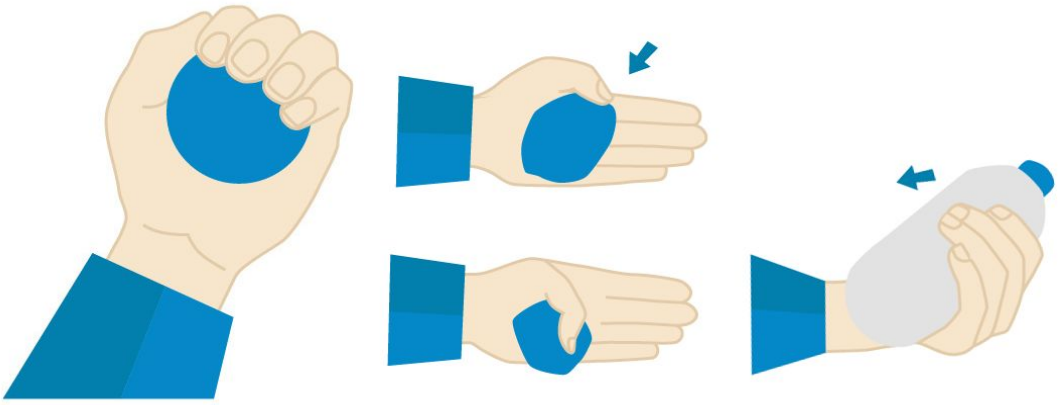


Figure 6. Example of therapeutic exercises using a therapeutic ball, a therapeutic putty and water bottle [23].

Rheumatoid Arthritis and Systemic Sclerosis

RA is a chronic inflammatory disorder which is caused when body tissues are attacked by the immune system. RA causes symptoms throughout the whole body, but synovial joints are the most affected body parts in case of RA. When affecting lining of joints, RA causes swelling in joints which may in severe cases eventually lead to deformity of joints and disability of hand. If RA occurs in the wrist, the nerve affecting the whole hand functioning might be compressed by inflammation and cause carpal tunnel syndrome. RA can occur at any age and it is more common with women. There is no known cure for RA, but regular hand therapy exercises have been known to be beneficial to maintain mobility of joints and strength of muscles [24].

SSa also known as systemic scleroderma is a disease affecting skin, fingers, toes, digestive system and internal organs like heart, lungs and kidneys. SSa is caused by overproduction of fibrous protein called collagen in tissues. That leads skin and connective tissues to harden and tighten. It might affect hand mobility depending on the size of the affected area. SSa is more common in women aged 30 to 50 years. There is no known cure for SSa. Hand therapy is used for pain management and maintenance of mobility and strength of hand [25].

4.7 Hand Rehabilitation Devices

A key for a successful hand rehabilitation session is the quality of the session. Hand rehabilitation exercises must be done on a regular basis and the exercises must be done in the right way. Hence a patient must have motivation to complete exercises regularly. A therapist has an important role supervising and guiding in rehabilitation exercises ensuring them to be done properly. A hand rehabilitation session as an telemedicine application in other words a cyber therapy session, can be done unilateral or bilateral. In a unilateral cyber therapy session a patient does rehabilitation exercises independently for example with a device equipped with sensors. The data from the sensors is saved in a server and obtained and analysed later by a therapist. In a bilateral cyber therapy session a patient is connected for example through a video conference with a therapist and sensor equipped rehabilitation device can be used in addition to that. In both unilateral and bilateral cyber therapy sessions the technological challenge is remote monitoring and guiding the cyber therapy session. In this section studies, prototypes and equipment related to those technological challenges are presented.

Remote Monitoring of Hand Rehabilitation Session

In 2013 a study of remote monitoring of 10 RA and 10 SSc patients at their rehabilitation session for a 12 weeks period was done in University of Cagliari in Italy. All the patients were attending the rehabilitation session from their home using a special device created for the study, which is presented in figure 7. The device contains six tools to execute different hand rehabilitation exercises of pinch, grip, opposition of a thumb, turning objects with finger and tapping fingers. The device is equipped with sensors to each tool to monitor execution of the movement of the hand in rehabilitation exercises. It also has a skin temperature probe to measure temperature of the hand and to determine blood flow with SSa patients in order to evaluate the effect of the rehabilitation exercise. Traditional exercises typically done at home are hard to standardise in order to achieve correct execution. This study tries to prove that the quality of rehabilitation exercises are improving when rehabilitation exercises done at home are remotely monitored with sensors [26].

Figure 7. Telerehabilitation device [26].

According to study, a twelve week clinical trial with RA and SSc patients was promising, there was improvement in condition among patients and the device was mostly prefered over traditional hand rehabilitation exercises. Studies like this proves that telemedicine is a suitable and even preferred option to organise hand rehabilitation sessions [26].

Prototypes of Hand Rehabilitation Devices

For post stroke patients there have been studies with exoskeleton prototypes. One of the prototypes is HandSOME presented in figure 8.

Figure 8. HandSOME [27].

It uses a four bar linkage to coordinate the movement of the metacarpophalangeal joints and the thumb carpometacarpal joint and elastic cords to add resistance. For some stroke patients this device was too difficult to use, but some patients achieved improved function of hand according to study [27].

HANDEXOS exoskeleton consists of five individual finger modules. Separate finger module is presented in figure 9.

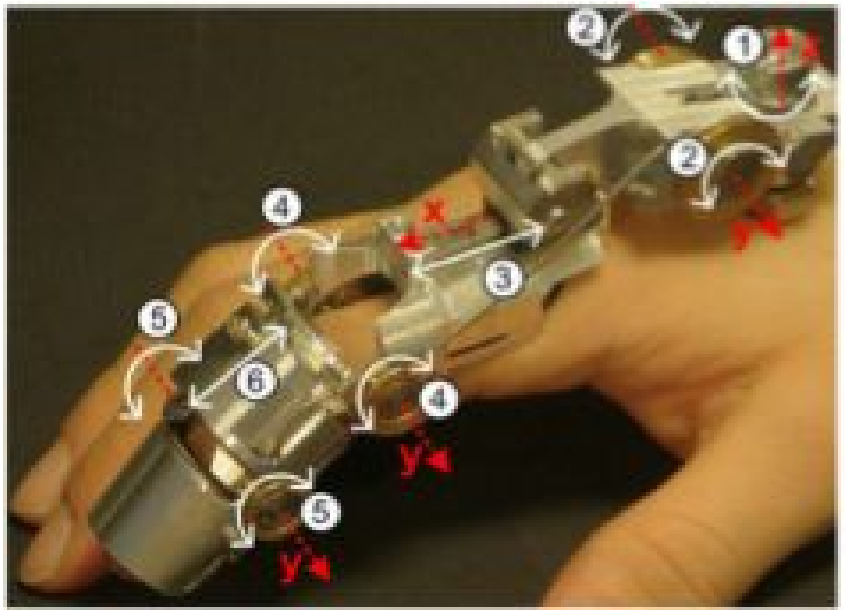


Figure 9. HANDEXOS figer module [28].

The module is a three links structure with three force sensors, each phalanx has its own sensor to monitor forces when the finger is moving during rehabilitation exercises. This study was for mechatronic design of hand rehabilitation exoskeleton and hence no patients were not involved with this study. This study gave a viewpoint for possible exoskeleton design for this thesis [28].

5 Design and Development Process

This section presents the design and development process for a UI of a medical device according to standards IEC 62366-1:2015 and ISO 14971:2007. The design and development process is demonstrated with development of an UI for a hand rehabilitation device intended for telemedicine use.

5.1 Requirements Specification

At the beginning of the design and development process of a UI, requirements should be specified. The requirement specification is devided in three sections such as technical requirements, business requirements and regulatory requirements.

Requirements specification is presented in figure 10. In the technical requirements section function and performance of a medical device is defined. In the business requirements section the business model of a medical device is defined. In the regulatory requirements section legislation, regulations and standards of selected market areas are defined. Each section is dependent on each other and requirements on one section affect the other two sections [29].

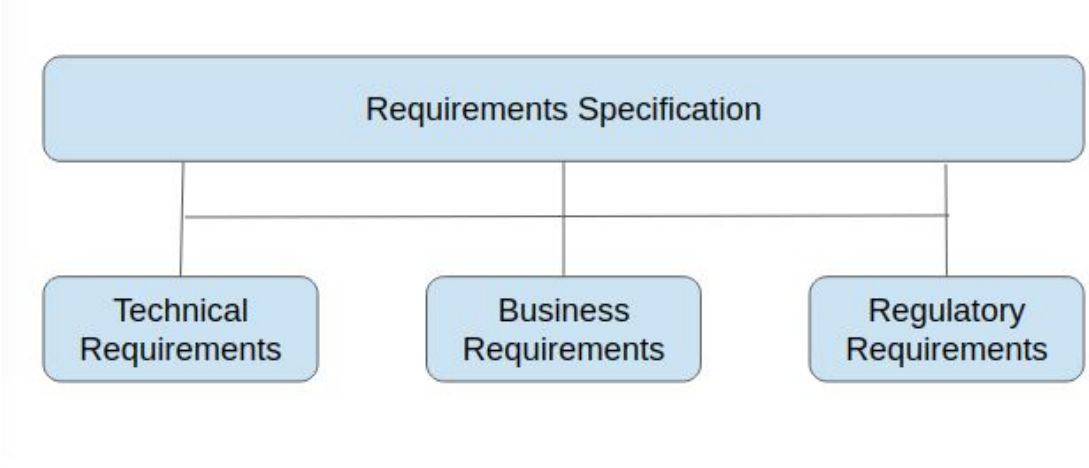


Figure 10. Requirement specification [29].

For definition of requirement specification it is needed to have a specific process. In this thesis requirements specification process is applied in a way presented in figure 11. A requirements specification process presented in figure 11 has three phases. Definition of a design and development problem and a business problem, functional analysis and regulatory requirements. Those three phases define requirement specifications for the design and development process [29].

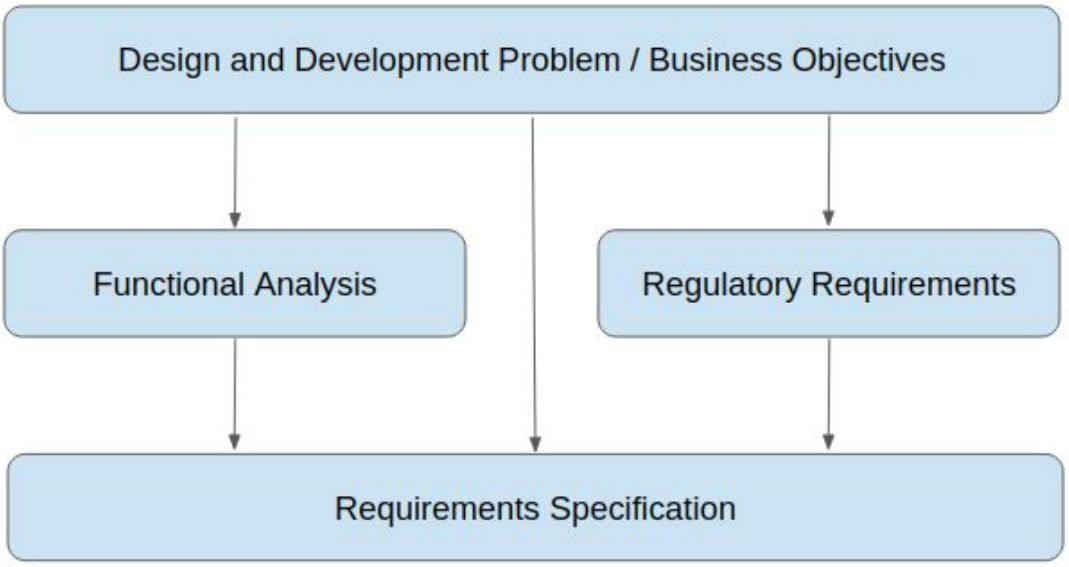


Figure 11. Requirement specification process [29].

Technical requirements are presented in table 3 from user, function, purpose, environment and usage point of view. Those requirements are obtained by recognising who is using the device, what the device is meant to do, why the device is meant to use, where the device is used and when the device is used [29].

Table 3. Preliminary technical requirements

Technical Requirements	
Users	Patients recovering stroke, rheumatoid arthritis and systemic sclerosis
Functions	Hand rehabilitation device suitable for telemedicine use, the device should guide user how to wear and start the device, how to do rehabilitation exercises and how to stop and store the device, the device should produce feedback and data of the usage for therapeutical evaluation
Purpose	To complate hand rehabilitation exercises properly
Environment	Used in patients's home environment
Usage	Used during hand rehabilitation session

Business requirements are presented in table 4 from targeted user, targeted business value, targeted market area, targeted business environment and targeted schedule point of view. Those requirements are obtained by recognising who the users are, what is the business value, what is the market area, what kind of business environment exists and what is the time required to enter the market [29].

Table 4. Business requirements

Business Requirements	
Targeted Users	Patients recovering stroke, rheumatoid arthritis and systemic sclerosis
Targeted Business Value	The use of telemedicine in hand rehabilitation has benefit to offer rehabilitation services apart from time and location. Areas suffering from shortage of healthcare professionals are beneficiaries. The use of telemedicine enables continuous rehabilitation sessions and hence better results from recovery.
Targeted Market Area	EU and EEA
Targeted Business Environment	Telemedicine in technologically point of view is in adapting stage. There is very little applications on the market, but it is also possible that it will take long period of time to become mainstream technology.
Targeted Schedule	Market approval within 10 years

Functional analysis should be done at the very beginning of the design and development process in order to get a vision for what the developed medical device looks like from the functional point of view. Functional analysis has been carried out and presented in a functional analysis system technique (FAST) diagram in figure 12.

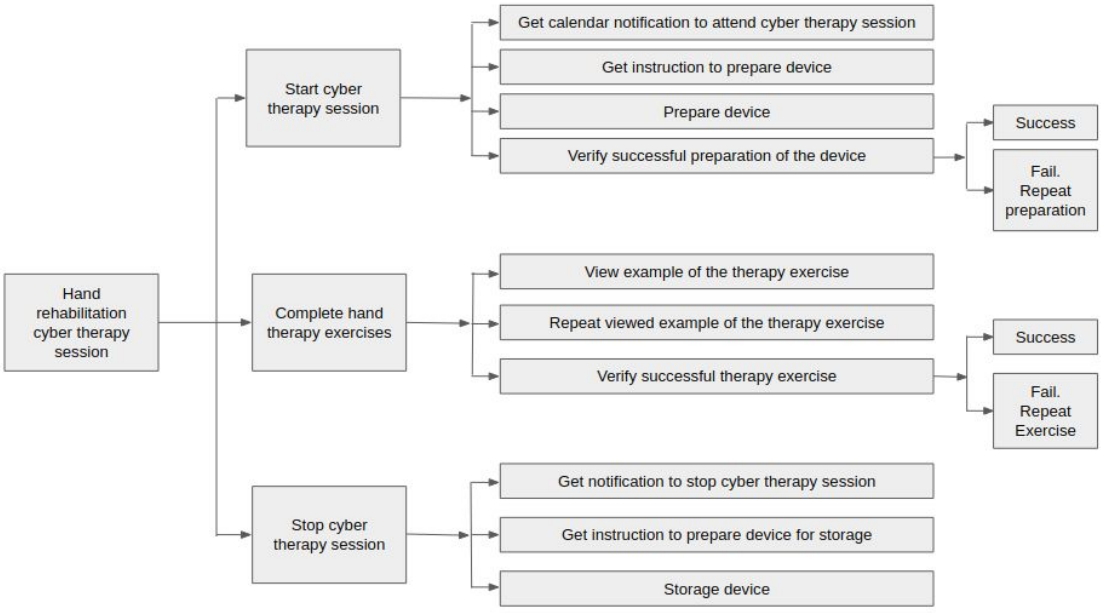


Figure 12. FAST diagram of hand rehabilitation device.

Functional analysis using FAST diagram provides layout of functions of a medical device. On this stage a medical device is not designed and it is still not clear what the medical device will look like, but there is clear vision of its functions. When results of functional analysis exist, business, technical and regulatory requirements can be reviewed before locking up requirement specification.

Regulatory requirements are presented in table 5.

Table 5. Regulatory requirements.

Regulatory Requirements	
Regulation	Regulation (EU) 2017/745
Harmonised Standards	Standard ISO 14971, Standard ISO 13485, Standard IEC 62366-1 and Technical Report IEC TR 62366-2

Regulatory requirements suggest the use of harmonised standards for design and development process [29].

5.2 Use Specification

The usability engineering process according to standard IEC 62366-1:2015 starts with preparation of use specification. That is the very first thing to do and the use specification also gives input for the risk management process according to standard ISO 14971 which is associated with standard IEC 62366-1 in this design and development process. Preparation of use specification is presented in sub clause 5.1 in standard IEC 62366-1:2015. It is said in the sub clause 5.1 that the use specification must be prepared by a manufacturer. The use specification must include an intended medical indication, intended patient population, intended part of the body which the medical device is interacted with, The use specification must also include intended user profile, use environment and operating principle of the medical device [18].

Table 6 presents a use specification of hand rehabilitation device, which is used as a demonstration in this thesis. The use specification is divided in sections device section, user section and use environment section. Use specification indicates that there are large variations in user and use environment profiles since the user is layman and can be anybody and use environment is home environment and can be anything. That will create challenges for design and development tasks.

Table 6. Use specification of hand rehabilitation device [x].

Device	
Intended Medical Indication	Telemedicine hand rehabilitation device for post-stroke, -rheumatoid arthritis and -systemic sclerosis rehabilitation of a hand.
Intended Patient Population	Age: 18-99+ Median age: 65-75+ years, gender: 50 % are female and 50 % are male.
Intended Part of Body to Interact	Skin, hand, wrist and arm below elbow
Operating Principle	Hand rehabilitation system for telemedicine use. A patient and a therapist are in different locations. Communication on-line. Exoskeleton with sensors is used to supervise and ensure correct exercise. Augmented Reality user interface is used to guide patient.

User	
Occupational description	Layman. Assumed to have no professional experince.
Demographic characteristics	Gender: 50 % are female and 50 % are male. Age range: (18-99+) years, median age: 65-75+ years.
Physical characteristics	Male and female average hand size range: 152 mm - 203 mm
Skills	Layman. Large variation in skills.
Potential impairments	People in their mid-40s and older can have a reduced ability to focus on near objects, therefore use of reading glasses is required. People at 50 years and older might have a progressive degree of hearing loss. Patients at old age might have minor short-term memory problems.
Performance shaping factors	Layman. Large variation occurs.
Learning style	Layman. Large variation occurs.

Use Environment	
Architectural	Large variation
Equipment, furniture, and supplies	Large variation of furniture, equipment and internet connections.
Personnel	Telemedicine application, available on-line.
Lighting	Typical to home environment
Noise	Typical to home environment
Climate	Temperature range is normally 18 °C to 22 °C. Relative humidity range is normally 40-60%
Potential distractions	Typical to home environment

5.3 Intended Use and Classification

Defining intended use is a starting point of the risk management process according to standard EN ISO 14971:2007. Input for the risk management process is from use specification of design and development process according to IEC 62366-1:2015. According to standard EN ISO 14971:2007 for intended use and identification of characteristics related to safety of the medical device, the risk management process must commence if a device is considered as a medical device [15]. According to medical device regulation (EU) 2017/745 in clause 2 (1) a medical device means any apparatus intended by the manufacturer to be used, alone or in combination for human beings for monitoring, treatment of an injury or disability [11]. Hence a hand rehabilitation device meets the definition of a medical device.

Table 7 presents a classification of a medical device. Rules for classification are found on the regulation (EU) 2017/745. An exoskeleton and AR device which are parts of the hand rehabilitation device are classified in table 7.

Table 7. Classification of Hand Rehabilitation Device

Classification			
Component	**Intended use**	**Rule**	**Class**
Exo-skeleton	For hand rehabilitation exercise and for monitoring execution of exercises	9	2a
AR device	For guidance to use exo-skeleton and complete rehabilitation exercises	1	1

A medical device could consist of multiple components. Intended use needs to be defined for each component individually. It is possible to combine all the components under the most demanding class that one of the components have. At this point of a design and development process it is not ideal to lock classification for the whole device, since it will affect the design choices.

5.4 Characteristics Related to Safety

According to standard EN ISO 14971:2007 in sub clause 4.2, it is required by a manufacturer to identify characteristics related to safety of the medical device. Annex C in standard EN ISO 14971:2007 presents questions that can be used to identify characteristics related to safety of the medical device [15]. Questions are not profound and it is advised to add more questions which are more specific to a medical device under development. Questions are presented on tables 8 and 9.

Table 8. Questions C.2.1 - C.2.13 to identify characteristics related to safety of the medical device.

C.2.1 What is the intended use and how is the medical device to be used?	Intended to use for hand rehabilitation. It is used as telemedicine application.
C.2.2 Is the medical device intended to be implanted?	No
C.2.3 Is the medical device intended to be in contact with the patient or other persons?	Yes, but contacting only skin.
C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with the medical device?	Plastic, rubber, fabric, stanless steel and aluminium
C.2.5 Is energy delivered to or extracted from the patient?	Yes. There is small amount of force applied to exo-skeleton in order to cause resistace
C.2.6 Are substances delivered to or extracted from the patient?	No
C.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	No
C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?	Yes. Light cleaning regularly.
C.2.10 Is the medical device intended to modify the patient environment?	No
C.2.11 Are measurements taken?	Yes. Sensors in exo-skeleton are measuring movements.
C.2.12 Is the medical device interpretative?	Yes
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	No

Table 9 presents questions C.2.14 - C.2.28 from annex C in standard EN ISO 14971:2007 [15].

Table 9. Questions C.2.14 - C.2.28 to identify characteristics related to safety of the medical device

C.2.14 Are there unwanted outputs of energy or substances?	No
C.2.15 Is the medical device susceptible to environmental influences?	No
C.2.16 Does the medical device influence the environment?	No
C.2.17 Are there essential consumables or accessories associated with the medical device?	Yes. AR device, internet connection.
C.2.18 Is maintenance or calibration necessary?	Yes
C.2.19 Does the medical device contain software?	Yes
C.2.20 Does the medical device have a restricted shelf-life?	No
C.2.21 Are there any delayed or long-term use effects?	No
C.2.22 To what mechanical forces will the medical device be subjected?	In exo-skeleton resistive force occurs during rehabilitation exercies
C.2.23 What determines the lifetime of the medical device?	Electronics, materials, mechanisms
C.2.24 Is the medical device intended for single use?	No
C.2.25 Is safe decommissioning or disposal of the medical device necessary?	No
C.2.26 Does installation or use of the medical device require special training or special skills?	No
C.2.27 How will information for safe use be provided?	Introduction by healthcare professional and user's guide
C.2.28 Will new manufacturing processes need to be established or introduced?	No

Tables 8 and 9 indicates that questions C.2.1 - C.2.5, C.2.9, C.2.11, C.2.12, C.2.17 - C.2.19, C.2.22, C.2.23 and C.2.27 are needed to take into consideration during the design and development process.

5.5 User Interface Characteristics Related to Safety

According to Standard IEC 62366-1:2015 in sub clause 5.2, it is required to identify UI characteristics related to safety and potential use errors. It is required to identify UI characteristics related to safety by a manufacturer as part of the risk management process according to standard ISO 14971:2007. Questions C.2.29 - C.2.34 found in annex C of standard ISO 14971:2007 could be used as the basis for identification [18]. Questions C.2.29 - C.2.34 are presented in table 10.

Table 10. Questions C.2.29 - C.2.34 to identify UI characteristics that could impact safety.

C.2.29 Is successful application of the medical device critically dependent on human factors such as the user interface?	Yes
C.2.29.1 Can the user interface design features contribute to a use error?	Yes. It is plausible.
C.2.29.2 Is the medical device used in an environment where distractions can cause use error?	Yes. It is plausible.
C.2.29.3 Does the medical device have connecting parts or accessories?	Yes
C.2.29.4 Does the medical device have a control interface?	Yes
C.2.29.5 Does the medical device display information?	Yes
C.2.29.6 Is the medical device controlled by a menu?	Yes
C.2.29.7 Will the medical device be used by persons with special needs?	Yes
C.2.29.8 Can the user interface be used to initiate user actions?	Yes
C.2.30 Does the medical device use an alarm system?	Yes
C.2.31 In what way(s) might the medical device be deliberately misused?	External force applied to the device, both AR device and exo-skeleton
C.2.32 Does the medical device hold data critical to patient care?	Yes
C.2.33 Is the medical device intended to be mobile or portable?	Yes. Portable
C.2.34 Does the use of the medical device depend on essential performance?	Yes

Table 10 indicates that all of the questions C.2.29 - C.2.34 are needed to take into consideration during the design and development process.

It is instructed by technical report IEC TR 62366-2 in sub clause 9 that functional analysis, task analysis, cognitive task analysis, workload assessment, interviews could also be used to identify the UI characteristics related to safety and potential use errors. Function analysis for a hand rehabilitation device is presented in table 11. Functional analysis presented in table 11 is beneficial for detecting potential use errors and to use them to enhance design choices. For example a hand rehabilitation device which is intended to be used as a telemedicine application, it is essential to ensure correct execution of rehabilitation exercises. From task analysis it is noticed that humans are not good for detecting small hand movements. Hence hand movements should be detected by sensors of the device [19].

Table 11. Function analysis for human versus machine capabilities.

Humans do not excel in	**Machines excel in**
Noticing small hand movements	Noticing small hand movements with sensors
Force: Limited strength.	Great forces possible.
Accuracy: Unreliable, makes constant and variable errors.	Great accuracy attainable.
Humans excel in	**Machines do not excel in**
Visual information processing system extremely logical and flexible	Need to be monitored.
Can reason inductively; can follow up intuition.	Inductive reasoning not possible.
When highly motivated, can perform under adverse conditions with parts out of order (injuries).	Needs to get careful maintenance. Might not operate at all, if some parts are broken.

5.6 Known or Foreseeable Hazards and Hazardous Situations

According to Standard IEC 62366-1:2015 in sub clause 5.3, a manufacturer must identify known or foreseeable hazards and hazardous situations of the medical device [18]. According to technical report IEC TR 62366-2, identification of known or foreseeable hazards and hazardous situations is part of the risk management process described in ISO 14971, hence the manufacturer is required to analyse all hazardous situations [19].

Table 12 presents harm due to risk caused by use errors or poor usability according to annex B of standard IEC 62366-1. The manufacturer is advised to consider the full range of use scenarios and associated factors that could lead to harm, including use scenarios preventing a user from effectively using a medical device as proposed [18].

Table 12. Harm due to risk caused by use errors or poor usability.

Hazard	Hazard - related use scenario	Harm	User Interface risk control measure
Too much force on exo-skeleton during rehabilitation	For different heathconditions there must be adjustable resistance in exo-skeleton in order to get efficient exercises for different patiens. A patient might get wrong force setup.	Dislocation of joint	Force setup need to be clear to use
Wound from sharp edges	Exo-skeleton might have sharp edges	Wound	Rounded edges where possible, soft materials
Wrong execution of rehabilitation exercise	Incorrect execution for rehabilitation exercises by a patient	No progress in rehabilitation	Use of sensors, instructions, clear UI
Unable to do rehabilitation exercises	Health condition of a patient is too severe to use any device	No progress in rehabilitation	Specification of who is able to use the device

5.7 Hazards and Sequences of Events Leading to Hazardous Situations

According to standard EN ISO 14971:2007 in chapter 4.3, a manufacturer must compile documentation on known and foreseeable hazards associated with the medical device both normal and fault conditions. According to standard EN ISO 14971:2007 annexes E.2 and H.2.4 could be used as a guidance [15]. Table 13 presents examples of initiating events and circumstances according to annex E.2.

Table 13. Identified foreseeable sequences of events.

General Category	Initiating events and circumstances	Identified Foreseeable Sequences of Events
Incomplete requirements	*Inadequate specification of design parameters, operating parameters, performance requirements, in-service requirements (e.g. maintenance, reprocessing), end of life*	- Inadequate specification of design parameters, operating parameters, performance requirements, in-service requirements
Manufacturing processes	*Insufficient control of changes to manufacturing processes* *Insufficient control of materials/materials compatibility information* *Insufficient control of manufacturing processes* *Insufficient control of subcontractors*	- Insufficient control of materials/materials compatibility information
Transport and storage	*Inadequate packaging* *Contamination or deterioration* *Inappropriate environmental conditions*	- Inadequate packaging - Inappropriate environmental conditions
Environmental factors	*Physical (e.g. heat, pressure, time)* *Chemical (e.g. corrosions, degradation, contamination)* *Electromagnetic fields (e.g. susceptibility to electromagnetic disturbance)* *Inadequate supply of power* *Inadequate supply of coolant*	- Force applied to a patient's hand - Inadequate supply of power
Cleaning, disinfection and sterilization	*Lack of, or inadequate specification for, validated procedures for cleaning, disinfection* *and sterilization* *Inadequate conduct of cleaning, disinfection and sterilization*	- Lack of inadequate specification for validated procedures for cleaning - Inadequate conduct of cleaning
Disposal and scrapping	*No or inadequate information provided* *Use error*	- No or inadequate information provided - Use error
Formulation	*Biodegration* *Biocompatibility* *No information or inadequate specification provided* *Inadequate warning of hazards associated with incorrect formulations* *Use error*	- No information or inadequate specification provided - Use error
Human factors	*Potential for use errors triggered by design flaws, such as* *- confusing or missing instructions for use* *- complex or confusing control system* *- ambiguous or unclear device state* *- ambiguous or unclear presentation of settings, measurements or other information* *- misrepresentation of results* *- insufficient visibility, audibility or tactility* *- poor mapping of controls to actions, or of displayed information to actual state* *- controversial modes or mapping as compared to existing equipment* *- use by unskilled/untrained personnel* *- insufficient warning of side effects* *- inadequate warning of hazards associated with re-use of single-use medical devices* *- incorrect measurement and other metrological aspects* *- incompatibility with consumables/accessories/other medical devices* *- slips, laps and mistakes*	- Confusing or missing instructions for use - Complex or confusing control system - Ambiguous or unclear device state - Ambiguous or unclear presentation of settings, measurements or other information - Insufficient visibility, audibility or tactility - Poor mapping of controls to actions, or of displayed information to actual state - Controversial modes or mapping as compared to existing equipment - Incorrect measurement of sensors
Failure modes	*Unexpected loss of electrical/mechanical integrity* *Deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance* *to flow, electrical conductivity) as a result of ageing, wear and repeated use* *Fatigue failure*	- Unexpected loss of electrical and mechanical integrity - Change in resistance as a result of ageing, wear and repeated use - Fatigue failure

According to standard EN ISO 14971:2007 in chapter 4.4, reasonable foreseeable sequences or combinations of events possible resulting hazardous situations must be recorded. Methods in annex G can be used to recognise new hazardous situations. Those methods are Preliminary Hazard Analysis (PHA), Fault Tree Analysis (FTA), Failure Mode and Effects Analysis (FMEA), Hazard and Operability Study (HAZOP) and Hazard Analysis and Critical Control Point (HACCP). Annexes H.2.4.5 and E.4 also provide examples of hazardous situations [15].

5.8 Hazard Related Use Scenarios

According to Standard IEC 62366-1:2015 in chapter 5.4 in, a manufacturer must identify and describe the reasonably foreseeable hazard-related use scenarios associated with the hazards and hazardous situations [18]. Examples contained in annex B of standard IEC 62366-1 are presented in table 14 of section 5.5 in this thesis.

Table 14. Identified and described hazard-related use scenarios.

Hazard	Hazard - related use scenario	Harm	User Interface risk control measure
Too much force on exo-skeleton during rehabilitation	For different heathconditions there must be adjustable resistance in exo-skeleton in order to get efficient exercises for different patiens. A patient might get wrong force setup.	Dislocation of joint	Force setup need to be clear to use
Wound from sharp edges	Exo-skeleton might have sharp edges	Wound	Rounded edges where possible, soft materials
Wrong execution of rehabilitation exercise	Incorrect execution for rehabilitation exercises by a patient	No progress in rehabilitation	Use of sensors, instructions, clear UI
Unable to do rehabilitation exercises	Health condition of a patient is too severe to use any device	No progress in rehabilitation	Specification of who is able to use the device
Poor packaging	Packaging of the device is insufficient. Components, cables, etc. are not organized well and will be wear down quickly or will be lost.	Components get damaged or lost. Rehabilitation exercises will be interrupted.	Packaging with compartments
Lack of regular maintenance	Due to lack of regular cleaning of the device there will be malfunctions and wear down of materials.	Device won't function properly. Rehabilitation exercises will be interrupted.	Maintenance instructions designed with special care
Poor instruction or guidance	Due to poor instruction or guidance, use of the device will be improper.	Rehabilitation exercises will be interrupted.	Instructions and guidance designed with special care
Confusing or complex presentation of device state or actions	Confusing or complex presentation of device state or actions will cause unintentional misuse of the device.	Rehabilitation exercises will be interrupted.	Device state indication designed with special care
Poor visibility	Poor visibility will lead to unintentional misuse of the device.	Rehabilitation exercises will be interrupted.	Large enough icons and animations in AR environment
Incorrect reading of data	Incorrect measurement of sensors will give false indication about execution of rehabilitation exercises.	No progress in rehabilitation	Quality of sensors
Power failure	Power loss will interrupt or corrupt rehabilitation exercise.	Rehabilitation exercises will be interrupted.	Battery indicator
Software failure	Software error will interrupt or corrupt rehabilitation exercise.	Rehabilitation exercises will be interrupted.	Quality of code

5.9 Use Scenarios for Summative Evaluation

According to Standard IEC 62366-1:2015 in chapter 5.5, a manufacturer must select hazard-related use scenarios for summative evaluation [18]. According to Standard IEC 62366-1, a manufacturer must select either all hazard-related use scenarios or subset based on severity. According to annex A sub clause 5.5 a medical device can have only few or very large number of hazard-related use scenarios. There are three options for manufacturer:

- Include all hazard related use scenarios
- Include a subset of the hazard related use scenarios based on the severity of the potential harm that could be caused by use error
- Include a subset of the hazard - related use scenarios based on the severity and additional circumstances specific to the medical device and the manufacturer

Technical report guides that summative evaluation should cover a demonstration that users are able to accomplish the intended purpose of the medical device as described in the use specification.

Since this is the very first iteration of the medical device under development, all hazard related use scenarios are included. Further the development progresses it is possible to narrow down into use scenarios more important. However it should be noted that summative evaluation is not performed in this study.

5.10 User Interface Specification

According to Standard IEC 62366-1:2015 in chapter 5.6, a manufacturer must establish UI specification [18]. Example of UI requirements is presented in table 15. According to technical report IEC TR 62366-2 a UI specification is a document consisting of UI requirements.

Table 15. UI requirements.

User Interface Requirements		
User Interface Element	**Expressed User Need**	**User Interface Requirement**
Physical buttons	Physical Buttons i.e. power, should be visible and indicate whether it is on/off	Physical buttons should include leds for indication
Locking mechanisms of exo-skeleton	Locking mechanisms should be easy to use with only using other hand	Only locking mechanisms usable with one hand are allowed
Calendar notification	Calendar notification should be visible for users with weakened eyesight	Calendar notification icon should large enough
Guidance for locking exo-skeleton	Guidance for locking mechanism should be provided	Guidance for locking/unlocking the exo-skeleton should be indicated with for example arrows in AR environment
Indication for progress in different tasks	Indication for whether tasks were pass/fail should be provided	Guidance for passing or failing tasks should be indicated with for example text in different colors in AR environment
Instruction for rehabilitation exercises	Guidance for rehabilitation exercises should be provided	Instruction video of rehabilitation exercises or similar should be provided in AR environment
Rehabilitation exercise tasks	Rehabilitation exercise tasks should be visualised during exercises	Rehabilitation exercise tasks should be visualised during exercises in AR environment
Indication for completing exercise	Indication for completing exercise should be provided	Indication for completing exercises should be indicated with for example text in AR environment

According to technical report IEC TR 62366-2 the UI specification is based on the use specification, known and foreseeable use errors and selected hazard-related use scenarios [19].

5.11 User Interface Evaluation Plan

According to Standard IEC 62366-1:2015 in chapter 5.7.1, a manufacturer must establish a UI evaluation plan for UI specification [18]. Table 16 presents a template for UI evaluation plan accordion to technical report IEC TR 62366-2. It is a recommendation and can be altered to better meet requirements of a UI under development [19].

Formative evaluation planning according to standard IEC 62366-1 is presented in table 16. Sub clause 5.7.2 expects that formative evaluation plan addresses what evaluation methods are being used, which part of a UI is evaluated and when to perform each of the UI evaluations. Formative evaluation is used to find errors in UI design that could cause harmful use errors. Formative evaluations are voluntary and they are done as often as project specifications allow them to be performed [18].

Table 16. UI evaluation plan.

User Interface Evaluation Plan	
Test Purpose	To identify usability problems in user interface design after each design cycle
Test Method Overview	Heuristic evaluation is method to identify usability problems. User interface is evaluated through well known usability issues or defined design requirements. Method requires minimum of three person for evaluation. The user interface is evaluated by evaluator independently indentify elements that have usability problems. Heuristic evaluation is a formal method suitable for the first iterations of user interface design.
Test Items	Paper prototype of AR user interface environments
Test Materials	Set of 14 heuristics for evaluation of user interface
List of Tasks Based on Selected Hazard-related Use Scenarios	Heuristics: - Consistency and standards - Visibility of system state - Match between system and world - Minimalist - Minimize memory load - Informative feedback - Flexibility and efficiency - Good error messages - Prevent errors - Clear closure - Reversible actions - Use users' language - Users in control - Help and documentation
Data Collection Techniques and Methods	Evaluator independently review user interface through 14 heuristics and rates severity on scale 0-4.
Data Analysis Methods	Statistical analysis

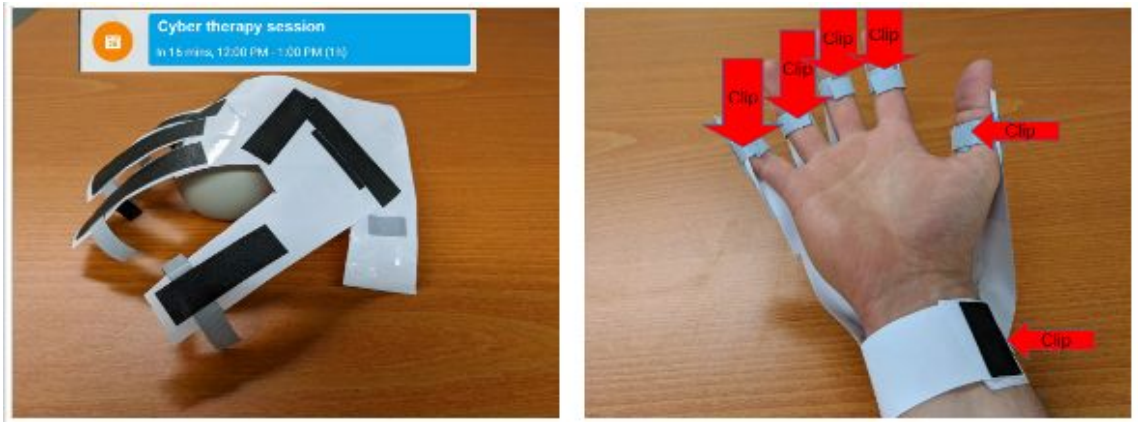
Standard IEC 62366-1:2015 in sub clause 5.7.3 defines summative evaluation planning as well, but it should be noted that summative evaluation is not performed in this thesis and hence there is no summative evaluation plan. Summative evaluation is used to confirm safety of developed UI. It is performed to make a final evaluation of a medical device so to determine whether or not the UI has acceptable safety [18].

5.12 Design of the User Interface

Design and implementation of the UI According to Standard IEC 62366-1:2015 in chapter 5.8 are presented in figure 13 - figure 17. Figures present sketches of AR UI from a view of a patient. Sketches are preliminary designs and should not be considered as final design.

In figure 13 it is presented how AR UI is expected to work at the beginning of a cyber therapy session. A Cyber therapy session starts with calendar notification which is seen on the left. It notify a patient for an upcoming cyber therapy session to prepare for the session. Next step is to prepare an exo-skeleton for the session. On the right it is presented how AR UI guides a patient for wearing the exo-skeleton and how to attach it properly.

Figure 13. Design of AR UI at the beginning of cyber therapy session.

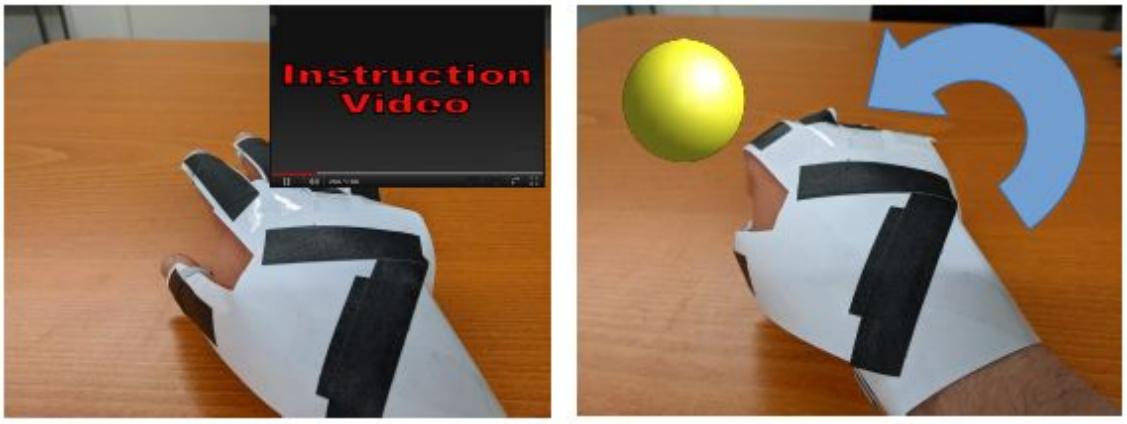


In figure 14 it is presented how AR UI verifies whether preparation of an exo-skeleton is succeeded. On the left it is presented with a notification with a green font for successful preparation of the exo-skeleton. On the right it is presented with a notification with a red font for unsuccessful preparation of the exo-skeleton, which it also advises to redo preparation of an exo-skeleton.

Figure 14. Design of AR UI for verification of preparation of exo-skeleton.

In figure 15 instruction and performing hand rehabilitation exercises are presented. A Cyber therapy exercise starts with an instruction video presented on the left. After viewing a video a patient performs exercise according to video with the help AI UI seen on the right. There is a virtual therapeutic ball needed to grasp and variants of arrows guiding towards correct exercise movement.

Figure 15. Design of AR UI to perform rehabilitation exercises.



In figure 16 it is presented how AR UI verifies whether single repeat of a rehabilitation exercise is succeeded. On the left it is presented with a notification with a green font for successful rehabilitation exercise. On the right it is presented with a notification with a red font for unsuccessful rehabilitation exercise. Single repeat of rehabilitation exercise must be done again.

Figure 16. Design of AR UI for verification of single repeat of rehabilitation exercise.

In figure 17 it is presented how AR UI is working at the end of a cyber therapy session. On the left it is presented how UI notifies a patient that session is completed. Green text notifies a patient that a cyber therapy session is completed. Next step is to prepare an exo-skeleton for the session. On the right it is presented how AR UI guides a patient for removal and storage of the exo-skeleton.

Figure 17. Design of AR UI at the end of cyber therapy session.

5.13 Formative Evaluation

Formative evaluation of UI presented in chapter 5.12 in this thesis is presented here. It is chosen to perform heuristic evaluation for the designed UI. Heuristic evaluation is a method to evaluate usability of UI. The method evaluates UI by going through a selected number of usability heuristics. Usability heuristics are a set of issues derived from previous experiences. Heuristics are evaluated by giving each heuristic severity rating [30]. Severity ratings used in this evaluation are presented in table 17.

Table 17. Severity ratings of heuristic evaluation [30].

Severity Rating	
Not a usability problem at all	0
Cosmetic problem only. Need not be fixed unless extra time is available	1
Minor usability problem. Fixing this should be given low priority	2
Major usability problem. Important to fix. Should be given high priority	3
Usability catastrophe. Imperative to fix this before product can be released	4

Heuristic evaluation performed in this chapter is recommended by technical report IEC TR 62366-2 and it uses 14 different heuristics. Tables 18 and 19 presents heuristics evaluation of AR UI of hand rehabilitation device demonstrated in this thesis as a part of design and development process [19].

Table 18. Heuristic evaluation of designed UI including heuristics 1-7.

Heuristic			Severity	
1	**Consistency and standards.** Users should not have to wonder whether different words, situations, or actions mean the same thing. Standards and conventions in product design should be followed.	a. Sequences of actions (skill acquisition)	2	1.5
		b. Color (categorization)	1	
		c. Layout and position (spatial consistency)	2	
		d. Font, capitalization (levels of organization)	1	
		e. Terminology (delete, del, remove, rm) and language (words, phrases)	2	
		f. Standards (e.g., blue underlined text for unvisited hyperlinks)	1	
2	**Visibility of system state.** Users should be informed about what is going on with the system through appropriate feedback and display of information.	a. What is the current state of the system?	3	3.0
		b. What can be done at current state?	3	
		c. Where can users go?	3	
		d. What change is made after an action?	3	
3	**Match between system and world.** The image of the system perceived by users should match the model the users have about the system.	a. User model matches system image	3	3.0
		b. Actions provided by the system should match actions performed by users	3	
		c. Objects on the system should match objects of the task	3	
4	**Minimalist.** Any extraneous information is a distraction and a slow-down.	a. Less is more	1	1.0
		b. Simple is not equivalent to abstract and general	1	
		c. Simple is efficient	1	
		d. Progressive levels of detail	1	
5	**Minimize memory load.** Users should not be required to memorize a lot of information to carry out tasks. Memory load reduces users capacity to carry out the main tasks.	a. Recognition vs. recall (e.g., menu vs. commands)	3	3.0
		b. Externalize information through visualization	3	
		c. Perceptual procedures	3	
		d. Hierarchical structure	3	
		e. Default values	3	
		f. Concrete examples (DD/MM/YY, e.g., 10/20/99)	3	
6	**Informative feedback.** Users should be given prompt and informative feedback about their actions.	a. Information that can be directly perceived, interpreted, and evaluated	2	1.0
		b. Levels of feedback (novice and expert)	0	
		c. Concrete and specific, not abstract and general	2	
		d. Response time (0.1 s for instantaneously reacting; 1.0 s for uninterrupted flow of thought; 10 s for the limit of attention)	0	
7	**Flexibility and efficiency.** Users always learn and users are always different. Give users the flexibility of creating customization and shortcuts to accelerate their performance.	a. Shortcuts for experienced users	0	0.0
		b. Shortcuts or macros for frequently used operations	0	
		c. Skill acquisition through chunking	0	
		d. Examples: Abbreviations, function keys, hot keys, command keys, macros, aliases, templates, type-ahead, bookmarks, hot links, history, default values, etc	0	

Heuristics 2, 3 and 5 in table 18 indicates major usability problems and should be fixed with high priority.

Table 19. Heuristic evaluation of designed UI including heuristics 8-14.

Heuristic			Severity	
8	**Good error messages.** The messages should be informative enough such that users can understand the nature of errors, learn from errors, and recover from errors.	a. Phrased in clear language, avoid obscure codes. Example of obscure code: "system crashed, error code 147."	3	3.0
		b. Precise, not vague or general. Example of general comment: "Cannot open document."	3	
		c. Constructive.	3	
		d. Polite. Examples of impolite message: "illegal user action," "job aborted," "system was crashed," "fatal error," etc.	3	
9	**Prevent errors.** It is always better to design interfaces that prevent errors from happening in the first place.	a. Interfaces that make errors impossible.	3	3.0
		b. Avoid modes (e.g., vi, text wrap). Or use informative feedback, e.g., different sounds.	3	
		c. Execution error vs. evaluation error.	3	
		d. Various types of slips and mistakes.	3	
10	**Clear closure.** Every task has a beginning and an end. Users should be clearly notified about the completion of a task.	a. Clear beginning, middle, and end.	0	0.7
		b.Complete 7-stages of actions.	0	
		c. Clear feedback to indicate goals are achieved and current stacks of goals can be released. Examples of good closures include many dialogues.	2	
11	**Reversible actions.** Users should be allowed to recover from errors. Reversible actions also enco exploratory learning.	a. At different levels: a single action, a subtask, or a complete task.	3	3.0
		b. Multiple steps.	3	
		c. Encourage exploratory learning.	3	
		d. Prevent serious errors.	3	
12	**Use users' language.** The language should be always presented in a form understandable by the intended users.	a. Use standard meanings of words.	1	1.0
		b. Specialized language for specialized group.	1	
		c. User defined aliases.	1	
		d. Users perspective. Example: "we have bought four tickets for you" (bad) vs. "you bought four tickets" (good).	1	
13	**Users in control.** Do not give users that impression that they are controlled by the systems.	a. Users are initiators of actors, not responders to actions.	3	3.0
		b. Avoid surprising actions, unexpected outcomes, tedious sequences of actions, etc.	3	
14	**Help and documentation.** Always provide help when needed.	a. Context-sensitive help.	3	3.0
		b. Four types of help. (Task-oriented; alphabetically ordered; semantically organized; search)	3	
		c. Help embedded in contents.	3	

Heuristics 8, 9, 11, 13 and 14 in table 19 indicates major usability problems and should be fixed with high priority.

5.14 Feedback from First Iteration of User Interface

Design cycle of the design and development process for a medical device demonstrated in chapter 5.13 ends in heuristic evaluation presented in table 18 and table 14. It is presented in figure 2 that after formative evaluation when more refinement is needed, UI specification must be revisited and some modifications need to be done. If it is not needed for more refinement or such action is not sufficient to remove usability problems, moving forward is the next step. The next step is to define if there are new problems found. If it is defined that there are new problems, use specification presented in chapter 5.2 must be revisited and some modifications need to be done.

It is clear after heuristic evaluation in chapter 5.13 that modifications must be done. There are eight major usability problems identified in table 18 and table 19. Hence UI specification presented in chapter 5.10 should be modified first and then redesigned prototype according to modifications should be evaluated again with heuristic evaluation. This procedure can be done as long as it is decided that refinement of UI specification would not be sufficient action to take. Defining that refinement of UI specification is not sufficient measure to take, next step is to move into definition of new problem which leads to modification of use specification. This action has more impact on design and development of UI since it starts the whole process again. That means the risk management process must be revisited and likely modified. This will likely cause schedule conflicts on the design and development project and the whole project including other processes around medical device development and raise of costs. However this might be the scenario despite carefully established specifications, since new products like the cyber therapy device presented in this thesis are new compared to existing medical devices that might have decades of service history.

6 Discussions and Conclusions

This section presents discussion and conclusions of the overall work, results and observations of this study.

6.1 Discussions

The objective of this thesis was to study the design and development process required for a UI of a medical device in the EU. It was clear in the beginning of the study that there is a legislative extent hence the study was steered towards harmonized EU standards. All the legislation of a medical device is defined in the regulations of the EU and there are no obligations for manufacturers of medical devices to use harmonized standards, but since harmonized standards are foreground on the political agenda of the EU, the use of harmonized standards are preferred. This study is focused mostly on the standards EN ISO 14971 and IEC 62366-1 which are the main structure of design and development process of a UI of a medical device. It is however important to understand that the design and development of a UI of a medical device is done by a manufacturer of that very medical device who is obligated to establish other processes by the regulation of the EU. A quality management standard for life-cycle processes of a medical device is defined in standard ISO 13485 including process for design and development. It is important to understand how vast is the organisation required to manufacture a medical device for example with processes for project management, logistics, manufacture, etc.

In this thesis it was chosen to visualise the very first cycle of the design and development process with a cyber therapy device for hand rehabilitation in other words a telemedicine application of hand rehabilitation device. Design and development of a telemedicine application is a challenging task in a way that a patient operates a medical device from over a distance, most likely from home. Without claiming that other medical devices are far more easier to design and develop, telemedicine applications have a distinctive feature of two users and hence two UIs. One is for a healthcare professional and the other is for a patient. A UI for a patient is challenging since a home environment is a vast definition as well as user profile for a patient. Patients with

different backgrounds including education, age, profession, culture, etc have different thought processes and that creates different mental models in other words different ways to approach the use of a medical device. Usability in general is related to a mental model in a way that understanding a mental model of a user is the foundation of a good conceptual model. Good conceptual model is the foundation of good UI and good UI is the foundation for good usability in other words UX. For a medical device good usability is a requirement defined by legislation to ensure safety. For example complicated UI that has multiple functions is prone to generate human errors leading to dangerous situations for a patient and a user. Hence the development and design of a UI of a medical device is extremely important to do carefully.

6.2 Conclusions

The objectives of this thesis which include the visualisation of the design and development process of a UI of a medical device was achieved and it provided information that was beyond the scope of the research questions of this thesis. In other words more was accomplished than what was expected with the defined research questions. That is mainly, because it is difficult to define research questions with less knowledge and experience in the beginning of the research.

As an important observation, user research is likely the most important task in a UI development of a medical device. User in other words human is the most complicated factor since there are endless combinations of occupations, educations, backgrounds like parenting, cultures, health conditions, physical aspects, etc. A user defines how a medical device should be used which relates to safety, the other important issue in a medical device development. A human is prone to errors or more precisely behavior of a human lead to situations considered unsafe. It is extremely important to profile a user of a medical device as carefully as possible since that enables constraining the user profile for example into a certain geographical area like the EU or profession like a doctor. Carefully established use specification is the foundation of a usable medical device, because that affects all the way down to design requirements that are a

necessity for successful design of a medical device. A usable medical device is safe to use, hence usability of a medical device is regulated by the legislation, which has been approached in this thesis.

Research of human anatomy, health conditions and treatment of those health conditions will offer designers who are working on a medical device development a valuable aspect to think outside the box. It is extremely important for designers to understand that when developing a medical device it is not a traditional product, but it has intended use specified which is also regulated by the legislation. The more designers are oriented into these issues the more usable and safe medical devices become.

Standards EN ISO 14971 and IEC 62366-1, which the design and development process studied in this thesis is based on, establishes the process that meets the legislation and provides guidelines to high level safety aspects. However it is important to understand that the design and development process presented in this thesis is for a UI of a medical device. There are other standards as important for medical device development as well that are needed to take into consideration when thinking about the big picture of medical device development. They all share the same value which is safety first in medical device development.

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