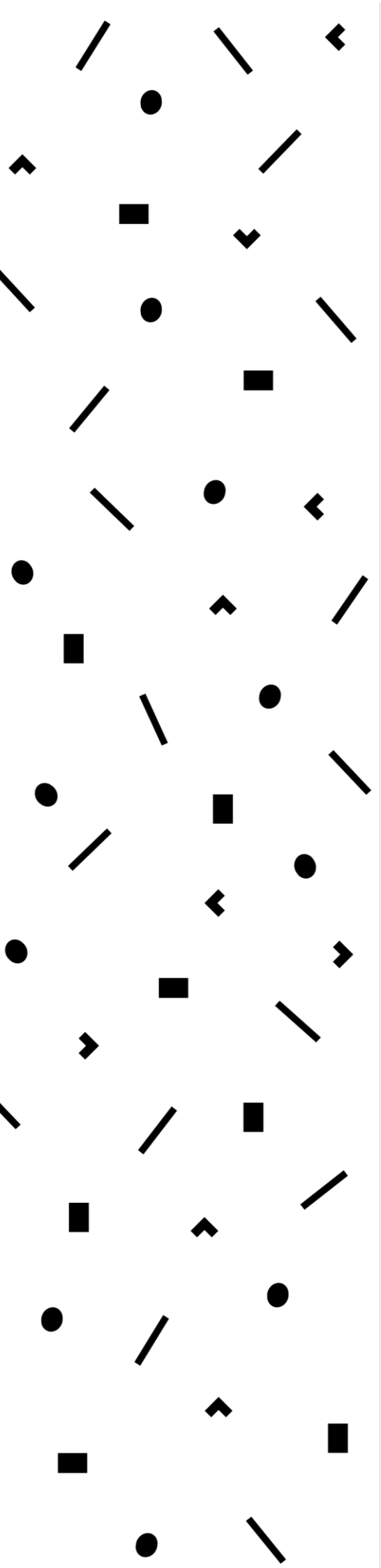

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DESIGNING USABILITY INTO OPERATING TABLE REMOTE CONTROL

LAHTI UNIVERSITY OF APPLIED SCIENCES
Degree programme in Information and Communications Technology
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RÄSÄNEN, MERVI: Designing usability into operating table remote control

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ABSTRACT

Medical device manufacturers are required to apply usability engineering, often used as a synonym for human factors engineering, to design and develop medical devices. The most important goal here is to minimize use-related hazards. Usability engineering must be applied since the earliest phase of the product development process, even before design.

The aim of this study was to design usability into operating table remote control according to the regulations. The subject was limited to the early phase analysis and evaluations. The theoretical framework for the thesis was built by investigating the medical device regulations, the most important of those being the usability standard IEC 62366-1:2015. The definition of usability and the methods to evaluate usability were also investigated.

The empirical study was conducted to gather knowledge on the users and the use context of the operating table remote controls by observing and interviewing operating room professionals in the operating rooms of ten hospitals, including six hospitals in Finland, two hospitals in Denmark and two hospitals in Portugal. The interviews (n=63) were semi-structured, conducted one-on-one. The results were analyzed using the qualitative approach.

According to the results, the users value simple and easy-to-use remote controls of the operating table. The remote control must be robust and reliable to ensure safe use, and it should not contain any excessive features, which might confuse the user. From the users´ viewpoint, safety is an essential aspect when considering usability. The remote controls evaluated by the users in the field study consisted a number of features and functions which were not used, mostly not even known by the users. The training was often missing, which seemed to have a significant effect on this.

Key words: usability, usability engineering, human factors engineering, medical device, IEC 62366, operating table, remote control

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Degree Programme in Information and Communications Technology

RÄSÄNEN, MERVI: Leikkauspöydän kaukosäätimen käytettävyyssuunnittelu

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TIIVISTELMÄ

Terveydenhuollon laitteiden valmistajien on sovellettava tuotekehitysprojekteissaan käytettävyystekniikkaa tuotteiden suunnittelun alkuvaiheista lähtien. Käytettävyystekniikan tärkein tavoite on vähentää terveydenhuollon laitteiden käyttövirheisiin liittyviä vaaratilanteita.

Tämän opinnäytetyön tavoitteena oli suunnitella leikkauspöydän kaukosäätimen käytettävyys regulatiivisten vaatimusten mukaisesti, rajaten aihe tuotekehitysprojektin alkuvaiheisiin. Teoreettisen viitekehyksen muodostivat regulatiiviset vaatimukset, näistä tärkeimpänä terveydenhuollon laitteiden käytettävyystekniikkaprosessin määrittävä standardi IEC 62366-1:2015. Työn teoriaosassa tutkittiin lisäksi käytettävyyden määritelmää, sekä terveydenhuollon laitteiden käytettävyyden arviointiin soveltuvia metodeja.

Empiirisessä osassa tutkittiin leikkauspöydän käsiohjaimen käyttöä havainnoimalla ja haastattelemalla leikkaussalihenkilökuntaa 10 sairaalakohteessa. Tutkimuskohteista kuusi sairaalaa sijaitsi Suomessa, kaksi Tanskassa ja kaksi Portugalissa. Haastattelut olivat puoli-strukturoituja yksittäishaastatteluja, niitä toteutettiin yhteensä 63. Tulokset analysoitiin kvalitatiivisen tutkimuskäytännön mukaisesti.

Tulokset osoittavat käyttäjien arvostavan leikkauspöydän kauko-ohjaimissa yksinkertaisuutta ja helppokäyttöisyyttä. Toimintojen luotettavuus ja kauko-ohjaimen kestävyys koettiin tärkeiksi, käyttäjät korostivat vastauksissaan turvallisuusnäkökulmaa. Vastauksista kävi ilmi, että leikkauspöytien kauko-ohjaimissa oli lukuisia toimintoja ja ominaisuuksia, jotka eivät olleet käytössä lainkaan. Useimmat näistä toiminnoista olivat käyttäjille täysin tuntemattomia, mikä johtui tulosten perusteella käyttökoulutuksen puutteesta.

Asiasanat: käytettävyys, käytettävyystekniikka, terveydenhuollon laitteet, lääkinnälliset laitteet, IEC 62366, leikkauspöytä, kaukosäädin

CONTENTS

1 INTRODUCTION

‘Usability’ is commonly described as user-friendliness, and when something is easy and pleasant to use it may be described possessing ‘good usability’. When medical devices are in question, in addition to user satisfaction, usability includes aspects of effectiveness and efficiency, which all can either increase or decrease safety (IEC 62366-1:2015, 10). Considering the safety of a variety of medical devices used by modern medicine, the definition is deepened from user-friendliness to a matter of life and death.

It has been estimated that the global volume of surgery in 2012 was over 300 million operations (Weiser et al 2015). The number of medical devices, as well as the number of users and individual use situations of those devices in this volume can only be imagined. Unfortunately, all of the operations in a volume like this, do not go as planned. It is not a challenging task to find publications related to adverse events happening in the operating rooms. There are near-misses reported, and even worse, patients falling from the operating table on the floor, causing death (Booth et al 2016; Razavian & Thurn 2013; Tepfer 2012; Kelby 2010; Dauber & Roth 2009; Irons 2009). Wiklund and Wilcox (2005, 169) refer to the report published by Institute of Medicine (2000), To Err Is Human, when stating use errors to be quite common in the practice of medicine. They argue time pressures and fatigue, abundant in the most health-care environments, to be recognized as key factors to use errors. Further, they write, medical device manufacturers can help reducing use errors in the clinical setting by applying usability engineering.

The usability of medical devices has recently gained a lot of attention from regulatory authorities. Standard IEC 62366-1 was published in Europe by the International Electrotechnical Commission (IEC) in 2015 and a guidance document by U.S. Food and Drug Administration (FDA) in 2016, both requiring manufacturers to apply *usability engineering,* often used as a synonym for *human factors engineering,* when designing and developing medical devices. The usability engineering process is suggested as a tool

for the medical device manufacturers to minimize use errors and use-related hazards caused by inadequate usability of medical devices. A clear statement for the manufacturers is enhanced by using the term ‘use error’ instead of ‘user error’. This is to express the responsibility of the device manufacturer: the aim is to minimize or eliminate the potential of the user to commit an error in the first place while using the medical device. (IEC 62366-1:2015; FDA 2016.)

1.1 Commissioning company

The commissioning company of this thesis, Merivaara Corp., is a Finnish medical device manufacturer. The company was established in 1901 and the production of hospital furniture began in 1910 with the first operating tables. Today Merivaara Corp. provides a wide range of medical devices, such as operating tables and surgical lights, birthing and patient beds, trolleys and stretchers, as well as solutions for integrating operating room devices, data and image management. The company has global distributors and customers; it is actively exporting to over 120 countries. Merivaara Corp. employs about 120 people, most of them at the headquarters in Lahti, where the company´s R&D, production, sales, marketing and after-sales service functions are located. (Merivaara 2017.)

The company complies with EU directives for medical devices, all Merivaara´s products bear the CE marking. The company´s quality management system is certified according to ISO 9001 and ISO 13485 standards, and the environmental management system according to ISO 14001 standard. Merivaara Corp. has stated the user experience of the customers and uncompromised quality to be the most important values of the company. The focus, when designing and developing Merivaara´s products and solutions, is on getting a better understanding of the demanding environment of the healthcare personnel. The company has recently won two awards in the field of designing for its new surgical light: the Finnish Fennia Prize Award 2017 and the international Red Dot Award, Product Design 2017. Alongside a high standard of design, usability is

stated to be a criterion of selection, in both of these design competitions. (Merivaara 2017.)

Optimal patient positioning in a surgical operation is essential to provide the best surgical access and to minimize potential risks associated with the positioning (Pudner 2010, 23-24; Lukkari et al 2007, 210-212). Operating tables are thus equipped with moving, adjustable joints and detachable sections to provide the ideal table configuration and patient positioning for each operation. The operating tables have to be adjustable also for ergonomics of the surgical team. Modern, electric operating tables contain a set of functions and features for the users, controlled via remote controls. By commissioning this thesis, Merivaara Corp. seeks a better understanding of the operating table users, especially related to the remote controls. There were some previous usability tests conducted by an external supplier for the company, but none of them related to the use of the operating tables or the remote controls. In addition, a solid knowledge of the current usability standards related to the medical device manufacturing, as well as of the applicable usability methods suitable for the operating tables, was needed.

1.2 Purpose of the thesis

The purpose of this thesis is to evaluate and design usability according to the regulations into a new operating table remote control. The subject is limited to the preliminary analyses and evaluations, and as a result of those, the thesis aims to define the user requirements of the new product.

1.3 Research questions

The aim of the thesis is to define the user requirements of the new operating table remote control. The main research questions are:

> *Which features of the operating table remote control are important to the users?*
>
> *Which features have an effect on the usability of the operating table remote control?*

These main research questions generated subquestions, which also needed to be answered during the research.

As a theoretical background, the medical device standards related to the usability were investigated to clarify the required usability engineering process for medical devices. The main focus in the standards being on the safety of the medical devices, the subquestion derived from them is:

> *Which features of the operating table remote control are important to guarantee the safe use of the operating table?*

The definition of usability, usability engineering and the methods to evaluate usability are also researched in the thesis. This theoretical basis gave rise to a new research subquestion:

> *Which usability methods are appropriate to evaluate the usability of the operating table remote control?*

1.4 Theoretical framework

The theoretical study investigates the regulatory requirements of the medical devices, the most important of them being the Medical Device Directive (93/42/EEC). There are harmonized standards for the manufacturers to follow to demonstrate the compliance with the requirements. The content of standard IEC 62366-1 *Application of usability engineering to medical devices* (2015) is presented in detail, because it is

seen as the most relevant, when creating the theoretical framework for this thesis.

A wide range of standards, regulations and directives related to medical device manufacturing had to be investigated to form a clear understanding of the regulative framework of medical device manufacturing. Previous thesis works guided in gathering the knowledge for this. Rane (2015) has researched the regulatory requirements of the product development process of class I medical devices in her thesis and compiled a set of noteworthy issues, which must be known by the medical device manufacturer to comply with these requirements. Kanervo (2016) has investigated the regulations related to placing a medical device on the market in Europe. She states that the manufacturer bears a wide responsibility of the safety of the medical device, across the entire product life cycle. However, the medical device safety is not the sole responsibility of the manufacturer, she writes. According to the Finnish legislation, a professional medical device user bears responsibility of using the device according to the use instructions given by the manufacturer.

Kaivosoja (2015), Nissinen (2013) and Keränen (2010) have investigated medical device usability. They have referred to the previous version of medical device usability standard IEC 62366 published in 2007 in their thesis papers, thus presenting the usability engineering process that differs in detail from the process that forms the theory basis for this thesis. Aho (2015) has researched the IEC 62366-1 standard and describes the usability engineering process, while the focus is on the software of the medical device. There was no previous research found related to the usability of the operating tables or their remote controls.

As this thesis relates to the medical devices, the quality management system must be stated. It is essential for the safety of the medical devices and must be applied for developing and manufacturing medical devices. In this thesis, however, the focus is on the development process of the new product and the usability engineering process. Thus the company´s quality management system is left out of the scope of this research. The

risk management process is required to be closely related to the usability engineering process by the standard IEC 62366-1 (2015). The final focus is here on the early stage usability research and evaluation, so the risk management process is not within the scope of the thesis. Both of these aforementioned are presented shortly in Chapter 2, which presents the legislation and regulations of medical devices overall.

The definition of usability, medical device usability and the methods to evaluate the usability as well as the methods of usability engineering are of crucial importance when creating the theory basis for the research.

1.5 Empirical study

In the empirical study, a user research is conducted at the early phase of the development process to gather knowledge on operating table users. This is done by conducting semi-structured interviews and observation in the real operating room environment. Data collected through the field studies is analysed using the qualitative approach.

2 LEGISLATION AND REGULATIONS

The term “medical devices” includes a wide variety of equipment from simple, home use items like sticking plasters or pregnancy tests, to highly sophisticated, computerized items like diagnostic imaging equipment or robotic surgical systems. All medical devices must be safe and effective for their intended use. The patient is the ultimate user and, therefore, no compromises are possible. To confirm this, the medical device industry is a strictly regulated business. This statement was given by Tom Ståhlberg in the foreword of his guidance book to Finnish medical device companies regarding international medical device regulatory requirements. In the guidance book, Ståhlberg presents two complementary approaches needed to meet the most stringent product safety and efficacy requirements related to medical devices: the product must meet all product related requirements and the company must meet all quality management system requirements. (Ståhlberg 2015, 5-9.)

2.1 Medical Device Directive

Globally, the requirements and regulations relating to the safety and performance of medical devices vary from one country to another. In fact, in some countries there is no legislation that applies specifically to the medical device industry. This does not make the situation any easier for the manufacturer: if there are no specific regulations considering the medical device products, the medical devices are regulated with some other requirements, making the situation even more complicated. In Europe the core legal framework consists of three directives, harmonized in the 1990s:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990)
- Council Directive 93/42/EEC on Medical Devices (MDD) (1993)
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998)

These three main directives have been supplemented over time by several modifying and implementing directives. Medical Device Directive 93/42/EEC has been modified five times, including the last technical revision brought about by directive 2007/47/EC. (Ståhlberg 2015, 15, 18, 23; Medical Devices 2017.)

The directives are supplemented by guidelines, EU MEDDEV guidance. These guidelines are drafted by authorities charged with safeguarding public health in conjunction with all stakeholders; industry associations, health professionals associations, Notified Bodies and European Standardization Organizations. These guidelines are not legally binding, but for the medical device manufacturer it is advisable to follow them, due to the participation of the aforementioned interested parties and the experts from competent authorities. (Ståhlberg 2015, 28; Guidance 2017.)

In Finland, the medical device directives are transposed to the Finnish Medical Device Act 629/2010. The national supervisory authority for welfare and health in Finland is Valvira, the competent authority monitoring the compliance of medical devices with the legislation and regulations. Valvira has also named two Notified Bodies in Finland, SGS Fimko Oy and VTT Expert Services Oy, which can be used when a third party is required to assess the compliance with the directives and regulations. (Ståhlberg 2015, 20; Medical Device Act 629/2010; Valvira 2017.)

It is noteworthy that besides the aforementioned directives there are other directives that may impact the medical device manufacturing based on device features, exemplified in a list in Appendix 1 (Ståhlberg 2015, 26-28). Considering the scope of this thesis, the most relevant is directive 93/42/EEC on Medical Devices (later *Medical Device Directive* or *MDD*) and its amendment 2007/47/EC. Thus these are the ones investigated more closely when building a theoretical framework for this research.

A ‘medical device’ is defined in Medical Device Directive, Article 1, as

> *“any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*
>
> *— diagnosis, prevention, monitoring, treatment or alleviation of disease,*
>
> *— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
>
> *— investigation, replacement or modification of the anatomy or of a physiological process,*
>
> *— control of conception,*
>
> *and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”.* (Directive 93/42/EEC, Article 1.)

The manufacturer must first define the intended use for the product, and based on that definition decide if a product concerned is a medical device, and if it therefore comes within the scope of the MDD. Further, the MDD divides products into different classes: I, Im (with measuring function), Is (provided sterile), IIa, IIb and III, based on risk and intended use, which determines the relevant conformity assessment procedure (Appendices 2-7). Regulatory control increases from class I to class III. To be compliant with the MDD, the manufacturer must classify the medical device product correctly. (Directive 93/42/EEC, Article 9; Annex IX.)

The manufacturer must demonstrate conformity to all requirements listed within the MDD and other directives, regulations and MED DEVs, if applicable for the device in question. The essential health and safety requirements set the necessary precautions and requirements to be considered in the design, manufacturing, use and disposal of medical devices in Annex I. The focus of this research being on the usability of the medical device, it is essential at this point to refer to a revising statement given in amendment 2007/47/EC:

> *“As design for patient safety initiatives play an increasing role in public health policy, it is necessary to expressly set out the need to consider ergonomic design in the essential requirements. In addition the level of training and knowledge of the user, such as in the case of a lay user, should be further emphasised within the essential requirements. The manufacturer should place particular emphasis on the consequences of misuse of the product and its adverse effects on the human body.”* (Directive 2007/47/EC, Recital 18.)

The above mentioned statement is found in the first paragraph of the essential requirements of the MDD, relating to all classes of medical devices. It sets strict requirements for medical device usability to ensure that the medical devices are designed, manufactured and also used in a way that does not lead to unnecessary risks to patients or users:

> *“The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include:*
>
> *— reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and*
>
> *— consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).”* (Directive 93/42/EEC, Annex I; Directive 2007/47/EC.)

The MDD outlines the minimum requirements for ensuring the safety and performance characteristics for medical devices in the European market. A medical device manufacturer must be able to demonstrate clearly that the product meets the relevant regulations. One way to do this is to follow the harmonized standards, which are developed under the mandate of the European Commission for the application of Union harmonization legislation. While the use of a harmonized standard is not always

mandatory, it is highly recommended for the manufacturer, as it represents the best practice and technical state of the art. To support the compliance with the directives, the manufacturer must also maintain technical documentation required by the directives and prepare the Declaration of Conformity. This self-declaration is applied only for the medical devices of class I, whereas those with the higher classification need to be regulatory reviewed by the third party, Notified Body. When all the essential requirements of the directives are met, manufacturer may affix the CE marking (Conformité Européenne) to the medical device. By affixing the CE marking, the manufacturer indicates that he takes full responsibility for the conformity of the product with all relevant requirements. Without the CE marking, on the other hand, the medical devices are not allowed to be placed on the market in Europe. (Ståhlberg 2015, 28-29, 32, 48, 55; CE marking 2017.)

As stated earlier, the need to consider usability in medical devices is inherent in the general essential requirements of the MDD. Other essential requirements also address specific usability concerns in the MDD. The requirements regarding design and construction set requirements for the function of the controls and indicators to be clearly specified on the devices. If any instructions required for the medical device operation or a visual system for indicating the operating or adjustment parameters exist, this information must be understandable to the user and, as appropriate, the patient. Each device must be accompanied by the information needed to use it safely, taking into account of the training and knowledge of the potential users. There are harmonized standards for medical device manufacturers to follow, to confirm these above mentioned usability requirements are met. These standards are presented more closely in Chapter 2.2. (Directive 93/42/EEC; Directive 2007/47/EC, Essential Requirements 12.9, 13.1.)

Besides the product related requirements, the MDD also sets requirements for the quality management system (QMS). This is to ensure the ability of the manufacturer to consistently meet the requirements at every stage of the product lifecycle. Following the European harmonized

standard, ISO 13485, is the most widely used approach in the field of medical device industry to demonstrate the conformity with the MDD. The standard ISO 13485 specifies requirements for documented procedures for a quality management system including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices. Further, the management of a company must take an active part in the establishment and maintenance of the quality policy for the company. (Ståhlberg 2015, 66-75; ISO 13485 2016.)

There are specific requirements for the periodic management reviews of the quality management system, likewise for documenting all process and product related actions to ensure effective planning, operation and controls of the quality management processes:

> *"All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records"* (Directive 93/42/EEC, Annex II; Directive 2007/47/EC.)

Safety being the major concern in the field of medical devices, an essential part complementing the quality management system is the risk management. The MDD requires the manufacturers to apply the risk management firmly through the product lifecycle:

> *"The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:*
>
> *— eliminate or reduce risks as far as possible (inherently safe design and construction),*
>
> *— where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,*
>
> *— inform users of the residual risks due to any*

> *shortcomings of the protection measures adopted."* (Directive 93/42/EEC, Annex I.)

The harmonized standard ISO 14971 specifies a process for the manufacturer to identify the hazards related to medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. Meeting the requirements of ISO 14971 manufacturer demonstrates the conformity with the MDD requirements considering the risk management. A risk consists of a hazard, which is a potential source of a harm, and the probability and severity associated with the hazard (i.e. how likely the hazard is to happen and how bad are the consequences). The manufacturer must identify and address the possible risks associated with the use of the device, is stated in the MDD. Hereby, this standard is closely connected to the other standards related to the usability requirements. (Ståhlberg 2015, 71; ISO 14971:2007.)

2.2 Usability standards for medical devices

As already mentioned, for demonstrating the conformity of the medical device product with the regulations, there are harmonized standards for manufacturers to follow. One such standard is IEC 60601-1, applying to medical electrical equipment, setting the general requirements for basic safety and essential performance. Noteworthy is, that for demonstrating the conformity with this standard, manufacturer must also comply with all requirements of this standard referring to. The standard IEC 60601-1 (2005, 102, 333) sets the requirement for the medical device manufacturer to apply usability engineering process and refers to the collateral standard for more detailed requirements for this usability engineering process: IEC 60601-1-6 *Medical electrical equipment – Part 1-6: General requirement for basic safety and essential performance – Collateral standard – Usability.* Further, this collateral usability standard is extended by referring to the standard IEC 62366 *Medical devices – Application of usability engineering to medical devices*. For example, clause 4.2 and subclause 4.2 of IEC 60601-1-6:2010 (edition 3.0) states the following:

> *“A usability engineering process complying with IEC 62366 shall be performed.”* (IEC 60601-1-6:2010, Clause 4.2, 8)
>
> *“While the usability engineering process described in IEC 62366 is more mature and refined than the process in the second edition of IEC 60601-1-6, it is fundamentally the same process involving the same elements.”* (IEC 60601-1-6:2010, Sublause 4.2, 11)

Practically, the harmonized standard IEC 62366 is the one that sets the detailed description for the usability engineering process for medical device manufacturers to apply, not only for the medical electrical equipment, but all medical devices. That is to say, when complying with IEC 62366, the medical device manufacturer meets the other mentioned requirements related to the usability issues.

According to the device in question, there are other directives beside the MDD, which may set requirements related to the usability. For example, the Machinery Directive (2006/42/EC) requires human factors and ergonomic design strategies. Further, there are ergonomics and human factors related standards, human-computer interaction standards, and alarm and warning standards that have not been included in the scope of this thesis.

2.3 IEC 62366

The primary standard that medical device manufacturers should follow to demonstrate the compliance with the MDD usability requirements is the IEC 62366 *Medical devices – Application of usability engineering to medical devices*, in conjunction with the ISO 14971 *Medical devices – Application of risk management to medical devices*. This IEC 62366 was published by International Electrotechnical Commission (IEC) first in 2007 and harmonized under the European MDD in 2008, it includes an amendment made in 2014. The standard has been revised by the first edition of standard IEC 62366-1 (2015) and the first edition of its complementary technical report IEC TR 62366-2 (2016). Although the new usability standard IEC 62366-1 was recognized by the U.S. Food and Drug

Administration´s regulatory authorities already in 2015 (FDA 2017), it has not been harmonized by the European Union by the time writing this thesis (Medical Devices 2017). The manufacturer may choose to apply the new version of the standard for providing the data and compiling a mapping file, that maps each clause of the old standard to matching clause(s) of the new version. Thus, all clauses of the old standard need to be covered and will be required at the current authority inspections in Europe. Various usability professionals in the field of medical devices speculate for the new standard IEC 62366-1 to be referenced in the list of European harmonized standards sooner or later, advising to apply the new version of the standard immediately. It is also pointed out, that the standard IEC 62366-1 has modernized the usability engineering process to be more efficient, and more robust to the wide range of user interfaces involved within the field of medical devices, without making any compromises to the safety. (Larsson 2016; Qserve 2016; Karn 2015; MD101 2015; Shortt 2015.)

In this thesis, the focus is on the new version of the standard setting IEC 62366-1 and IEC TR 62366-2 to be investigated more closely and leaving any further comparison between the old and the new standard out of the scope.

2.4 IEC 62366-1 Application of usability engineering to medical devices

This chapter presents the requirements for the usability engineering process as regulated in the medical device standard IEC 62366-1. The terminology and methodologies related to the usability and usability engineering are presented more closely in Chapter 3.

The first part of the usability standard, IEC 62366-1, strictly focuses on medical device usability as it relates to safety. It specifies a detailed usability engineering process required for the medical device manufacturing. The standard states the requirement for the manufacturer to establish, document, implement and maintain a usability engineering process to provide safety for the patient, user and others. These usability engineering activities must be carried out by personnel competent on the

basis of appropriate education, training, skills or experience. (IEC 62366-1:2015, Clause 4, 12-13.)

The usability engineering process is used as a tool to assess and mitigate risks associated with normal use of the medical device. It can be used to identify but does not assess or mitigate risks associated with abnormal use (IEC 62366-1:2015, Scope, 7). Normal use includes ‘correct use’, defined in the standard as ‘a use without use error’. In addition, the normal use includes use errors caused by ‘perception error’, by ‘cognition error’ or by ‘action error’. The perception errors mean failures in seeing visual information or hearing auditory information. The cognition errors again are memory failures, rule-based failures, or knowledge-based failures. Use errors caused by action error are failures to reach control, contact with wrong component, inappropriate force applied to component and failures to activate control. Abnormal use is not at the scope of the standard IEC 62366-1. It means exceptional violation, reckless use, sabotage or conscious disregard for the contraindications. Examples of all of these failures are presented in Figure 1. (IEC 62366-1:2015, 44.)

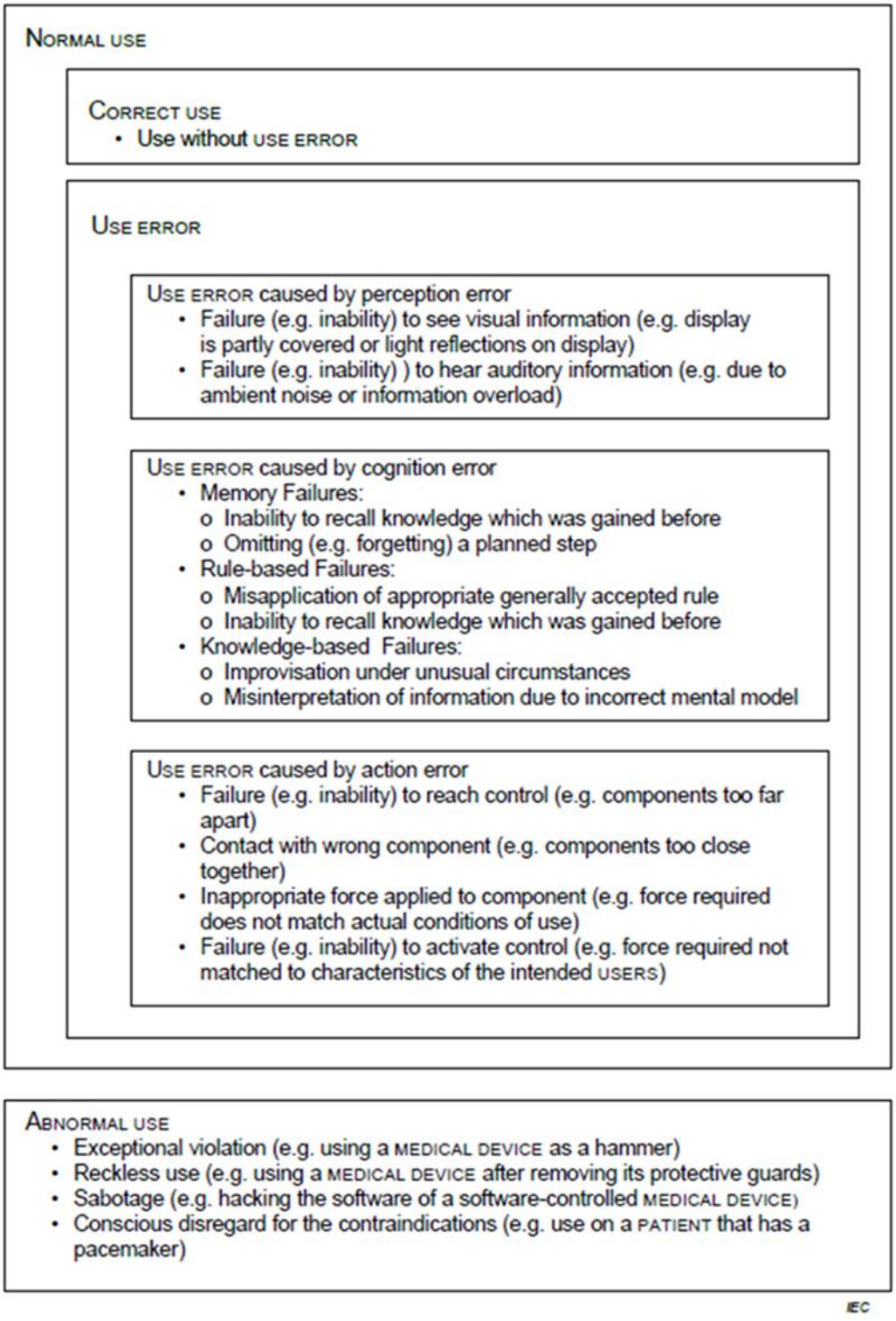

Figure 1. Interrelationships between the different types of medical device use, with examples (IEC 62366-1:2015, 44)

The main focus being on the safety of medical devices, the goal of the required nine-step usability engineering process is to identify and minimize use-related hazards at all possible stages of user interactions with the medical device. This statement includes, but is not limited to: transport, storage, installation, operation, maintenance and repair, and disposal of the medical device product. The standard describes the following nine steps of the usability engineering process in the logical order, but it is pointed out, that they may be carried out in a flexible order as appropriate:

1. preparing use specification
2. identifying user interface characteristics related to safety and potential use errors
3. identifying known or foreseeable hazards and hazardous situations
4. identifying and describing hazard-related use scenarios
5. selecting the hazard-related use scenarios for summative evaluation
6. establishing user interface specification
7. establishing user interface evaluation plan
8. performing user interface design, implementation and formative evaluation
9. performing summative evaluation of the usability of the user interface

Tailoring of the level of effort and the choice of methods and tools used to perform the usability engineering process may vary based on the product in question, considering e.g. size and complexity of the user interface or the severity of the harm associated with the use of the medical device. Essential is, that the manufacturer record the usability engineering activities in the usability engineering file (UEF) that becomes part of the required design history file for the medical device product. (IEC 62366-1:2015, Clause 4, 12-14.)

The usability engineering process is required to be closely related to the risk management process described in the standard ISO 14971. To reduce

the use-related risks, the manufacturer must use one or more of the following options, in the priority listed:

> a) inherent safety by design;
>
> b) protective measures in the medical device itself or in the manufacturing process;
>
> c) information for safety.
> (IEC 62366-1:2015 Clause 4.1.2, 13.)

If information for safety is used as a risk control measure for the medical device product, the manufacturer must ensure through the usability engineering process, that the information is “perceivable by, is understandable to, and supports correct use of the medical device by users of the intended user profiles in the context of the intended use environment”. (IEC 62366-1:2015, Clause 4.1.3, 13.)

2.4.1 Preparing use specification

The most important characteristics related to the context of use of a medical device product are identified in the use specification. These characteristics are defined by the manufacturer, based on the knowledge that is already available, and the knowledge that may be gained through user researches. Appropriate user research methods are selected, when needed, according to the medical device product in question, and possible open questions that need to be answered before the development of the product. At the early initial stage, the use specification can be as high-level as a preliminary draft of the statement of intended use. Later, the medical device use specification may be updated according to the findings of the user researches, to be the foundation for defining the user interface specification. The use specification characteristics that must be defined by the medical device manufacturer:

- **Intended medical indication** must be clearly specified. The user needs to understand the intended medical indication in order to determine whether a given medical device is appropriate for the patient at hand. This can include condition(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented.

- **Intended patient population** must be specified in order to define the limitations concerning the patient. This can include e.g. patient age, weight range, height range, health, or condition.

- **Intended part of the body or type of tissue applied to or interacted with** must be defined, if applicable to the product.

- **Intended user profiles** must be defined taken into account all humans that might handle, operate or interact with a medical device. This can include installers, engineers, technicians, clinicians, patients, caregivers, cleaners, sales, marketing, etc. It must be stated clearly if the patient is an intended user of the product or not. Factors that may effect on the use of the product are considered when developing a user profile, e.g.

  - age
  - gender
  - height
  - hearing
  - vision
  - computer literacy
  - values
  - motivations
  - linguistic and cultural background
  - level of education, experience and professional competence
  - training needed
  - potential disabilities of intended users

- **Intended use environment** must be specified for the product. The list of aspects that may need to be defined concerning the use environment are

  - sterile/non-sterile
  - single use or reusable (needing reprocessing between uses)
  - hospital use or home use
  - ambulance use
  - in hospital transport or wall mounted
  - general ward or operating theatre use
  - ambient lighting or noise levels
  - user´s personal protective equipment
  - temperature
  - humidity
  - light
  - noise

- **Operating principle**, i.e. physical methods used to accomplish the intended use of medical device and mechanisms by which it works are described.
  (IEC 62366-1:2015, Clause 5.1, 14; Subclause 5.1, 32-33.)

The most typical user research methods to this stage of usability engineering process are explained briefly in Table 1. If any user research is conducted, the results must be recorded in the usability engineering file. (IEC TR 62366-2:2016, Clause 8.4, 32-33.)

Table 1. Methods that can be used at the early stage of the usability engineering process. (IEC TR 62366-2:2016, Clause 8.4, 32-33)

Method	Description
Contextual inquiry and observation	An interview technique, which is conducted in the user´s actual workplace. The researcher observes users, while they are performing their tasks and discusses with them what they do and why.
Interview and survey techniques	Interviews and surveys can be conducted at any place and are not necessarily bound to the user´s workplace.
Expert reviews	Expert reviews can be a rapid means to identify the strengths and weaknesses (i.e. opportunities for improvement) of a comparable user interface. Such reviews can take various forms ranging in formality from an expert examining a medical device and citing its strengths and weaknesses in a brief memorandum to engaging several experts to review independently the medical device, identify potential improvements, prioritize the improvements, and then report their consensus findings.
Advisory panel reviews	An advisory panel typically includes 6 to 12 people who have diverse perspectives on the medical device in development. During an advisory panel review, the panel members discuss design considerations with the development team and can provide advice on design options.
Usability tests on comparable medical devices	The usability tests can identify the strengths and weaknesses of comparable medical devices and can provide an understanding of the mental model users have of the use of the comparable medical devices.

2.4.2 Identifying user interface characteristics related to safety and potential use errors

User interface characteristics that could be related to safety must be identified as part of a risk analysis. To identify the potential use errors, a task analysis or a function analysis may be conducted.

The task analysis produce detailed descriptions of the sequential and simultaneous manual and intellectual activities of the personnel who are operating, maintaining, or controlling the device or systems. Typically, a high-level task is defined first, and after that, the task is detailed in sub-tasks involved. A single sub-task is described to involve e.g. a sequence of steps such as acquiring information from a display, processing the information, making a decision, formulating an action plan, taking an action and acquiring feedback. The task analysis covers all user interactions with a product and it is conducted for each intended user profile. It includes the

consideration of the primary operating functions. The manufacturer should pay close attention to those tasks that have the potential to exceed the users´ capabilities and hinder the given medical device´s usability or cause unacceptable risk. (IEC 62366-1:2015 Clause 5.2, 15; IEC TR 62366-2:2016 Clause 9.2, 33.)

The function analysis is used to identify those functions a medical device should perform automatically or semi-automatically, functions that should be assigned only to users and functions that should be share between the medical device and the user. Typically, the manufacturer identifies first a medical device´s key functions, and then assigns the functions to the medical device or the user based on the known competencies of each. (IEC TR 62366-2:2016 Clause 9.2, 33.)

2.4.3 Identifying known or foreseeable hazards and hazardous situations

Known or foreseeable hazards and hazardous situations, which could affect patients, users or others, associated with the use of a product are investigated by:

- listing potential use errors by each intended user profile (see Chapter 2.4.2 Identifying user interface characteristics related to safety and potential use errors);
- reviewing historical internal post-production information on hazards and hazardous situations known for existing user interfaces of the former model of the device (if applicable), post-market surveillance, customer complaints and other available data on the former models of a similar product;
- reviewing publicly available databases (e.g. FDA Maude database) to find any known problems of the comparable products, if available.

The results of these findings must be handled in the risk management process of the product and recorded in the UEF. (IEC 62366-1:2015 Clause 5.3, 15.)

2.4.4 Identifying and describing hazard-related use scenarios

The manufacturer must identify reasonably foreseeable hazard-related use scenarios by further analyzing the previously identified hazards and hazardous situations. The description of each identified hazard-related use scenario must include all tasks and their sequences as well as the severity of the associated harm. Manufacturer should investigate not only specific tasks that the manufacturer intends the user to perform, but also other tasks and actions that the manufacturer does not intend the user to perform, but are reasonably foreseeable. These hazard related use scenarios result a list of the use-related risks that must be handled as a part of the risk management process. Also these are to be recorded in the UEF. (IEC 62366-1:2015 Clause 5.4, 15-16, Subclause 5.3, 34.)

2.4.5 Selecting the hazard-related use scenarios for summative evaluation

According to the standard IEC 62366-1 (2015), it is important for manufacturers to focus their attention and resources on the user interface elements that could have the most impact on users´ interactions with the medical device. In order to select which of the hazard-related use scenarios, if not all, to include in the summative evaluation, a selection can be based on

- the severity of the potential consequences of the associated hazards; focusing on hazards rather that risks because the probability of occurrence of encountering a hazard, which is one component of risk, can be very difficult to estimate, especially for a novel medical device for which no post-production data are available;
- the risk of the occurrence of harm to the patient or user.

The chosen hazard-related use scenarios to be conducted in the summative evaluation of the product must be presented and rationalized in the UEF. (IEC 62366-1:2015 Clause 5.5, 16; IEC TR 62366-2:2016 Clause 12.1, 38.)

2.4.6 Establishing user interface specification

User interface specification is a collection of design requirements that are specific to the medical device and describe the technical characteristics of its user interface. In particular: it includes design requirements for those elements of the user interface that are related to safe use including those that are risk controls. The user interface specification includes all means of interaction between the medical device and the user including both hardware and software interfaces. It may be defined as part of the user requirements or other specification documents (e.g. technical requirements might include display color, character size, or placement of controls), reference to these documents must be recorded in the usability engineering file. (IEC 62366-1:2015 Clause 5.6, 16.)

2.4.7 Establishing user interface evaluation plan

The plan for each usability test should be documented in the form of a protocol that explains the goals of and the methods to be used in the usability tests, including plans for the formative and the summative evaluations. As required in the standard IEC 62366-1:2015, Clause 5.7.1, such protocols include descriptions of the following:

a) participants in the usability test, to be representative of each intended user group;

b) test environment and other conditions of use, to be representative of the intended use environments;

c) the accompanying documentation to be provided during the usability test, if any; and

d) the training to be provided prior to the usability test, if any and the minimum elapsed time between the training and the beginning of the usability test.

The methods may be quantitative or qualitative. In addition to the methods described in Table 1 the user interface evaluation plan may consist of one or more of the following techniques: usability tests, expert reviews, heuristic analyses or a cognitive walkthrough. See the descriptions in Table 2. (IEC 62366-1:2015 Clause 5.7, 16-17; IEC TR 62366-2:2016 Clause 16.2, 53-55.)

Table 2. Methods that can be used in the usability evaluation (IEC TR 62366-2:2016 Clause 16.2, 53-55)

Method	**Description**
Usability tests	Exploring or evaluating a user interface with intended users within a specified intended use environment.
Expert reviews	Expert reviews depend on the knowledge and experience of usability specialists to identify design strengths and weaknesses and, subsequently, cite opportunities for design improvement. An expert review can be performed on design-concept sketches, working prototypes, and even medical devices already in use. In the case of an expert review of an unfinished design, many serious design shortcomings can be detected early and without incurring the higher costs normally associated with usability tests. However, if applied alone, this technique is unlikely to detect all of the design shortcomings.
Heuristic analyses	Heuristic analysis is a specialized type of expert review. The technique calls for one or more usability specialists to conduct an independent expert review of a given design's user interface based on selected usability engineering design heuristics. After identifying design shortcomings, each usability specialist estimates the degree of the shortcoming and describes in general terms a potential solution. Finally, the usability specialists compare their findings, develop consensus findings, and document their findings in a report.
Cognitive walkthrough	A cognitive walkthrough involves a researcher attempting to determine what is expected of the user by: – walking through a preliminary design completing the tasks as though the researcher is the user; – leading subject matter experts through these tasks; or – leading representative users through these tasks The goal is to determine whether users understand what they need to do for each task, sub-task or step and whether they understand when a correct or incorrect course of action has been taken.

User interface must be explored during user interface design and implementation conducting formative evaluations to identify the need for improvement or to confirm adequacy of the user interface. Intent is to explore user interface design strengths, weaknesses and find any unanticipated use errors. Formative evaluation is generally performed iteratively throughout the design and development process, but prior to summative evaluation, to guide user interface design as necessary. Formative evaluation is to be carried out to determine when no further iterations are needed and the product is ready for the final tests in summative evaluation. Formative evaluation can be conducted several times, but at least once, during design phase. It can be carried out on all aspects of the design, including instructions for use and training documents. (IEC 62366-1:2015 Clause 5.7.2, 17; IEC TR 62366-2:2016 Clause 16, 52-55.)

The final evaluation of the product is called summative evaluation. It is conducted at the end of the user interface development with the real end users and the final product featured with all the possible labels and the warnings, with the intent to obtain objective evidence that the user interface can be used safely. The summative evaluation plan shall consist all, or the selection of the hazard-related use scenarios. It must contain also the validation of the manual or instructions for use with intended users, if applicable. (IEC 62366-1:2015 Clause 5.7.3, 17-18; IEC TR 62366-2:2016 Clause 17, 55-57.)

2.4.8 Performing user interface design, implementation and formative evaluation

The user interface design and development should be conducted iteratively. Usability engineering, including formative evaluation(s), should begin early and continue iteratively throughout the product design and development process. Design and user interface requirements are updated if needed after (each) formative evaluation. (IEC 62366-1:2015 Clause 5.8, 18.)

2.4.9 Performing summative evaluation of the usability of the user interface

The summative evaluation is conducted to obtain objective evidence that the user interface can be used safely. If use errors by the users are found during the usability test, the root cause of each such finding must be identified. Both observations of user performance and subjective comments from the user related to that performance should be used to help identify the root cause. Any findings must be handled in the risk management process and record them in the UEF. (IEC 62366-1:2015 Clause 5.9, 19.)

2.5 IEC TR 62366-2 Guidance on the application of usability engineering to medical devices

The complementary part for the usability standard, technical report IEC TR 62366-2, presents broader aspects of usability of the medical devices. This technical report focuses not only on the usability as it relates to safety, but also on how usability relates to attributes such as task efficiency and user satisfaction, which can enhance a medical device´s commercial success. The technical report IEC TR 62366-2 does not contain requirements, it only provides guidance and tutorial information for applying usability engineering process required by IEC 62366-1, and as supporting goals other than safety. (IEC TR 62366-2 2016.)

3 USABILITY ENGINEERING

In the medical device standard IEC 62366-1 ‘usability’ is defined as

> *“characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency and user satisfaction in the intended use environment”.* (62366-1:2015 Clause 3.16, 10)

Further, it defines the term ‘usability engineering’, also used as a synonym for ‘human factors engineering’, as

> *“application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of medical devices (including software), systems and tasks to achieve adequate usability”.* (62366-1:2015 Clause 3.17, 11)

Another international standard, ISO 9214-11 Ergonomic requirements for office work with visual display terminals (VDTs) – Part 11: Guidance on usability, describes ‘usability’ as

> *”extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use”.* (ISO 9241-11:1998)

Noteworthy in the latter mentioned definition is the statement of the specified users, their specified goals and the specified context of use, in order to determine the effectiveness, efficiency and satisfaction of a product. These definitions need to be investigated more closely, as well as others related to the usability engineering terminology and methodology, by conducting a literature review.

3.1 Definition of usability

In the literature there is a wide range of definitions for usability. Jakob Nielsen (1993) deepens the traditional ‘user friendliness’ by describing broader issues to be considered relating to the subject. He defines usability to be a part of the system acceptability, which again is a combination of social acceptability and practical acceptability. Practical acceptability can

be analyzed further, according to Nielsen, within various categories such as cost, compatibility with existing systems, reliability, as well as the category of usefulness. Usefulness is described to be the issue of whether the system can be used to achieve some desired goal. In the Nielsen´s model of system acceptability (Figure 2), usefulness is broke down into two categories of utility and usability. Utility of the system is described as the question of whether the functionality of the system in principle can do what is needed, and usability again, is described as the question of how well users can use that functionality. (Nielsen 1993, 23-25.)

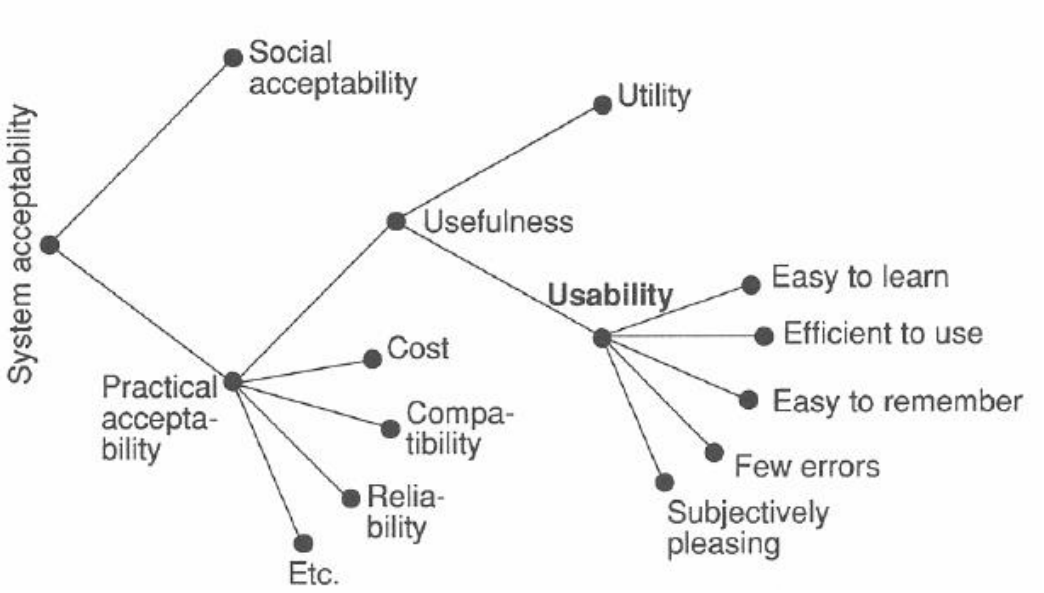

Figure 2. A model of the attributes of system acceptability (Nielsen 1993, 25)

Nielsen points out, that usability is not a single, one-dimensional property of a user interface. Instead, it has multiple components and is traditionally associated with five usability attributes: learnability, efficiency, memorability, errors and satisfaction (Nielsen 1993, 26). These usability attributes are explained by defining how they should be taken into consideration in the system as follows:

- *Learnability*: the system should be learned easily and effectively to accomplish basic tasks; it refers to novice user´s experience on using the system
- *Efficiency:* once user has learned the system, it should be efficient to use; it could even provide some additional advanced features for expert users to increase the level of their performance
- *Memorability*: the system should be easy to remember, so that it is easy to return to use after a period of not using it; casual users, using the system intermittently, should be able to remember how to use the system based on their previous learning
- *Errors*: the number of errors that could happen when using the system should be minimized, recovering from error situation should be easy, and catastrophic errors must not be possible to occur
- *Satisfaction*: the system should be pleasant to use

Nielsen (1993, 16) sees it useless to describe any detailed advice how to make an interface good. This is because of a wide range of different systems, products and user interfaces; no guidance would be enough to suite for all of them. Usability engineering process, on the other hand, can be seen well established and applying equally to all user interface designs. “Each project is different, and each final user interface will look different, but the activities needed to arrive at a good result are fairly constant”, Nielsen states. To achieve good usability in the final product, the usability engineering process has to be applied since the early stages of the product development before the product has even been designed (Nielsen 1993, 71). The same manner of approach has already been presented in this thesis by describing the standard requirements for medical device usability (Chapters 2.2-2.4). In the next chapter, the standard statements relating to the usability engineering process are complemented with wider literature references.

3.2 Usability engineering lifecycle

Usability engineering is described in the literature as a set of theories and methods that aims at making the interaction between user and device more efficient and pleasant. Sinkkonen et al (2006) state that usability relies on research done in the field of cognitive psychology, as well as research related to human-computer interaction. They remind, that psychology and the cognitive sciences have studied people and the way they function, including learning, recollection, motivation and alertness, for a long time. The basic psychological structures can be generalized, but information about group´s beliefs and skills can only be gained by asking or observing a representative of that group. It is pointed out to be essential, when developing a product, to gather knowledge of the users: who they are, what their goals are, where they use the product, what they are doing when they use it, and what demands all these factors place on usability of the product. (Sinkkonen et al 2006, 9; 11; 28.)

Xristine Faulkner (2000, 12-13) shares the vision of usability engineering as an entire process of producing usable products from requirements gathering to installation, paying close attention to the needs of users. The crucial step to be taken first in the product development process, according to Faulkner, is the same as described by Nielsen (1993) and Sinkkonen et al (2006): know the user (Faulkner 2000, 22). Faulkner presents, that designers must understand the user requirements, as well as the environment in which the product is to be used, to be able to design the product right (Faulkner 2000, 85). The same approach is required, as presented earlier in Chapter 2.4.1 of this thesis, also by the medical device standard IEC 62366-1 (2015). A solid understanding of users, their tasks and individual characteristics and differences, must be gained early in the development phase (Nielsen 1993, 43).

When considering the users, it is vital to understand their overall goals, all needed information to achieve these goals, as well as their current approach to the task, and the way they deal with exceptional circumstances or emergencies, Nielsen states when presenting a task

analysis (Nielsen 1993, 75-76). The task analysis should provide a clear understanding for designers of what the system must do, resulting as an appropriate design, Faulkner argues (Faulkner 2000, 63-64). However, understanding the user´s goals, according to Faulkner, should be considered even more intently (Faulkner 2000, 81). This is to say, a system must not necessarily follow the same tasks as the user performs; it can be designed to replace some of these actions while achieving the same goal, and this way enhance the overall performance.

The usability engineering process, as already noted, needs to be applied since the initial phase of the product development. When solid understanding of the users´ needs is gained, the usability engineering process provides methods to turn those needs into a usable product. In the Nielsen´s model of usability engineering lifecycle, there are several stages presented (Table 3). Not all projects can afford to use all of these; the extent of the needed usability engineering process depends on the characteristics of the project in question. An overall usability plan listing the usability activities to be performed throughout the lifecycle, should be established as early as possible in the project. Nielsen states the lifecycle model to emphasize, that one should not rush straight into design. (Nielsen 1993, 72; 112.)

The lifecycle model is presented also by Faulkner (2000, 15). The basic idea of usability engineering lifecycle model by Nielsen and Faulkner can be seen very similar to the nine-step process presented in the standard IEC 62366-1. In all of these aforementioned, the usability engineering process is iterative, starting from user research and keeping the end users involved in the entire product development process. The standard highlights the need to apply usability engineering process to minimize potential use errors, thus improving the safety and effectiveness of the device. Nielsen presents another approach by stating usability of each product contributing to the company´s general reputation as a quality supplier, when just a single product with poor usability can cause severe damage to the sales of the entire product family (Nielsen 1993, 72). This

wider perspective of usability is introduced also in the medical device guidance, IEC TR 62366-2 technical report (2016).

Table 3. Stages of the usability engineering lifecycle model by Nielsen (1993, 72).

Usability engineering lifecycle	
1. Know the user	a. Individual user characteristics b. The user´s current and desired tasks c. Functional analysis d. The evolution of the user and the job
2. Competitive analysis	
3. Setting usability goals	a. Financial impact analysis
4. Parallel design	
5. Participatory design	
6. Coordinated design of the total interface	
7. Apply guidelines and heuristic analysis	
8. Prototyping	
9. Empirical testing	
10. Iterative design	a. Capture design rationale
11. Collect feedback from field use	

3.3 Usability engineering methods

While usability engineering requires early and continuous focus on the users, there is a wide range of methods available that can be applied for different stages. Some of these methods are mentioned earlier in the Chapter 2 of this thesis, when describing the standard IEC 62366-1 requirements and suggested techniques for the usability engineering process (Chapter 2.4.1, Table 1 and Chapter 2.4.7, Table 2). Comparing different methods taking into consideration the costs versus the benefits is not at the scope of the thesis. Rationalization when choosing a certain usability method for a certain product has to be made according to the project and the product in question. There is a guidance for this in the literature, for instance Nielsen (1993) presents issues to consider when prioritizing usability activities (Nielsen 1993, 17, 112). As this thesis concentrates on the early user research and defining user requirements for the new medical device product, those methods suggested to be used at the early stage of the usability engineering lifecycle, are the ones investigated more closely here. The later stage evaluation techniques including the detailed usability evaluation metrics and usability testing methods are not studied detailed in this research, as they will not be applied in the empirical study of this thesis.

3.3.1 Ethnographical approach: observation

To begin with, this statement by Nielsen (1993,1) highlights the essentiality of observation as an early stage usability method: “Just a simple field trip to observe users in their own environment working on real-world tasks can often provide a wealth of usability insights”. Observation is argued to be a vital usability engineering method widely in the literature.

Wiklund and Wilcox (2005) provide a number of alternative approaches to the subject of medical device usability in their book. To understand the medical device users and the environment in which a medical device product is used, the ethnographical approach, observing the real users in the real use context, is stated to provide an advantageous approach. This

is, according to Wiklund and Wilcox, because ethnographic methods do not begin with the assumption that the researcher already understands what is going on, which again might prevent the real understanding. Observing the users help the developers to understand the product´s strengths and limitations from the user´s point of view. It is pointed out, that what people say, is in general only part of the story about user needs. The users´ behavior may reveal attributes related to the product performance even when the users don´t say a word. This approach is stated to yield typically richer, more vivid and concrete information compared with any other usability engineering method. One challenge, also pointed out to be a critical factor, when using the ethnographic method, is time. This method requires the researcher to spend a lot of time in the real use environment observing the users, because understanding what someone needs is a complex and time-consuming process. The ethnographic methods mean going to wherever real users routinely use the product making every attempt to learn from their activities. If the product is not yet available, the research is conducted by observing the users working with something like it, for instance, a competitor´s product, Wiklund and Wilcox suggest. (Wiklund & Wilcox 2005, 62-64, 69-70.)

3.3.2 Interviews

Interviews are not necessarily bound to the real use environment, they can be conducted at any place. They help to gather information on user´s knowledge, perceptions or opinions. Interviews can be conducted in a one-on-one manner or as group interviews. (IEC TR 62366-2 2016, 8.4.3; 31-32.)

Interview technique can range from structured to unstructured, and all stages between. In the structured interviews the users are asked questions and they are expected to answer by selecting from a given set of the responses. In the unstructured interviews the questions are open-ended, and the users may lead the discussion themselves to the direction of those issues, they see being important. Faulkner (2000, 42-43) presents the

semi-structured interview technique to be frequently the most useful. By using that, the interviewer can ensure that the necessary questions are been covered adequately, but also individual responses may be gathered from the interviewees. When conducting an interview, Faulkner reminds, it is essential to test questions carefully beforehand, to ensure the right set of questions.

3.3.3 Contextual inquiry

An ethnographic interview, contextual inquiry, is conducted one-on-one in the context of use of a product, while observing the users performing their tasks. It gains to understand the behaviors of the users interacting with specified products by asking clarifying questions about their tasks, what they do and why. Contextual inquiry is conducted with as little interference from the interviewer to the users´ routinely task performance as possible. (Wiklund & Wilcox 2005, 72.)

3.3.4 Competitive analysis

As stated earlier, Wiklund and Wilcox suggest observing users´ interactions with a competitor´s product, as one way to conduct an observation (Wiklund & Wilcox 2005, 63). Analyzing competing products is brought up as a usability method to be used at the early stage of usability engineering lifecycle also by Nielsen (1993, 79). Users performing real tasks using competing products make it possible to learn how well its functionality and interaction techniques support those kind of tasks that the new product is expected to support.

In some development project a competitor analysis may be applied by using an expert panel consisting of the stakeholders involved in the project. This means gathering their direct opinions on the strengths and weaknesses of the comparable products. The competitive advantages of each product are discussed to develop a list of issues that need to be addressed in order to compete effectively and those desirable features that the new product could include. (Nielsen & Mack 1994.)

A noteworthy issue to mention when considering the comperable medical device products, is to research external resources providing data on adverse events related to the similar devices. Incident reports on comperable products can yield information about problems that have occured in the past with similar medical devices and should be considered early in the new product design. (IEC TR 62366-2:2016, Annex B, 66-67.)

3.3.5 Heuristic evaluation

There is a wide range of usability guideline collections for the user interface developers to follow. Nielsen (1995) suggests the list of ten principles for each developer of any kind of user interface to follow (Table 4). This list of usability heuristics can be used as a tool to find usability problems of the early user interface design, calling it ‘heuristic evaluation’ method. It is typically conducted by expert evaluators by going through the interface several times, inspecting the various dialogue elements and comparing them with the list of the recognized usability principles.

Table 4. Ten usability heuristics by Jakob Nielsen (1995)

Heuristic principle	**Description**
Visibility of system status	The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.
Match between system and the real world	The system should speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information appear in a natural and logical order.
User control and freedom	Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue. Support undo and redo.
Consistency and standards	Users should not have to wonder whether different words, situations, or actions mean the same thing.
Error prevention	Even better than good error messages is a careful design which prevents a problem from occurring in The first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to the action.
Recognition rather than recall	Minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate.
Flexibility and efficiency of use	Accelerators - unseen by the novice user - may often speed up the interaction for the expert user such that the system can cater to both inexperienced and experienced users. Allow users to tailor frequent actions.
Aesthetic and minimalist design	Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.
Help users recognize, diagnose, and recover from errors	Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.
Help and documentation	Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, focused on the user's task, list concrete steps to be carried out, and not be too large.

3.3.6 Prototyping

In the product development, it is important to get the users´ feedback on the design at an early stage on the development project, so that it is possible to refine the design, if needed. It is advisable to use simulating of products in order to enable early user testing to be performed even before more sophisticated, working prototypes are available. (Wiklund & Wilcox 2005, 103-111.)

The first tests with the users can be conducted using ‘paper mock-ups’ or ‘storyboards’. These are usually based on paper printouts of the user interface, screen designs, dialog boxes and pop-up menus. Faulkner (2000, 101) argues to use rather paper-based than on-screen system prototypes. This is seen as a cheap, but effective method allowing designers and end-users to discuss the system together.

3.3.7 Usability testing

Usability test, also referred to as user testing, conducted with the real users is mentioned to be the most fundamental usability method. It is even described to be irreplaceable, since providing direct information about the users interacting with a certain product and exact problems there may exist while using it (Nielsen 1993, 165). In the usability test the users are asked to perform certain predefined tasks with the product and the researcher observes the test.

There are many test methods to follow when conducting a usability test, ‘thinking aloud’ being the most usable and widely used of them (Sinkkonen et al, 2006, 244). Thinking aloud requires the users to continuously verbalize their thoughts while performing the tasks.

The usability test may include a set of measurements to collect quantified data during the test. Such measurement methods contain e.g. the time users take to complete a specific task, the ratio between successful interactions and errors, the number of times the user expresses clear

frustration (or clear joy), just to mention a few of the list presented by Nielsen. (Nielsen 1993, 193-195.)

Usability problems found during a usability test are advisable to rate based on their severity. Nielsen (1993, 103) suggests the following rating scale, with a proposed advice how to deal with each type of error, presented in Table 5.

Table 5. Rating scale for usability problems by Jakob Nielsen (1993, 103)

Rate	**Description**
0	This is not a usability problem at all
1	Cosmetic problem only – need not be fixed unless extra time is available on project
2	Minor usability problem – fixing this should be given a low priority
3	Major usability problem – important to fix, so should be given a high priority
4	Usability catastrophe – imperative to fix this before product can be released

When catastrophic errors occur, they indicate that usability tests were started too late in the process, and will often demand extensive corrective procedures. While fixing minor errors is usually easy, fixing them can significantly clarify the system as a whole. (Sinkkonen et al 2006, 249.)

3.4 Medical device usability

The users should be able to use a device correctly and safely since the very first time they interact with it, argues Wiklund and Wilcox (2005, Foreword) when presenting a goal of excellent medical device. Further, they state, this could happen preferably without training or reading the manual. The advisable way to accomplish the noble goal is to concentrate on usability from the beginning to end of the development process. This approach is very similar to the approach presented in the standard IEC 62366-1, and so is their statement related to the use errors. It is pointed

out, that the designers must focus on minimizing the chance of use errors, giving users the opportunity to recover from error when they occur, and mitigating the adverse consequences of use error when they cannot be prevented. (Wiklund & Wilcox 2005, Foreword.)

Wiklund and Wilcox (2005, 171-179) have listed, together with other professionals in the field of medical devices, a set of design practices especially important for protecting against common use errors (Table 6). These guidelines, though incomplete, represent a reasonable starting point for designing an error-resistant medical device, they state.

Table 6. Design practices for an error-resistant medical device (Wiklund & Wilcox 2005, 171-179.)

Guideline	Description
Guard critical controls	Requiring a deliberate actuation of the control, like pressing or holding the power-on key to turn the machine on or off
Confirm critical actions	Giving users a chance to reconsider critical actions that are not easily reversed and to correct their mistakes
Make critical information legible and readable	Presenting vitally important information in a strictly reliable manner, like making text very large
Simplify and ensure proper connections	Making it physically impossible to insert the wrong cable or tube into a particular port, like using visual or tactile cues to provide additional protection by establishing associations, or mental dovetails, such as color- and shape-coded ports
Use tactile coding	Making devices and their associated controls recognizable by touch alone using tactile cues, including the feel of a switch, the force required to actuate it, and the distance the switch travels; adding audible clues, such as clicking and beeping sounds
Prevent the disabling of life-critical alarms	Preventing the turning alarms off, and also making alarms smarter
Present information in a usable form	Providing immediate or direct access for the users to information in its final, most usable form; using values in their appropriate units of measure
Indicate and limit the number of modes	Indicating a device´s operational mode so that it is apparent at a glance; limiting the number of modes to just a few that users can commit to memory
Do not permit settings to change automatically	Preventing device resetting or changing its operational state automatically, like returning unexpectedly to default values without the user knowing; minimally, indicating clearly any changes at the device display, which were not initiated by the user
Reduce the potential for negative transfer	Following the industry conventions or the standards related to a particular device, as well as those of other devices used within the same care environment
Design in automatic checks	Extending of device´s alarm system by adding software routines that detect possible use errors; like alerting users to unusual or potentially dangerous settings

4 MODERN OPERATING TABLES

Patient positioning is a critical component of a surgical procedure. The goal is to provide optimal visualization of and easy surgical access to the surgical site. Thus, different operations require placing a patient in a particular physical position. Surgical position must be safe to an individual patient taking into account each patient´s physical characteristics and condition. Consideration should be given to avoiding nerve and joint injury, mechanical trauma such as shearing, friction burns and damage to soft tissue, and ensuring that the patient is physically well supported. Moving and positioning patient requires coordination and cooperation from the whole surgical team, and using relevant aids and methods, to reduce potential injury to both personnel and patient. (Pudner 2010, 23-24.)

Operating tables consist of a table top, column, attachable sections and asseccories. The column of the table is either fixed to the floor, or the table is transportable with a trolley, and ‘mobile’ tables with their wheels. To meet the requirements of optimal patient positioning for different specialties, modern operating tables are modifiable, equipped with adjustable joints on the table top sections. The table tops are typically provided with side rails and a wide range of attachable accessories, to provide the ideal positioning for each operation, and each patient (Figure 3-4). Operating tables have to be adjustable also to improve work ergonomics of surgical team. (Lukkari et al 2007, 210-212.)

Figure 3. Mobile operating table Promerix™ by Merivaara Corp. (photo: Merivaara Corp., marketing brochure)

Figure 4. A variety of attachable sections and accessories of Promerix™ operating table (photo: Merivaara Corp., marketing brochure)

The electric adjustable movements of operating tables are controlled via corded hand control or remote control (Figure 5). Also foot control units are available for some operating tables, but those are left out of the scope of this thesis. A control panel is located in the side of the column of an operating table and provides similar functions to adjust the operating table (Figure 6). The control panel is typically used as a ‘secondary’ or a ‘back-up’ control unit, if the hand control or remote control is not available.

Figure 5. Remote control of the Promerix™ operating table (photo: Merivaara Corp., marketing brochure)

Figure 6. Control panel of the Promerix™ operating table (photo: Merivaara Corp., marketing brochure)

There are typically at least the following adjustments on modern electric operating tables, which are controlled via corresponding function buttons of the control unit: height adjustment up / down, Trendelenburg / reverse Trendelenburg, lateral tilt left / right, longitudinal slide towards head / feet, back section up / down, legs up / down and divided leg sections up / down. “Trendelenburg” here means a position in which patient´s feet are higher than head. In addition to the mentioned adjustments, many operating tables provide pre-programmed positions to be adjusted with pressing one button, such as ‘flex’, ‘reflex’ and ‘zero-level’, some of them containing also a button for pre-programmed ‘beach chair’ position (Figure 7). If the memory feature is provided in the operating table, the user may save the current adjusted position, and recall the same position later by using the memory button.

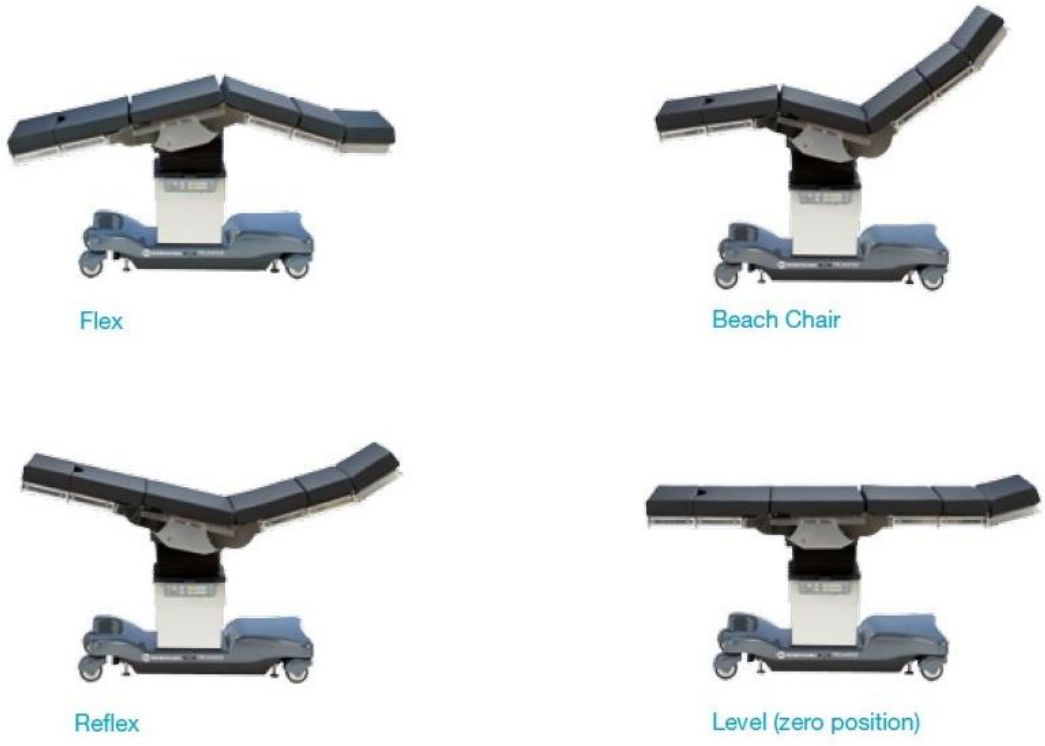

Figure 7. Pre-programmed positions of the operating table (photo: Merivaara Corp., marketing brochure)

5 EMPIRICAL STUDY

The focus of this thesis being on the early stage of the development of the operating table remote control, the aim of the research was to define the user requirements for it. Mechanical, electrical and software development, as well as graphical user interface designing, were left out of the scope concentrating exclusively on the usability designing. Prior to this research, there were many open questions to be answered, before designing the new remote control. Reliable knowledge on the operating table use and end users was needed. The usability methods selected for this purpose are presented and justified individually in this chapter.

5.1 Adaptation of the competitive analysis and expert panel

The researcher had no earlier experience of the operating room environment or operating tables. Thus, it was essential for her to conduct a competitive analysis first to gain overall understanding of the operating tables, and especially of the remote controls available in the market. This can be seen as an initial research phase of this thesis.

Five manufacturers´ operating tables were investigated via internet and marketing brochures, concentrating on the functions and features of the remote controls. Those were analyzed and compared in detail, resulting in a picture of the current state of the competitive products. The researcher presented the findings for the stakeholders, and an expert panel, in this case meaning the project team of the new product, discussed the results. Interesting features were listed for further consideration:

- providing display on the remote control
- providing a touch screen
- displaying continuous table status on the remote control
- displaying numeric values of the adjusted position
- displaying tilt angle on the remote control
- displaying picture of the adjusted position of the operating table
- displaying warning messages on the remote control

- displaying battery status
- displaying table and column lock status
- providing adjustable speed for the user to select
- the number of the memory positions available
- providing preprogrammed positions
- providing backlight on the buttons
- providing language selection

The expert panel also discussed the open questions there were related to the operating table use. This was to obtain a consensus of opinion on the most important issues for this research. Based on the discussions with the stakeholders, the researcher then developed the questions for the interviews to be conducted with the end users during field study (Appendix 8). These included questions related to e.g. use of the preprogrammed positions and memory feature, opinion on the symbols of the buttons and the way the buttons were located on the remote control. It was also stated to be essential to find out which features, in the users´ opinion, made for good or poor usability, and if there were any features they would like to add to the remote control to make it even better for their work. The goal was to gain design input from the users for developing a new remote control.

5.2 Semi-structured interviews

The interview technique chosen for this research was semi-structured interview. This was to ensure that all interviewees were asked the same set of questions, but there was also room for individual responses and wider discussions. The questions for the semi-structured interviews were prepared to cover the topics of the research questions of this thesis and later, by analyzing the results, answer to those research questions. The questions were tested with the target respondents at a hospital, which was not part of the final research. The testing of questions is mentioned to be vital to ensure that the interviewer asks the right questions (Hirsjärvi & Hurme 2000, 72-73). It was noticed to be essential in this research too by

guiding the researcher to reshape the questions to be asked, as well as to change the order of the questions, and to ensure the focus is on the right target respondents, before the actual interviews took place.

The target respondents for the semi-structured interviews were the end users of the operating table remote controls. This target group included medical professionals working in the operating room, i.e. surgical nurses, scrub nurses, anesthetist nurses, anesthesiologists, surgeons and residents. Operating theatre practitioners were seen as important respondents in this research, since they are involved in patient positioning, thus using the operating tables and the remote controls. Cleaners were considered to be target respondents too, though it was obvious that they need to use only limited functions of the remote controls. The respondents were asked a permission for recording the interview.

5.3 Observation

Wiklund & Wilcox (2005, 85) argue, “what people say provide only part of the story about user needs”. Further, they state that the observational techniques are essential to complement the understanding of the user needs. The users may not always be able to tell about the usability problems they have had when using the device. The users might not even remember the common errors which they have faced with the device or the difficulties they have had as novice users, when learning how to use certain features of the device. The users may fail to mention how small percentage of the functionality of the device they are currently using. (Wiklund & Wilcox 2005, 89). The observation applying the ethnographic approach that was used in this research was seen as a useful way to find out the gaps there might be between what users say and what users do. It was also seen essential for the researcher to be able to understand the use environment, use cases and the users.

The field studies were planned to be conducted in various hospitals, spending a full day at each of them. To get the best understanding of the operating table users working in the different operating room environments

with specific demands, it was seen preferable to conduct observation in the operating rooms of different surgical specialities (e.g. ocular surgery, neurological surgery, orthopaedic surgery). The target number of hospitals for this research was set to be ten. User profiles to be observed in the field studies were the actual users of the operating table remote control.

The documenting was made by the author using notes and photographing the use environment, operating tables and remote controls, paying extra attention that there were no operating room personnel or patients presented in the photos.

5.4 Field study data analysis

Hirsjärvi and Hurme (2000) remind that the researcher should plan carefully how to analyze the data prior to conducting the field study. Further, they suggest the researcher analyzes the data, e.g. transcribes the interviews, as soon as possible after the data is collected. Hirsjärvi and Hurme write that the 'fresh material' inspires the researcher better. Furthermore, they point out that if there is something missing from the collected data that could be complemented more easily straight after the interviews. On the other hand, the researcher should be able to view the data on the wide perspective, and this may take time in the analyzing phase. (Hirsjärvi & Hurme 2000, 135-136.)

In this research the data collected through the field studies was analyzied using the qualitative approach. The researcher transcribed the interviews mostly after each field study day, or the day after that. The answers were written from word for word to an excel table, recording answers from one hospital to one sheet in the excel document. Any comments that were not directly related to the question, or seen overall important to the subject in question, were left out of the results table. The researcher also summarized the answers in a shorter form, when required, paying attention not to confuse the actual point stated by the interviewee. This was to keep the results table clear, and to make it more convenient for the

researcher to analyze the data further. The answers were arranged according to the questions, and grouped by the themes (Chapters 7.1-7.8).

The observational data was already in written form, in the notes made by the researcher at the surgical departments. The most important issue about this observational data was the instant feedback to the researcher gained by analyzing the data already at the field study, while observing the users. It was essential for the researcher to get to know the users, in the real use context. The observational data was analyzed later as a complementing part to the interviews, but it also resulted in some new insights. The observational data is written in the results sections separately (Chapter 7.9).

5.5 Ethical considerations

The ethical considerations are stated in this chapter according to a guidance book written by Olli Mäkinen (2006). This includes all phases of the research: planning, conducting and reporting the research.

The research permission for the field studies was applied literally according to the procedures of each hospital, including the written thesis proposal of the research and the confidentiality agreement. In the field studies there was no direct contact to the patients of the hospitals. The patients were not interviewed, photographed nor disturbed in any way. The observational field studies in the operating rooms were conducted as unobtrusively as possible. Participation of all respondents was voluntary. The respondents gave their answers anonymously, and their privacy will be kept when handling the results and publishing the study. The background details of the respondents that were asked in the end of the interview are as follows:

- age group (<20, 20-29, 30-39, 40-49, 50-59, >60)
- gender
- professional status
- work experience in the operating room (years)
- surgical specialty
- the name of the hospital area

The research material gathered is used only for the purpose described in this thesis. The material will be kept private and archived by the researcher. The names of the hospitals participating in this research will be kept only for the researcher for recording purposes, and they are not published in the thesis.

The researcher had no financial relationship with the commissioning company while conducting the research, though travelling expenses for the field studies were paid by Merivaara Corp.

5.6 Trustworthiness

In addition to the ethical considerations stated in the previous Chapter 5.5, it is essential to evaluate the trustworthiness of the research possessing a qualitative approach. According to Tuomi and Sarajärvi (2003, 129, 135-138), trustworthiness is based on the researcher observering “good scientific practice”. They argue that it is the researcher´s responsibility to give reliable answers for the reader, related to the research and data collected. They suggest a set of nine aspects to be evaluated (Table 7).

Table 7. Trustworthiness evaluation in this thesis according to Tuomi and Sarajärvi (2003, 135-138).

Aspect	Implementation in this study
The object and purpose of the study.	The object of this study were operating table remote controls. The purpose of the study was to find out which features of the operating table remote controls are important to the users, and which features have an effect on the usability of the operating table remote control. Especially issues dealing with safety were considered. The research aimed to create user requirements for a new operating table remote control of Merivaara Corp.
Your own commitments as a researcher in the study.	The secondary purpose of this study, a subjective target for the researcher, was to gain a solid understanding of the current legislation and regulations related to the medical device usability, and gather an inclusive knowledge of different usability engineering methods to be able to plan, execute and report them in the product development process. The researcher had noticed the need for usability engineering at her work as a software testing engineer in the field of medical devices, and wanted to be able to apply the usability engineering methods fully at her work in the future.
The data collection.	The research took place in June - July 2016 at ten hospitals (six hospitals in Finland, two hospitals in Denmark and two hospitals in Portugal). The interviews were semi-structured, and the questions were planned with the help of the Merivaara Corp. project team and the researcher´s tutor. The interviews were conducted one on one, at the surgical department, mostly in the operating room, where the respondents were holding the remote control and even adjusting the operating table while answering to the questions. The interviews were recorded using the author´s mobile application in the interview situation, if appropriate. Otherwise, the researcher wrote the answers down and checked separately that the answer was recorded correctly to the notes. Transcribing was performed after each field study day, or the day after that. Observation was conducted at the hospitals to complement the semi-structured interviews. The researcher took notes while the users performed their tasks in the operating room. She also photographed the use context, use environment, operating tables and the remote controls, when appropriate. Patients were not interviewed or photographed.
The study data suppliers.	The target respondents were the end users of the operating table remote control including medical professionals working in the operating room, i.e. surgical nurses, scrub nurses, anesthetist nurses, anesthesiologists, surgeons and residents. Also operating theatre practitioners were the target respondents, as they are involved in the patient positioning and use the remote controls. Cleaners belong to the target group, as they are the users of the remote control too. The interviewees were selected from the target users mostly by using the application of so called 'snowball sampling'. This means that the researcher invited the first target user for the interview at each field study location by herself, and after interviewing the first one, she or he was asked to suggest the following person for the interview. Participation was voluntary, and the answers were given anonymously.

Aspect	Implementation in this study
The study data suppliers (continued).	In addition to the interviewed persons, there were also a number of other users, which were not interviewed, but only observed while they were performing their tasks in the operating room. Some of the users were both observed and interviewed.
Researcher - data supplier relationship.	The researcher had no earlier experience of the operating room environment. The end users had a friendly, co-operative attitude towards the researcher, and most of them wanted to explain their answers in detail (even by adjusting the operating table to show, or test, how it worked) to make the researcher understand their point correctly.
Duration of the study.	Interviews took place in June - July 2016, transcriptions and analyzing the data in August 2016. The first version of the results report took place in September 2016, when the researcher presented the findings at Merivaara Corp. The final version of this thesis is written in April 2017.
The data analysis.	The transcribed interview data was analyzed using the qualitative approach. The answers were grouped by the themes, i.e. collecting similar answers under the same theme. The observational data provided mainly complementary results to the grouped themes, but also new findings were brought up. These were reported separately. The numeric value (% of the given answers) were calculated only for those issues which were related to the most used buttons (or those buttons, which were not used at all). The results are reported in Chapter 7, presenting the results of the interviews in 7.1-7.8, and the observational results in Chapter 7.9.
Reliability of the study.	The interviews were made according to an interview guide, to ensure every interviewee was asked the same set of questions. Still, there was variety in the order of the questions, as well as in the wideness of the discussions. With some respondents the researcher was able to discuss the operating room issues in a wider perspective, and ask more questions related to the surgical operations overall. From the researcher´s viewpoint, it was very fruitful and instructive. With some other respondents only the set of preplanned questions were presented, because there was no more time for the interview, or the respondent did not seem to be willing to spend any “extra” time at the interview. If the interviewer had been somebody other than the researcher, the interview situations would have been different: e.g. if any extra questions had been asked or not, and which those questions would have been. Observational study would probably have resulted in a partly different outcome, due to the fact that there was no firm plan which activities the researcher would record during the observational study.

Aspect	Implementation in this study
Reliability of the study. (continued)	The fact that the research was conducted in Finland in Finnish, and the answers were translated later into English by the researcher, may have had a minor effect on the quotations stated in Chapter 7. In Denmark and Portugal, on the other hand, the language used in the interviews was English, which may have had a minor effect on the answers given by the target users. Still, the answers of the interviewees were seen as very important to complement the results. For this reason, a lot of quotations are included in the results chapter. About the generalization of the results of this study, it can be stated to give a good insight into the users of the operating table remote controls. There were participants involved in this research from three different countries, ten different hospitals, and presenting several different surgical specialties. There were novice users, casual users and expert users involved, both female and male, possessing different professional statuses and belonging to different age groups. These are the factors that make the viewpoint of the research wider. Any private medical clinics were not involved in this study. This could be seen as a further phase for the research to find out if any new user needs would be brought up in a field study conducted at a private medical clinic.
Reporting of the results	See Chapter 7 for the results and Chapter 8 for the conclusions.

6 FIELD STUDY IMPLEMENTATION

6.1 Field study places and time schedule

The target number of the hospitals set in the planning phase for this study was ten, and it was met. Eventually, there were six hospitals in Finland, two hospitals in Denmark and two hospitals in Portugal involved in the research.

The field studies were conducted during the time period of 6 June – 20 July 2016. The author of the thesis spent one working day at each hospital, from 7.30-8.30 am to 3.30-4.30 pm. In one hospital, the field study was conducted spending two days, at two separate surgical units. The results of these two surgical units are presented separately in the results. Thus the eventual number of the observation days, and the number of the field study sites, is 11, though the number of the hospitals involved in the study is ten.

There were both central hospitals and university hospitals involved in the research, no private hospitals or clinics were visited. The number of the central hospitals was seven and the number of the university hospitals was three.

In the planning phase, one of the most important issues concerning the field studies was the aim to conduct the field study research in hospitals observing various surgical specialties to gather a wider perspective of the different use contexts. This goal was met during the study, too. During an observation day, it was usually possible to observe many kind of operations, according to the schedule of the surgical unit.

Surgical specialties that were observed in the study are listed below:

- Endocrine Surgery
- Eye Surgery
- Gastroenterology
- General Surgery
- Gynaecology
- Neurologic Surgery
- Ophthalmologic Surgery
- Orthopaedic Surgery
- Urology

In the planning phase of the research it was decided that the hospitals for the field study are not limited in any way according to the manufacturer of their operating tables. The basic functions of all operating tables and the remote controls are the same. Further, it was considered a fruitful aspect to include a range of remote controls to be evaluated in the research. At those hospitals which were involved in the field study, there were operating tables from five medical device manufacturers, Merivaara Corp. being one of them. The only demand for the operating table considering this study was that the table was controlled via remote control or via hand control. All hospitals involved in the study used mostly operating tables fulfilling this demand. Still, in some of the hospitals there were a few operating rooms equipped with older devices. In such cases, the operating room tables were adjusted and controlled manually, and therefore these operating rooms were not involved in the observation at the hospital.

6.2 Semi-structured interviews

The target number of the semi-structured interviews (later ‘interview’) on each observation day was three. This target was met, except in two hospitals, where only two interviews were conducted. This was due to the busy schedule at the surgical department during the observation day, and the fact that no more target users were available for the interviews. In three hospitals, up to eight interviews were conducted during a field study day.

The total number of interviews was 63. The interviewees were selected from the target users by applying the so called ‘snowball sampling’. This means that the researcher invited the first target users for the interviews at each field study location by herself, and after interviewing them, they were asked to suggest the following persons for the interview (Hirsjärvi & Hurme 2000, 59). This was essential for the researcher in many field study places, because otherwise it would have been very difficult to find the available medical professionals for the interview at the busy scheduled surgical department.

All interviews were conducted at the surgical department, most of them in the operating room. All but one of the interviews were conducted so that the interviewee was able to see and hold the remote control of the operating table while answering the questions.

In 53 cases of all interviews the evaluated control device for the operating table was a cordless remote control. In ten interviews a corded hand control of the operating table was evaluated, due to the fact that in certain operating rooms the corded ones were used. In the interviews this was taken into consideration by proposing the questions using a term ‘hand control’. Later in this thesis however, the term used in the results chapter, is a ‘remote control’. If there is a specific issue related to those answers concerning only the corded hand controls, it is expressed separately.

The users were encouraged to take their time to think about the questions and also use the remote control to adjust the operating table, if needed while answering. An interview took from 10 minutes to one hour depending on the schedule and attitude of the interviewee. Some of the interviewees explained their answers by showing the operating table functions to the author while answering the questions. During the interviews, some clarifying questions needed to be asked besides the 15 main questions, to ensure that the answers were understood correctly. Some of the interviews had to be split in two or more parts, because the interviewee completed some tasks at the operating room in the middle of the interview.

In Finland the interviews were conducted in Finnish and in Denmark and Portugal in English. The interviews were recorded by the author´s mobile phone´s recording application, when appropriate. Some of the interviews were conducted in occupied operating room in circumstances where the recording was not possible. In those cases, the author took more time to write each answer down and checked afterwards with the interviewee that the answer was correctly understood and recorded to the notes.

The total number of the interviews being 63, the professional status of the interviewees was as follows

- Surgical nurses 29
- Operating theatre practitioners 15
- Nurse anesthetists 12
- Anesthesiologists 5
- Cleaners 2

There were 45 female and 18 male participants in the interviews. Age and gender distribution is seen in Figure 8.

The participants had all together 818 years of working experience in the operating room environment. The distribution of the working experience is presented in Figure 9.

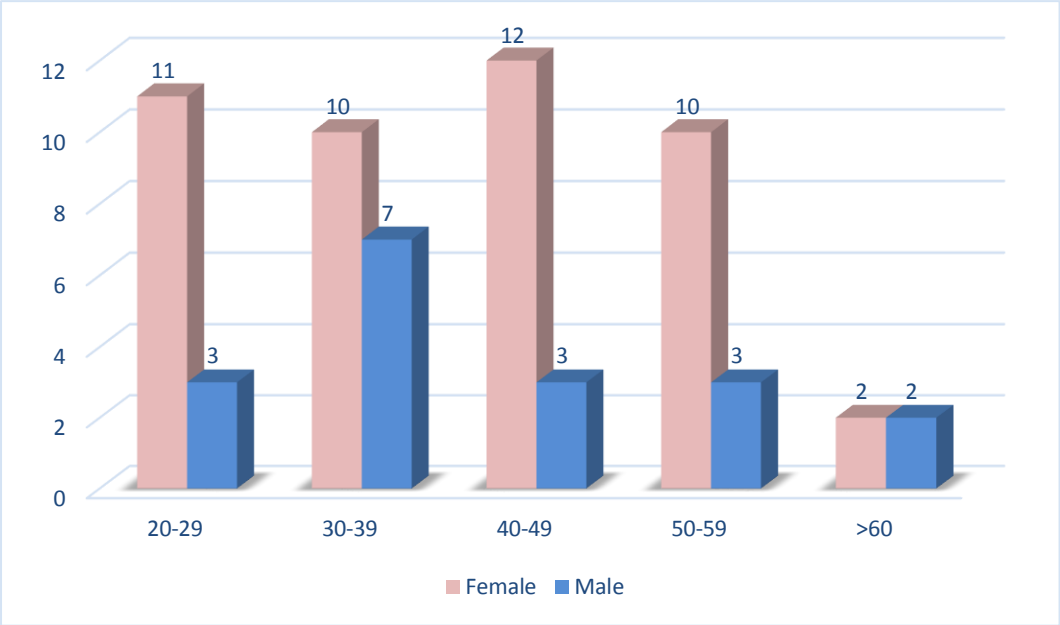

Figure 8. Age and gender distribution of the interviewees

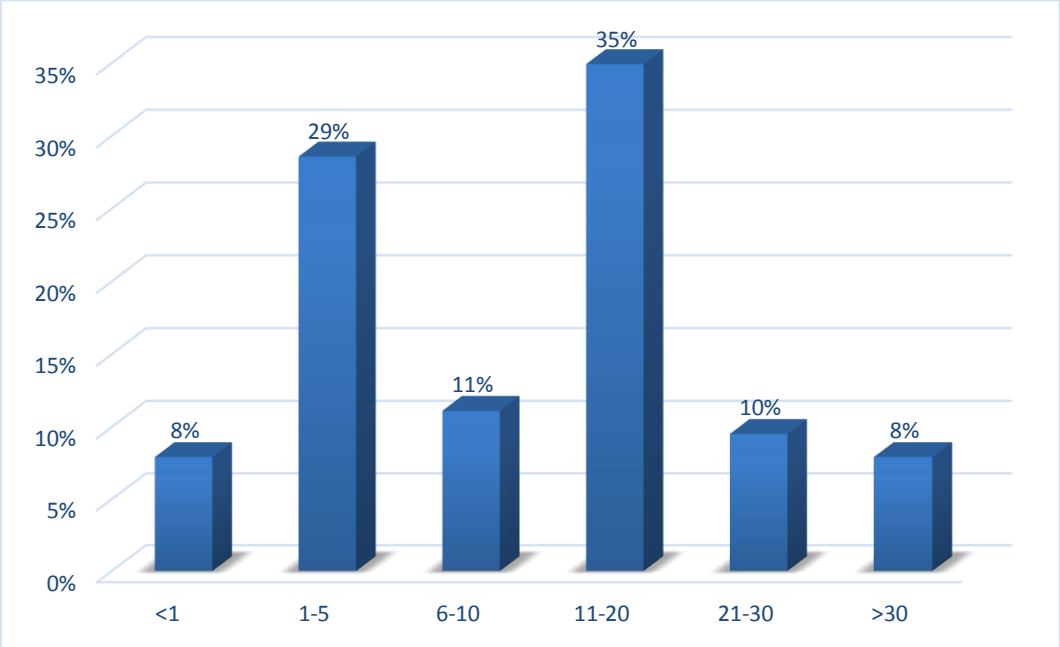

Figure 9. Working experience (years) at the operating room

6.3 Observation

Observation was conducted at the operating room by observing the operating table users. Practically, the researcher stood in a corner of the operating room taking notes during all phases of the surgical procedures, including the following

- the operating table was prepared for the next patient by attaching the needed accessories
- patient arrived in the operating room and was helped to move onto the operating table, and prepared for anesthesia
- patient was positioned for the operation, including the operating table adjusting
- surgical operation, including table adjusting, when needed
- patient position was normalized to the horizontal level
- patient was transferred to the hospital bed or transported with the table top to the recovery room
- cleaning procedures

Here are some examples of the operations which the author was observing: a discectomy, a tonsillectomy, a brain tumour surgery, a thyroid surgery and a C-section. In some of the operations, the author was observing only the patient positioning, when the operating table was adjusted, and in some operations the author was observing all of the earlier mentioned phases of the surgical operation. Photographs of the operating room environment, operating table and the use cases were taken, when appropriate. These photos were for the author only to help in analyzing the results. The photos are not published in this thesis.

7 RESULTS

The results, consisting of the answers to the 15 questions of the semi-structured interviews, are presented in this chapter by grouping the answers by themes. The direct quotes, the interviewees´ answers, are stated to illustrate the findings of a certain theme. The observational study provided mainly complementary results to the grouped themes, but the findings are presented separately. This is to keep it clear which are the comments given by the interviewees, and which are the notices made by the author. The answers are grouped as follows:

- Frequently used functions
- Rarely used functions
- Features which made a good remote control, in users´ opinion
- Features which were seen as frustrating or poor usability
- New features the users would like to see in the remote control
- Usability of the control panel of the operating table
- Usability of the other features of the operating table
- Adverse events related to the operating table
- Observational results

7.1 Frequently used functions

The results reveal that the most frequently used buttons of the operating table remote control are the table height adjustment, “Up / Down” buttons. This answer was given by 62 users (98%), only one of the interviewees did not mention this function as the most important one. Thus, the height adjustment was used by all professional groups: surgical nurses, operating theatre practitioners, anesthesia nurses, anesthesia doctors and cleaners.

> *“I don´t use this remote control very much… I do drive the table top up for the cleaning with this “Up” button.”*

The second most frequent answer, the “Trendelenburg / Reverse Trendelenburg” buttons, was answered by 46 participants (73%). In critical situations where the patient´s condition gets suddenly worse, the

“Trendelenburg” button, for adjusting patient´s head lower than feet, was said to be the most important. This button was used by the medical professionals. The cleaners, obviously, did not use Trendelenburg at all, nor any other buttons that were related to the patients´ position.

> *“This Trendelenburg is the most important button that we need to use in the case of emergency situations, if the patient´s condition changes quickly.”*

Other functions that were used frequently were longitudinal shift “sliding towards head / feet” (22 users, 35%) and “Tilting left, right” (21 users, 33%). These were used by the anesthesia professional and those of the users responsible for patient positioning. The later mentioned group also answered that “legs up/down” or “one leg up/down”, as well as “back up/down” are used too, when adjusting the patient to the desirable position for the operation.

> *“The adjustments are made totally according to the operation in question! Sometimes it is not needed to adjust the table at all, but we have also operations where it is necessary to adjust the table with many buttons, each part separately, bit by bit. All of these function buttons are important, in my opinion.”*

“Zero” button was not mentioned to be the most often used button at first, but when users were separately asked if they use the function, over half of the users (35 users, 56%) said they actually do need it at their work and use it often.

> *“Couldn´t this “Zero” button be colored with different color too, so it would be easier to find it among other buttons? It is needed very often and I really have to search for it each time!”*

7.2 Rarely used functions

Factory preset positions “Reflex” (6 users, 10%) and "Flex” (8 users, 13%) were used rarely, only by very experienced users of the tables. These buttons were not available in all of the evaluated remote controls, but users were asked to evaluate if they would use the functions or not, if they

existed. “Beach chair” adjustment was available in one of the remote controls, but none of the 8 users had used it.

> *“I know that some users use the preset features, but I am not used to using those. I don’t even know how these work.”*
>
> *“I can do the same adjustments by adjusting the sections separately, so I have not needed any of these preset functions.”*
>
> *“I use Flex and Reflex sometimes, because the positioning is faster with these!”*

The memory / recall feature was available only in 35 cases. All 63 users were asked to evaluate if they would use the memory features, if such features existed. Only one user out of all 63 interviewees said that the memory feature is used in certain surgical operations (kidney operations). A few users said they might use the feature for certain operations but have not done that so far, even it had been possible. The most common answer was that the memory / recall features are not needed, because the size, the condition and the physical characteristics of the body are individual for each patient, and each patient positioning had to be made for the certain operation and for the certain surgeon by adjusting the operating table carefully bit by bit. Many users felt that the whole memory feature is a safety risk, considering the large number of users that have to use the operating table and especially considering the beginners. A couple of the users had a positive insight and said that the memory functions could be used to help the beginners to preadjust the position for a certain operation.

> *“There is no need, or even possibility, to use any memory feature! Adjustments have to be made for each patient, operation and even for each surgeon separately every time to guarantee the patient safety!”*
>
> *“In my opinion this memory feature is a safety risk for the patient! I think that it could cause really dangerous situations, if someone, would accidentally press the memory position adjusting the operating table to an unwanted position!”*

> *“Maybe this memory function could be used for prepositioning the patient for certain operations or with a certain surgeon, and helping this way especially beginners or those users who are not that familiar with adjusting the table.”*

The buttons to reverse the table orientation were used only by the frequent users. Most of the other users did not know the function properly, and it was said to be a confusing feature of the operating table that often caused uncertainty among the beginners.

> *“This reversing table orientation: it´s a very confusing feature in the table, it is not known by all users.”*

The buttons that were not used at all were buttons without a clear, understandable symbol or text. Such buttons were e.g. green, blue, orange or red buttons without any text or symbol. Also the buttons with only one letter e.g. “F” or “V” were not used. Users did not know what these functions were meant for. “Stop” and “Off” buttons were not used either, and users did not see the purpose for those.

> *“I have no clue what happens with the blue button, or with the red one!”*

> *“I don´t really know why there is this STOP button. The movement of the table stops when I release the button anyway.”*

Other functions that were not used at all were those behind the display. Such functions are meant to be used by touching the touch screen and selecting the desired function from the display, or by pressing the buttons below the display. Typically users did not know which functions there were hidden behind the display, or they knew, but did not want to use those functions.

> *“I don´t even know which functions there are! I have never even tried to use that display.”*

> *“I know that there are many features and functions, but I don´t know how to use them.”*

7.3 Features which made a good remote control, in users´ opinion

The users answered that a good remote control of an operating table was very simple, not containing too many buttons, and that there must not be any “unnecessary” buttons or functions. It was mentioned by several interviewees that there may be dozens of users of the remote control and many of those are not frequent users (e.g. emergency duty). The remote control had to be as easy and simple as possible, so that even the beginners are able to adjust the operating table safely. The most needed functions had to be easy to find at the first glance, the users said. It was important that the most used functions were also ergonomically easy and pleasant to use.

> *“Less is more! Keep it simple!”*
>
> *“The remote control must not be the main thing here! It is needed among many other devices at the operating room. It has to be simple and easy to use for everyone, not too many features in it!”*
>
> *“The height adjustment buttons should be placed either to the top or to the bottom of the remote control. Now these “up” and “down” buttons are in the middle of other buttons and I have to search for them each time I need to use them.”*

Clear, logical symbols and pictures for each and every function were defined to be very important for the usability. The most important button in the emergency situation according to the users, “Trendelenburg”, has to be found quickly by everyone. It was mentioned to be a very good feature in the remote controls that the “Trendelenburg” button was colored yellow/orange/red to make it visible among other buttons of the remote control. Some users felt that texts beside symbols and pictures are useful and really help the user, but the others pointed out that the symbol itself had to be clear enough. It was also mentioned that if the text was only in English, it was not helping those users who did not speak English.

> *“This symbol would be easier to understand, if only the moving part of the table would be marked with a different color. Now it is not that obvious to understand the function of the button, because the patient image is colored too!”*

> *“What happens with this blue button or with the orange one…? I have no clue!”*

> *“I don’t understand English. These English texts beside the buttons do not help me.”*

The answers revealed that sometimes the operating room is darkened during the operation. It was seen as a good feature if the remote control or the buttons of the remote control were lighted to assist the work in the darkened room.

> *“More and more of our operations are conducted in the darkened operation room. Of course it helps a lot, if there are lights in the buttons of the remote control.”*

The remote control has to be very robust, because it drops easily to the floor, the users told. A proper and robust hook of the remote control was a valuable feature too, so that it is easy for the user to put the remote control hanging on the side of the anesthesia table or the operating table or wherever desired.

> *“The remote control drops easily to the floor and also gets collided to the other devices or equipment of the operation room. The remote control must be very robust!”*

The physical form of the remote control was mentioned too. A big size was mentioned to be a positive thing, because a smaller one would be lost more easily at the operating room. A good usability feature of the remote control, in the users´ opinion was, if it could be easily used with one hand. It was described to be very important in some situations, because the other hand of the user was e.g. holding the patient. The remote control must fit easily in hand and must not be too heavy to hold, even if the adjustment takes some time. Users do not usually wear gloves when using the remote control, though it was said that using right-sized gloves does not make any difference in pressing buttons or using the remote control.

> *“Absolutely the remote control has to be used with one hand only! I may have to support the patient´s head or leg or some other part of the patient´s body with the other hand, and at the same time to adjust the table. It is very important!”*

> *“All needed buttons must be easily available with one hand. I have a very small hand, it is not very easy to reach all of these buttons.”*

It was mentioned to be a good usability feature if the user could feel the “click texture” when pressing the button. This was explained to help to understand when the button was pressed properly.

An important thing, when considering the good usability of the remote control, was also the easy cleanability. The surface material and the design of the remote control had to be tolerable for the cleaning. One user, who was working in an operating room where they had a corded hand control pointed out, that the spiral cord is very difficult to clean.

Having a remote control, instead of a corded hand control to adjust the operating table was mentioned as one good usability feature for providing a possibility to adjust the table from the distance of the sterile area. In the answers it was mentioned also that it is good feature of the remote control, if it could be used without pointing towards the operating table, from any corner of the operating room, even if the remote control was placed in the wall charger. The signal of the remote control had to be very reliable.

> *“In my opinion, the remote control is definitely better for the usability. It is so much easier to adjust the table from the distance of the sterile operating area.”*

> *“This remote control is very good, because we can use it even when it is placed in the charger on the wall!”*

It was a crucial feature for the user when controlling the operating table with the remote control, that the movement was stopped immediately when the user releases the button. This was seen as an important safety feature beside it was a usability feature.

> *“Usually it is so, that the surgeon says how much the table needs to be adjusted. When the surgeon says “stop”, the adjustment must be stopped immediately!”*

7.4 Features which were seen frustrating or having poor usability

The functionality of the remote control has to be very reliable. It was seen very frustrating and a poor usability feature, if the signal of the remote control did not work properly. The users suspected that such problems were caused by the fact that the remote control had been dropped to the floor or got collided with other equipment of the operation room.

> *"It is very annoying if the signal is not working properly. It is a safety risk too, if the operating table cannot be adjusted the way it should be!"*

> *"I think this has been dropped to the floor and something has got broken inside of the remote control and that causes the signal problem. This remote control is not robust enough!"*

Another annoying thing, according to the users was if the remote control had to be first "woken up" e.g. by pressing "ON" button and only after that user was able to adjust the table. It was pointed out by many users that sometimes there were situations at the operation room, where the operating table had to be adjusted very quickly.

> *"This remote control goes to "sleep" mode by itself. I don´t understand why it does that! I have to press this "ON" button every time to wake it up before adjusting the table. That is frustrating!"*

> *"Sometimes this goes to "sleep" mode and it takes a few seconds before the table can be adjusted. I can tell you, that those seconds are long time to wait, in an emergency situation, when you should be able to adjust the table immediately!"*

The answers reveal that the remote control gets easily lost at the operation room. In the middle of all other equipment and papers in the operation room, it was said to be difficult to see where the remote control had been located. Many users mentioned that this is a real problem for them every day. One of the evaluated remote controls got a positive comment on its´ color, bright blue, for it was easier to find it at the operation room.

> *“We lost the remote control many times every day! Couldn´t it have a bright color, blinking light or beeping sound, or something that would help us to find it at the operation room?”*

> *“One good feature of this remote control: it is easier for us to find it because of its color! It is easier to see the turquoise remote control at the operation room!”*

Some interviewees said that they had difficulties to remember which button to use when tilting to right or to left.

> *“Sometimes I press the wrong button, when tilting left or right. It is difficult to remember which way it works.”*

> *“This tilting to right or left is always confusing for the beginners!”*

The “zero” level button is used by the cleaners when they are cleaning the operating table, but also by the medical professionals when normalizing the patient´s position after surgical operation. In the user´s point of view, the “zero” button should drive very smoothly and slowly the operating table to the horizontal level with the patient, from any adjusted position. It was seen as a poor usability feature, and also a safety risk, if the “zero” button drove the patient on the table to uncomfortable, even harmful, position or if the movements were too fast.

> *“I would like to use this zero button for normalizing the patient position after the operation, but it is not possible. The zero button drives patient to weird and dangerous position!”*

Texts, warnings and messages in the display are not detailed enough, the users said. It was seen as a good idea to use the display of the remote control to explain the error situations of the operating table to the users, but the texts should be easy to understand and detailed enough for that purpose.

> *“Texts for the error situations are not understandable, they are not specific enough.”*

The answers reveal a poor usability feature related to the charging of the remote control as well. Some of the remote controls were criticized for that

it was not possible to see the status of the battery of the remote control. Another poor usability issue concerning the battery charging was that, when user was not able to see, if the battery charging had started or not. This had caused situations where the remote control was placed to the charging unit, but not properly, and the charging had not started at all. Further, the charging cable plug-ins should be robust and easy to plug in.

> *"Usually we put the remote control to the charger overnight. This remote control could be placed to the charger so that it didn´t start charging, but user did not notice that! That caused problems, because next morning we couldn´t use the remote control, it had not any battery for the failed charging!"*
>
> *"No tiny pins in the charging cables for the remote controls! They are difficult to plug in and those get broken very easily!"*

7.5 New features the users would like to see in the remote control

The target users were asked, if they could think of any new features in the remote control they would like to have, to enhance the usability and the ease of use of the remote control. The most of the users answered they would not like to add any features or functions, rather the opposite, to keep the remote control as simple as possible.

> *"I wouldn´t definitely add any features, I would rather take some features off this remote control! Couldn´t these "locking" and "5th wheel" buttons, and also this "reversing orientation" button be only in the column?"*
>
> *"I prefer the old remote controls. They are so simple and easy to use, only the most important functions in the remote control. They are more robust also, compared with these new ones with the display."*

The users would like to see at a glance of the remote control, if the table already was at the horizontal "zero" level or not. In some remote controls this feature already existed, but not in all of them. In one case the feature did exist in the remote control, but it was not clear enough for the user. The interviewee had not noticed the feature at all and she even mentioned herself this issue would be "nice to have".

> *"That would be nice, if the remote control could tell me, if the table is already at the zero level or not! I would like to see at a glance, so I wouldn´t have to check that every time by pressing this "zero" button, just to be sure."*

If there is a display in the remote control, it should provide detailed, understandable texts to help the user. Some of the interviewees said they would like to know immediately what is causing the problem, if the operating table cannot be adjusted the way user wants to. In a current situation many of the operating tables are featured only with the audio alarms, but for the user it is sometimes difficult to understand what is wrong.

> *"Detailed text should be seen when some error situation has occurred. And clear instructions what is wrong or what to do, when the table cannot be adjusted any more!"*

> *"It could tell the reason why the adjustment is not working, e.g. in the situation if the table has already exceeded the adjustment limit. Now it gives the "beep", but it is not easy to understand the reason why the adjustment is not working, because you cannot see the table! It is covered with the surgical sheets! If the surgeon askes to adjust more and more Trendelenburg, but the table is already at the steepest position, it does not move. This could be seen at the display."*

One issue brought up, was an idea of a 3 D picture of the operating table and the patient, which could be in the display of the remote control. A user mentioned that a 3 D picture could help the user to understand which button to use when tilting left or tilting right. Sometimes it is very confusing for the user, because the remote control is used from any direction, the interviewee said. The user must remember to adjust the table according to patient´s left or right, and this may be difficult, especially for the beginners or rare users.

> *"Maybe a 3 D picture of the operating table with the patient could help user to see, which button is needed to be pressed when tilting to left or right."*

> *"In the operation the patient and the table are covered with the surgical sheets, user cannot see them. In the display, there could be a picture and a text telling the current position and adjustments of the table to the user."*

In those operating rooms, which were meant for the C-sections, the operating table had to be tilted 15 degrees to left during every operation. It was mentioned, that for those cases it would be ideal to have a remote control that would display the tilting degrees.

> *"During C-section operation it would be good for the user to see the tilting degree numbers, because tilting 15 degrees to left, is always used in these operations."*

One interviewee also mentioned, that the remote control could give some kind of alarm, if the weight of the patient was too much on the other side of the table. This would be a very important feature, because during long operations, there is always a risk of nerve injuries etc. if the position of the patient is not ideal.

Some of the users wished for a feature or function that could help the users to find the remote control, when it is lost somewhere in the operating room.

> *"There could be some kind of function, searching alarm or something, for helping us to find the remote control."*

Many of the remote controls were featured with the battery capacity and/or charging indicator leds, but not all. This feature was needed, the users said.

There were also a few functions mentioned, that some users would rather adjust by the remote control, instead of the manual adjusting. These were adjusting head support to ideal position for the patient, adjusting the leg sections or adjusting a separate leg section (in those of the operating tables, which had manual adjustable leg sections). Especially adjusting the head support was mentioned to be very difficult, it there was a sterile area and the adjustment had be done in the middle of the operation.

7.6 Usability of the control panel of the operating table

The end users were also asked if they had used the control panel of the operating table column, and if yes, what their opinion on using was. It was revealed that the control panel was used only in the emergency situations:

if the remote control was broken or lost, and the table had to be adjusted. Many of the interviewees had never used the control panel

> *"It is used only for emergency situations, as a backup, if the remote control is broken or lost."*

The location of the control panel was commonly criticized to be awkward and made the control panel very difficult to use, especially if there were surgical team operating at the sterile area and the adjustment had to be made during operation. On the other hand, there was not any better solution for the control panel location, the users said. A few of them would prefer to locate the control panel on the head side of the table column, but the most preferred to keep it in the side of the table, like it was in the most of the tables.

> *"Could it be on both sides of the operating table column? It always feels to be on the wrong side, if I need it!"*

In the users opinion, it was seen a very important issue, that there were a safety feature in the control panel preventing the buttons to be pressed accidentally. Some of the operating tables were featured so that, the user had to press two buttons at the same time to make the table move. In one operating table there was a button for opening the keyboard lock prior to be able to adjust the table with function buttons.

> *"It is essential to have this safety feature to prevent us pressing the function buttons of the column and moving table in the middle of the operation accidentally!"*

> *"It is important for the safety, but instead of needing both hands to use this… Maybe there could be just one button to open a keyboard lock and after that each function button would work with one finger to adjust the table."*

7.7 Usability of the other features of the operating table

The interviewees were asked their opinion on operating tables overall. Operating tables are most often used with detachable sections and accessories, to make them configurable, and suitable for the certain operation and for the certain patient. There were many issues pointed out

by the users, which could be improved to make the operating tables better, and safer. The accessories were mentioned to be too heavy and difficult to handle for the users, the ergonomics of the users should be thought better. Also the locking systems for attaching the accessories could be easier to use, and more reliable, the users said.

> *"Detachable parts are very heavy to handle and hard to attach and lock to the table."*
>
> *"Locking of these should be foolproof!"*
>
> *"Locking and unlocking of these accessories is easier when the button or locking system is visible for the user - not under the detachable part or under the table when I cannot see it!"*
>
> *"Detaching many accessories and many extra parts at the same time to the operating table must be possible, side rails of the operating table must allow many configurations with accessories"*

There are many sized patients, but also many sized users, which needs to be considered when designing the operating tables and the accessories. The side grips must suite to every user to help them attach, detach and carry the accessories. There must not be any sharp edges in any part of the accessories where user could cut one´s finger.

> *"Big manly hands must fit to the detachable parts´ side grips also! For me, it is difficult to carry these, my hands do not fit to the side grips."*
>
> *"Sharp edges on the sides of the accessories or somewhere else on the table – should not exist!"*

Plugging charging cable to the operating table was mentioned to be awkward task for the user. The location where user had to plug the mains cable was usually at the lowest part of the table, near the floor. This was seen as a big ergonomic problem. There was also one table with a serious safety issue related to the charging. The users of that operating table said, they were not able to charge it, when the height was adjusted to the lowest position, it was not possible to plug in the mains cable at all. This had

caused a serious safety issue in the middle of the operation, when the battery had run down.

> *"It must be easy to start charging the operating table in any position adjusted, also during the operation."*

> *"This location where I have to plug in the mains cable - it is just terrible! I must get down on my knees to plug in the cable, every day, in every operating room."*

The weight limits of the table were also discussed. Some of the users said, they would prefer to have the weight limit visible in the table column. It should be expressed very clearly what is the maximum weight (kg) which is allowed to the operating table to be adjusted to any possible position.

> *"Weight limit should be visible in the operating table column. Weekly there is a question, what is the maximum weight allowed to adjust the table to any position"*

7.8 Adverse events related to the operating table

At the end of the interview, the users were asked, if there had been any adverse events, or near-misses, related to the use of the operating table, which they would like to talk about. Many safety points were brought up in the answers. Most of these were such issues, which could had led to an adverse event, even a patient or user injury, but fortunately the users said, had not happened. Also a few near-misses were described by the interviewees, where a patient had been in a real danger to fall down from the operating table. These cases had happened when tilting the table. In this chapter, all discussed adverse-related issues are presented, no matter if the user had actually witnessed those happening in the operating room, or if the user was concerned of that particular safety issue as a serious risk for the patient or user safety. There are not many direct quotations presented in this chapter, because the answers are combined here as appropriate.

There were many risks considered by the users, related to adjusting the table. Both the patient safety, and the user safety, were brought up. It was also pointed out, that nerve damages were always a serious risk for the

patient safety, which needed to be taken into consideration when positioning the patient. A risk of the patient falling down from the table, exist always when tilting the operating table or adjusting the Trendelenburg, one interviewee said. The table tops were described to be very narrow, especially for the big patients. The operating team had to take care of using the safety straps and extra side supports when needed, especially for the big patients, some of the users mentioned. Confusion, when waking up from the surgery is common, and the users saw that as a risk to be considered to prevent the patient falling down from the table.

Reversing orientation of the operating table, as stated previously, was seen as a risk by the users. If the user did not notice the reversed orientation and pressed the wrong button, it could cause an adverse event, the users said.

The users' answers revealed that an extra attention for safety had to be paid if the operating table was adjusted in the middle of the operation. The surgical sheets prevented the user to see the patient and the table properly in those situations. Adverse event could happen causing harm also to those members of the operating room team near the table, surgeons and scrub nurses. If the height of the operating table was adjusted lower and the other users did not notice that, the table could drive down colliding e.g. surgeon´s knee under the table, one interviewee said. Another user mentioned, that they always talked aloud when started to press the function button of the operating table by saying "now moving", to caution the others.

One point, related to adjusting the operating table, was pressing the function buttons unconsciously. This could happen, one user mentioned, if the remote control had been placed hanging in the side rail of the operating table under the blankets and someone accidentally leans towards it pressing the function buttons and by that causing intended movements for the operating table. The other user had the same concern, describing a situation where a hospital bed or some other device needed in the operating room is brought next to the operating table and the remote

control is left in the middle. Thus the hospital bed could press the function buttons of the remote control unpurposely.

One issue related to the safety, as stated earlier, was the accessories. If a heavy accessory, or a table section, is improperly attached or locked to the operating table, it may fall down causing a serious risk to the patient, and to the user, if collided by the dropping accessory. Handling heavy accessories was also seen as a personal safety risk and a cause for poor ergonomics when the user had to attach or detach the heavy accessories.

When a mobile operating table was in question, a user saw a risk of patient leaning to the table, while the floor lock had not been activated. This could cause the patient falling down to the floor. The same risk was seen by the user with the hospital beds, if the floor lock had not been activated. Another feature related to the floor lock of the mobile operating table was mentioned to be an important safety issue: the function buttons did not work if the floor lock was not activated, a user said.

It was seen as a risk for the patient safety, if the remote control connection failed, when the operating table needed to be adjusted quickly in an emergency situation. One user was concerned of that, if the battery of the electric operating table run out and there were no other way to adjust the patient position manually, e.g. towards Trendelenburg. There was also concern of the combination of liquids there could be on the electric operating table. The interviewee was worried if the operating table was protected against the liquids good enough.

During the discussion of near-misses and adverse events related to the use of the operating table, one user pointed out the importance of training. The interviewee said, there could be more training available on the usage of the operating tables to help their own work. “One cannot start to practice with a real patient on the table”, the user stated.

7.9 Observational results

The observational results mainly complement the answers given by the users in the interviews, but also bring up some new aspects of the users, the usability of the operating table, remote controls and accessories, and the operating room as a use environment of the aforementioned. Those situations, where the user adjusted the operating table without anything special to mention, are not listed. Instead, those situations, which were related to a possible usability problem of the remote control or the operating table, are presented here.

The operating table was mainly adjusted one section, or one part of the table, at a time. The buttons for “flex” and “reflex” adjustments were used a couple of times for patient positioning, a memory recall feature was not used even once. In some operations the surgeon asked the operating table to be adjusted in the middle of the operation. This was performed by the person that happened to be the nearest to the remote control, usually by a nurse anesthetist. The remote control was typically placed on the anesthesia table, or near the anesthesia table, during a surgery. There were also a couple of cases, where it was left somewhere else in the operating room, thus stealing attention from adjusting the table to searching for the remote control first. During the field study, no situation happened, when the remote control would not have been found at all for adjusting the operating table.

As the interviews already revealed, there were a lot of functions in the remote controls, which were not known by the users at all. Some of the users mentioned first that they were using, and need, all buttons of the remote control, but when they were separately asked had they used e.g. the blue or the red one, or the “stop” button, the answer was typically “I hadn´t even noticed those before you asked”. Users discovered new functions of the remote control or control panel during interview by themselves, too. This was due to an interview situation, where they were not able to answer to some question, got curious of the issue themselves

and wanted to test without a patient on the table, how the device or certain “weird” button actually works.

A feature, which was not noticed by all users, was e.g. the light of one remote control describing if the table was at the zero level or not. Similar case was a search function that could be activated from the control panel of the column of one operating table. Both of these aforementioned were even brought up by the users as “nice-to-have” features – although these features already existed in the evaluated device the users discussed about.

Reversing orientation of the operating table was a confusing feature and during observation, there happened a situation that confirmed the statement. The orientation of the operating table had been reversed – apparently by mistake – and when the user had to adjust the table, the wrong part of the table was moved. The feature was not known by this user and the situation really caused confusion for all users in the operating room. The symbols and the lights of the operating table presenting the current orientation were obviously not informative enough for the users and it took a while until they got the issue clarified to be able to adjust the table correctly.

The aforementioned case, reversing operating table orientation, also brought up another feature causing uncertainty among users. In order to reverse the orientation, the button had to be pressed down for 2-3 seconds. There were no kind of instant feedback for the user to describe if something was happening or not, when user started to press the button. This resulted a comment from the user “Is this working or not…?” before the wanted function actually took place. This was a case also among some mobile operating tables, which needed the user to activate the floor lock prior to adjust the other parts of the table. The button for activating the floor lock had to be pressed for few seconds and for the user, there was no instant feedback showing that the function is working. In one operating room, the users were wondering why they were not able to adjust the table. The patient was already on the operating table. It took some time before

the reason was revealed: the floor lock was not activated and the table movements were prohibited because of that as a safety feature.

Observation confirmed also the statement of the difficultness to find the correct button for tilting the operating table to left or right. It happened a couple of times during a field study that the user started to press the opposite button first. One user had solved the problem by using the hand control upside down, whenever the user herself was located at the leg part of the patient. When the researcher asked about it, she answered, it helped her to remember which button to press for tilting the table. In some operating rooms the left and the right buttons were marked with “L” and “R”, or by circulating the other of the functions by the users.

Notable was, that using of the safety straps varied a lot according to the hospital location in question. At some hospitals the safety straps were used as a safety feature for every patient and every operation, and at the other hospitals those were nearly never used. The using, or not using the safety straps depended a lot of the operation and the patient in question, users told when asked about the issue.

In some hospitals there were operating tables from different manufacturers, the users had to use different kind of remote controls for adjusting operating tables in the different rooms of the surgical department. This was stated to be a very negative thing among users. Although the functions and even the symbols were about the same, the way the buttons were located at the remote control varied from the remote control to another. The users said, they would like to have a similar remote control in every operating room, so they wouldn´t have to search for the certain function of the remote control every time.

A control panel located in the column of the operating table was not known by all users. As an example of this, a cleaner was not able to drive the operating table to the highest position for the cleaning procedure, because she couldn´t find the remote control to adjust the table. There was a control

panel in the operating table column, but obviously the user was not familiar of using that to adjust the table height.

The users´ statement, that the remote control should be very robust, was confirmed by the observation. During the field study the researcher saw a few remote controls with a partially broken display causing an unclear symbols and texts at the display, and a remote control with a loosen hook, which caused a problem for keeping the remote control available for the users. The signal of one remote control was not working properly, and the user said, it had been like that since the first drop on the floor. Considering the wide variety of other devices around the operating room, the different positions the table had to be adjusted to, all the accessories, and the number of users, it came obvious to the researcher that the remote control may easily drop to the floor or get collided in a busy operating room.

7.10 User requirements for the new product of Merivaara Corp.

The results gained from the interviews and observation conducted in the hospitals were analyzed to provide a list of the user requirements for the new remote control of an operating table for Merivaara Corp.

7.11 Prototype of the remote control of Merivaara Corp.

The prototype of the new remote control of an operating table was developed in close collaboration with the Merivaara´s R&D team and an external designer. Each of the user requirements provided on the basis of the user research of this thesis were taken into consideration. Many of suggested issues can now be seen as a new, or modified, feature or function in the first prototype of the new remote control. However, all of the suggested features could not be taken into the new design. Some of the existing features of the previous remote controls were seen essential to keep, instead of modifying or replacing them with the new ones.

8 CONCLUSIONS

The purpose of this thesis was to design usability into operating table remote control, gather knowledge on the users and analyse the data to define the user requirements for a new product. In other words, the thesis aimed to gain design input to a new remote control focusing on the users´ viewpoint.

8.1 Research questions

There were many open questions related to the use of the remote control, which needed to be answered. The research questions were set to find the answers for these. In this chapter, the subquestions are presented prior to the main research questions, due to the fact that chronologically they were the ones answered first in this research. The answers for the questions are complemented here with the literature references, as appropriate.

As stated earlier, standard IEC 62366-1 (2015), presented in Chapter 2, is the one setting the usability requirements for the medical device manufacturer to follow. Further, stating the safety of the medical device to be the most important target for applying the usability engineering process, the subquestion derived was:

> *Which features of the operating table remote control are important to guarantee the safe use of the operating table?*

Although there were many safety related issues raised during the field study as presented in Chapter 7, it is necessary to point out that this is not all there is to the subject. The usability engineering process, according to standard IEC 62366-1 (2015), must define the potential use errors and hazard-related use scenarios (Chapter 2.4.2-2.4.4). In the time frame of this thesis, those were not defined firmly. The semi-structured interviews and the observation gave design input from the user´s point of view, which is essential to minimize the potential use errors, but further analyses of the detailed use scenarios will be needed to fulfil the standard requirements.

The terminology and the methods related to usability engineering were researched, as presented in Chapter 3, to find the answer to the subquestion:

> *Which usability methods are appropriate to evaluate the usability of the operating table remote control?*

The scope of the thesis being at the early stage of the development of the new product, the main target was clear: to get to know the user, to gain the user input to the design. It was a vital feature of this research that the field study was conducted in a number of different hospitals, observing different surgical operations. It was also important, that there were users involved in the study with different amounts of operating room experience, including novice users as well as expert users, and with different professional statuses and characteristics involved in the study. This way the user research can be seen wider, resulting in a wider perspective of the users. Conducting a field study in only one operating room would have resulted much more narrow set of results, even if the researcher had spent as long time there as this field study took (11 days).

The semi-structured interviews and the observation complemented each other, and were both essential methods to be used for this research. The researcher would not have been able to understand clearly the respondents´ answers in the interviews, unless she had spent time observing the real use cases. On the other hand, without speaking to the users, without asking their questions, the researcher would certainly have missed something relevant and made wrong assumptions based on the observation, and the users´ voice would not have been heard properly.

When conducting the interviews, it was vital also to have a remote control available for the users. Faulkner (2000, 81) states that the users do not always remember what they do when they are away from the task. Being able to hold the remote control, and even adjust the operating table while answering the questions, had a great impact on the users´ ability to give answers. Also Wiklund and Wilcox point out that questions about the

device might get the users thinking, but actually using the device is what gets them talking (Wiklund & Wilcox 2005, 66).

Other usability methods would be extremely useful at the other stages of the product development process, and even essential considering the usability engineering process required by standard IEC 62366-1 (2015). However, those stages were not included in this thesis and using other methods beyond the ethnographic approach when conducting semi-structured interviews and observation, for evaluating the usability of the operating table remote control would need further consideration. Obviously, at least usability tests with real users will be required during the development of the new remote control. These could be conducted using a prototype or prototypes and the final product. The planning, execution and reporting those tests need to be done according to standard IEC 62366-1 (2015), as presented in Chapter 2.4.7.

Finally, analysing further the results presented in Chapter 7, the following main research questions can be answered:

> *Which features of the operating table remote control are important to the users?*
>
> *Which features have an effect on the usability of the operating table remote control?*

From the users´ point of view, the safety is an essential aspect when considering the usability of the operating table remote control. On the basis of the research results, the operating table must response to commands given via remote control immediately, but the movements themselves have to be smooth, and slow rather than fast. The remote control has to be easy and simple to use, so that also novice users can use the remote control safely. The features that users value, in addition to this, are reliability and robustness. There should be no extra features, which might confuse the user, especially a novice user, or compromise the aforementioned reliability or robustness, because it would risk safety.

Referring to the literature, for example Faulkner (2000, 27) suggests to hide certain more advanced parts of the systems from the novice users. She states that it is not always necessary to show novice users all parts of a system at once. Instead more advanced parts could be hidden until the user has gained a certain level of confidence and experience. A similar aspect is presented by Nielsen (1993, 27-28). He points out the importance of easy learning, since the first experience most people have with a new system is that of learning to use it. Generally, Wiklund and Wilcox (2005, 161) remind, products get harder to use, as their complexity increases, presenting users more features and greater operational demands. This is argued to be compensated by the users by spending more time learning to use the product, or they may avoid using advanced features altogether. The results of this research confirm, the statement: the users were not using the special features, almost at all.

It became clear by analyzing the users´ comments that they prefer safety over 'quick' functions in adjusting the operating table. As a conclusion of this, the memory features, if included in the remote control in the first place, should be hidden, so that the novice users could not accidentally use them, or be confused by these features. Another such feature is reversing table orientation, which should be designed out of the remote control. It is suggested in the literature that overly dense-looking interfaces can be initially intimidating to nurses, technicians, and physicians and it may be difficult for them to pick out specific information (Wiklund & Wilcox 2005, 160). With a large number of different devices e.g. in the operating room, this can easily be understood. Again, in some hospitals involved in this research, there were operating tables, and remote controls, from several manufacturers providing a different set of function buttons to be used for adjusting the table.

Overall, the remote control must be designed so that there is nothing excessive. In the guidance for controlling complexity of medical devices, it is suggested for the manufacturers to take a critical look at a product´s feature set and see which features may be dismissed as more trouble for the users than they are worth (Wiklund & Wilcox 2005, 163).

The vital importance of training on how to use a medical device, or lack of the training, can be seen as a notable finding of this research. There were no question in the interview related to the training, but the issue came up by the users themselves several times during interviews. Many users argued that they had not received any training on how to use the features or functions of the operating table or the remote control. They had usually learned the basic functions, the most needed buttons, in the operating room with the help of a more experienced colleague. Through training on the features and functions of the operating table and the remote control had not taken place, and many users commented that to be the reason, why they did not know the remote control better. Training can be seen as part of the product, like required by standard IEC 62366-1 (2015), thus forcing the manufacturer to consider e.g. the training material too. However, like Wiklund and Wilcox (2005, 213) state, it is wrong by the manufacturers even to assume that all users will receive formal training before they use a particular medical device. In the real world, Wiklund and Wilcox argue, most caregivers worry about learning the basics and utilizing the special features only when necessary and, often, only as time permits. Nielsen (1993, 30) shares this view by stating that most users seem to plateau once they have learned “enough”. Unfortunately, he writes, this level of performance may not be optimal for the users who, by learning a few additional advanced features, would sometimes save more time over the course of their use of the system than the time it took to learn them (Nielsen 1993, 30).

Considering this research again, as mentioned in Chapter 7, many interviewees were ‘surprised’ when they found new features or functions during the interview session. Prior to the interview, many of the users, were not familiar with these features or functions at all. The training, and time spent on it, should be researched further, to be able to evaluate the effect it would have on using the wider set of features and functions of the operating table. It can be speculated, based on the interview situations mentioned earlier, that even a minor time devoted to familiarizing one to the use of the device would have a great impact. On the other hand,

Wiklund and Wilcox strongly suggest medical device manufacturers to use intuitiveness as a critical design feature (Wiklund & Wilcox 2005, 213).

8.2 Generalization and further suggestions

The methods used in this research can be generalized to be used at the early stage of any medical device development project. The user research can be performed similarly, by observing and conducting semi-structured interviews. The number of the field study places, as well as the number of interviews and the set of the questions to be asked, must be scaled according to the product in question.

The results related specifically to the operating table remote control gave a good knowledge of the users and use cases, thus providing a firm basis to define the user requirements of the new remote control, and further to consider those when designing the prototype. The aspects not covered in this research however, were the users at private medical clinics. A further phase of the research could include a small-scale field study conducted at some private medical clinic(s) to investigate if any new user needs are brought up.

The research results of this thesis may give a hint of the users´ viewpoint, which could also be considered in other medical device design projects. However, the contextual research is the only relevant way to get to know the users of a certain device throughly. Faulkner states that the users are not expert designers. They can help point out problems, but may not be able to provide answers (Faulkner 2000, 32). As the usability standard IEC 62366-1 (2015) requires, the manufacturers must be vigilant to hear the user´s voice to find out these problems at an early phase of the development project. The least expensive way for the usability activities to influence a product is to do as much as possible before design is started, Nielsen (1993, 72) states. Then it will not be necessary to change the design to comply with the usability recommendations. Further, he argues, this way it is possible to avoid developing unnecessary features.

End users´ point of view may vary a lot from the management of end users, when considering the end users to be the expert on the daily tasks they are performing (Faulkner 2000, 32). It would be interesting to study how much the end users´ opinion is taken into count, when deciding e.g. which operating tables are bought to the operating rooms of their work environment. These decisions may be based on some other values than the usability of the medical device, if the end users´ professional knowledge of their tasks is not asked.

8.3 Further suggestions for Merivaara Corp.

The focus of this thesis has been in the preliminary analysis and evaluation of usability by conducting a user research, and based on that, providing the user requirements for the prototype of the new remote control. The next phase in the development process will be evaluating usability of the remote control using methods like cognitive walkthrough and usability tests. Cognitive walkthrough has been presented in Chapter 2.4.7 (Table 2) and usability tests in Chapter 3.3.7.

Considering the fact that the operating table is a medical device, also design practices for protecting against common use errors, i.e. guidelines suggested by Wiklund and Wilcox in Chapter 3.4 (Table 6) are suitable for evaluating the remote control and the whole operating table. Development of a medical device product is advisable to be performed as an iterative process. Thus, modifications to the design of the remote control, based on further usability tests with the prototype, are possible.

9 DISCUSSION

At the time of finalizing this thesis, the European Commission has just approved a new regulation for medical devices, as stated by the press release on 5 April 2017. This *Medical Device Regulation, MDR*, will establish a modernized and more robust EU legislative framework to ensure better protection of public health and patient safety. The target is to improve the quality, safety and reliability of medical devices. These new regulations will be applied after a transitional period, namely three years after publication, in 2020. By that year, the medical device manufacturers must comply with the requirements of the new regulations. In this thesis, the content of the new regulations is not researched. (Council of the European Union 2017; Euroopan parlamentti 2017.)

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Euroopan parlamentti 2017. Ajankohtaista [accessed 19 April 2017]. Available in: http://www.europarl.europa.eu/news/fi/news-room/20170329IPR69055/l%C3%A4%C3%A4kinn%C3%A4lliset-laitteet-enemm%C3%A4n-turvallisuutta-ja-j%C3%A4ljitett%C3%A4vyytt%C3%A4

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Standards:

IEC 60601-1:2005, Ed. 3.0 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6:2010, Ed. 3.0 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

IEC 60601-2-46:2016, Ed. 3.0 Medical electrical equipment – Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

IEC 62366-1:2015, Ed. 1.0 Medical devices – Part 1: Application of usability engineering to medical devices

IEC TR 62366-2:2016, Ed. 1.0 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices

ISO 13485:2016 Medical devices. Quality management systems. Requirements for regulatory purposes

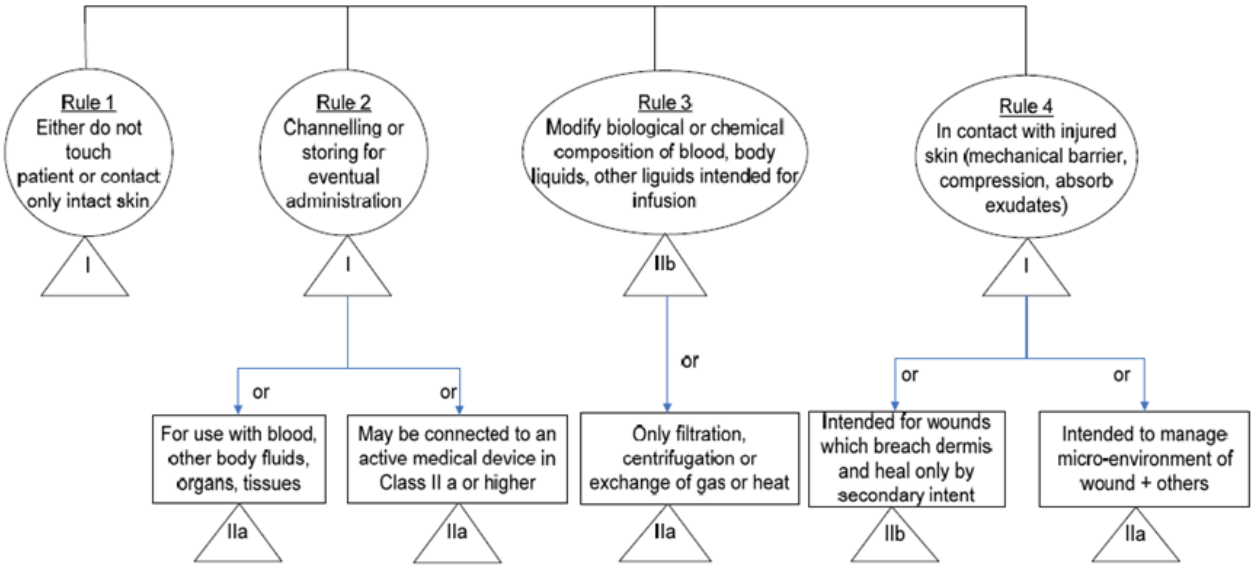
ISO 14971:2007 Medical devices. Application of risk management to medical devices

APPENDIX 1. Directives and regulations that may impact the medical device manufacturing, depending on the features and functions of the device in question. The list is not exhaustive.

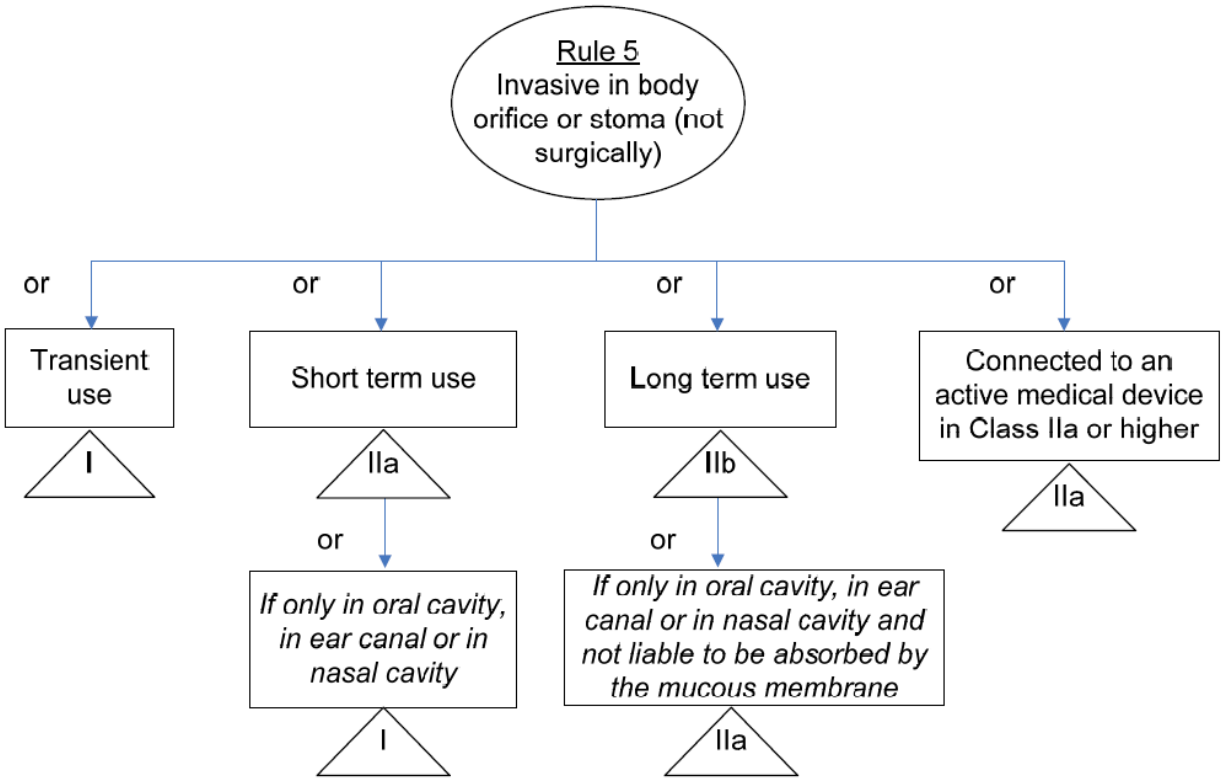
- Directive 2004/108/EC
- Directive 2006/95/EC
- Directive 2006/42/EC
- Directive 2000/70/EC
- Directive 2004/33/EC
- Directive 2002/98/EC
- Directive 2005/62/EC
- Directive 2002/98/EC
- Directive 2004/23/EC
- Regulation of 25/02/2011
- Directive 97/78/EC
- Regulation 1069/2009 of 21/10/2009
- Directive 86/609/EEC
- Directive 2003/32/EC
- Regulation 765/2008/EC
- Regulation 528/2012
- Directive of 19/11/2008
- Directive of 12/12/91
- Directive 2012/19/EU
- Directive of 8/06/2011
- Directive of 20/12/94
- Directive of 24/10/95
- Directive 2002/58/EC
- Directive of 30/06/97
- Directive of 5/04/2006

(Sthålberg 2015, 26-28.)

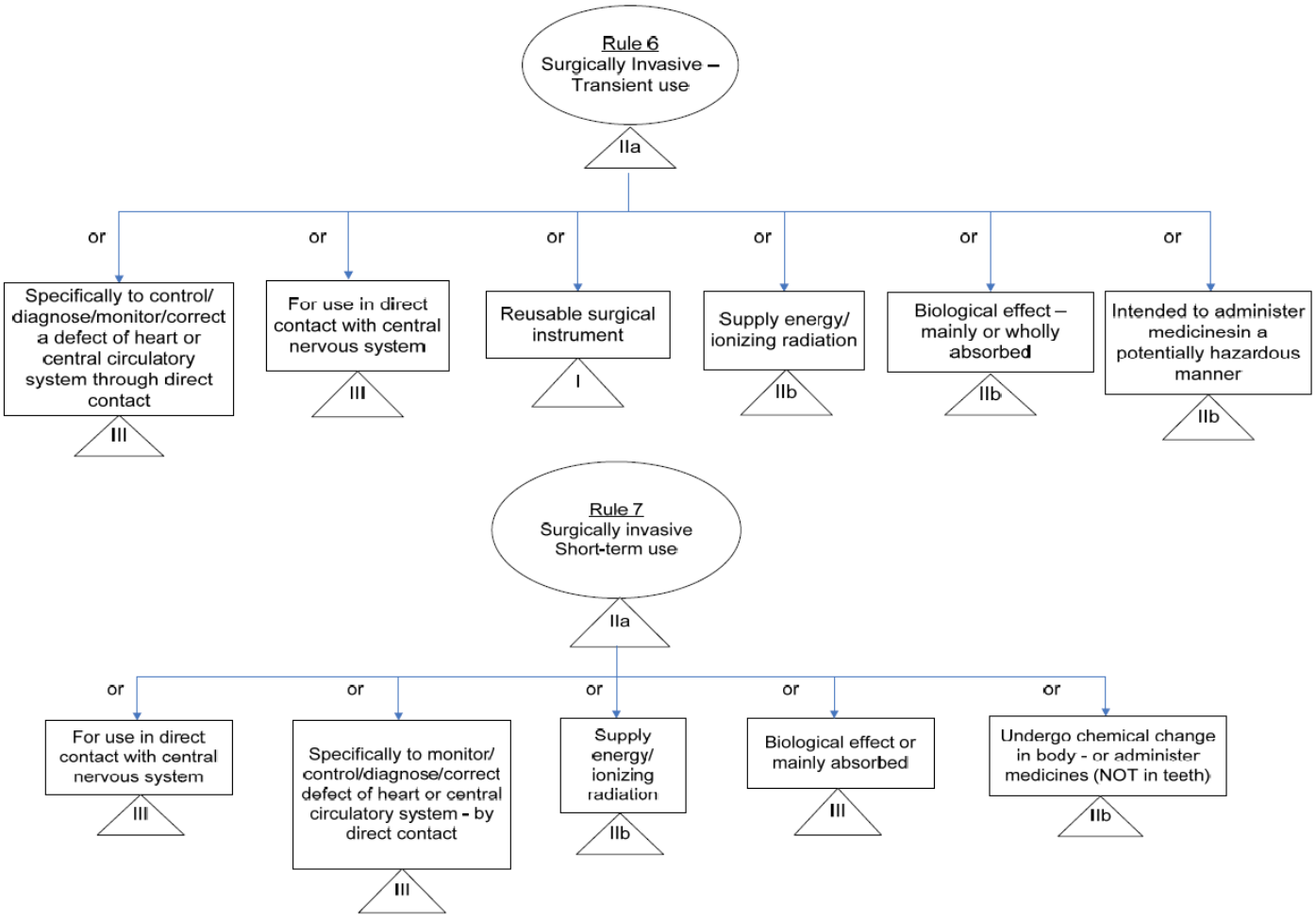
APPENDIX 2. Non invasive devices (Medical devices 2010)



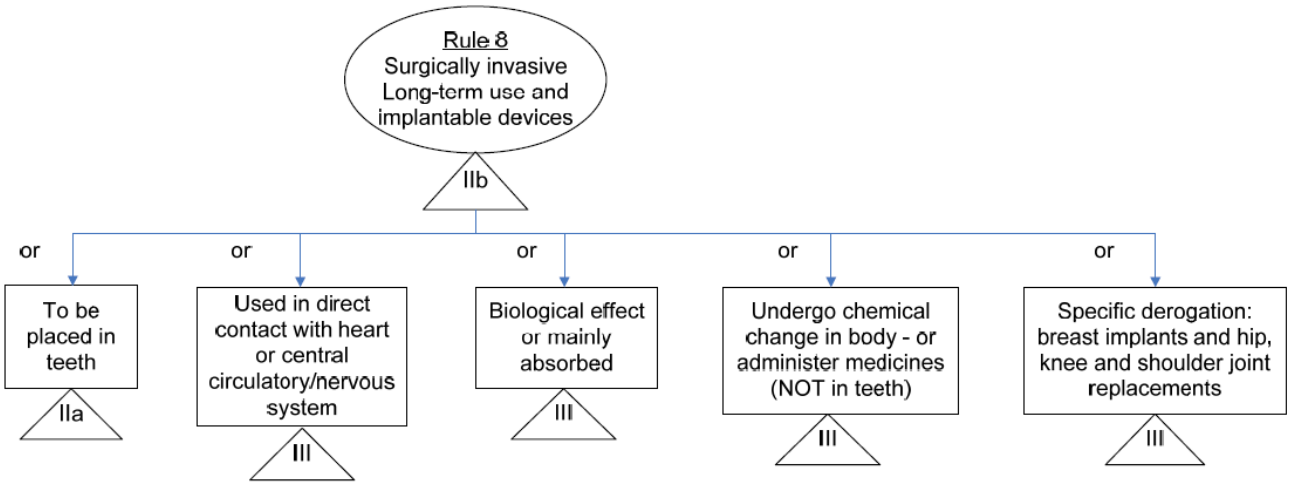
APPENDIX 3. Invasive devices (Medical devices 2010)



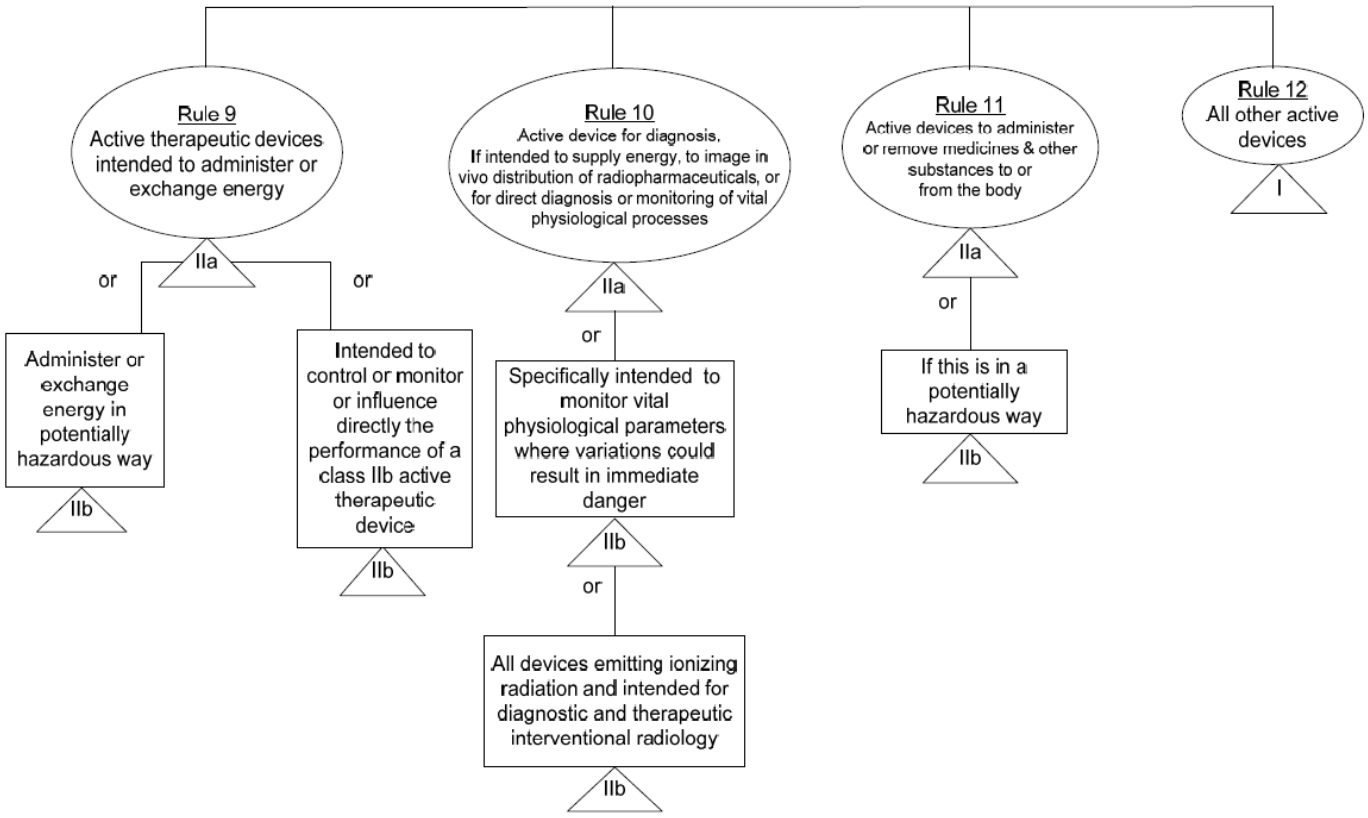
APPENDIX 4. Invasive devices (Medical devices 2010)



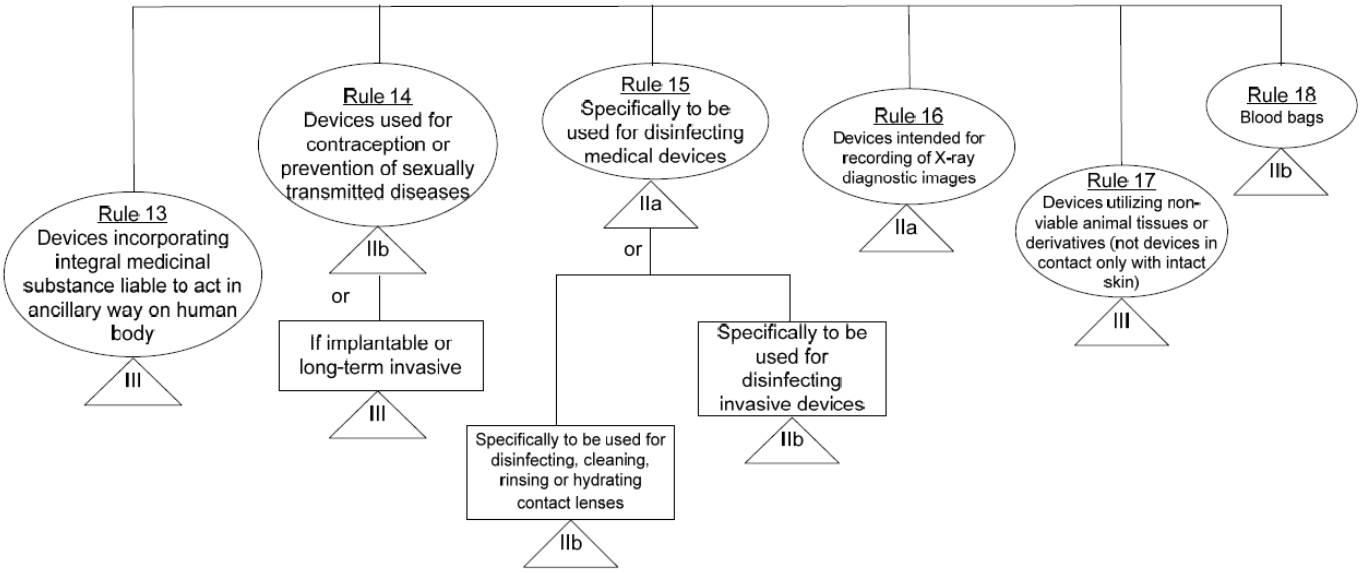
APPENDIX 5. Invasive devices (Medical devices 2010)



APPENDIX 6. Active devices (Medical devices 2010)



APPENDIX 7. Special rules (Medical devices 2010)



APPENDIX 8. Semi-structured interview questions

1. Which features/buttons of the hand control of the operating table do you use the most?
2. Are there some features/buttons you do not use at all?
3. Do you use…
   a) …factory reset positions (Flex, Reflex, Beach Chair, Zero) if they exist?
   b) …customizable memory/recall features, if they exist?
4. Which features make the hand control easy/pleasant to use, in your opinion?
5. Are there some features that make the hand control difficult or frustrating to use?
6. What do you think about the symbols of the hand control?
7. Are the buttons placed conveniently, in your opinion?
8. Is the size and the form of the hand control as comfortable and usable as you would like it to be?
9. What about using the hand control with gloves, is there any difference in usability?
10. Are there some extra features that you would like to have in the hand control to make it better for your work?
11. How often do you use the control panel of the operating table?
12. What do you think about the placement of the control panel?
13. What do you think about the usability of the control panel?
14. Is there something else you would like to say about the usability or the features of the hand control or the operating table overall?
15. Have there been any incidents, accidents or near misses in the operating room, where the operating table has been involved? Would you like to describe those situations?