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Utilizing computer-aided design for modeling and documenting the cabling of 5-channel mTMS prototype

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Abstract

Transcranial magnetic stimulation (TMS) is a method used for studying brain functionality. Multi-locus TMS (mTMS) aims to overcome the spatiotemporal limitations of current TMS technologies by integrating multiple coils into a single transducer. This new technology allows the stimulation of nearby cortical sites in succession. Furthermore, the stimulation locus, orientation, and intensity can be controlled electronically.

mTMS technology is currently developed in the European Research Council (ERC) Synergy project ConnectToBrain (C2B) managed by Aalto University in collaboration with Eberhard Karls University of Tübingen (EKUT), Germany, and University Chieti-Pescara, Italy. For exploring the commercial potential of this technology, a research-to-business (R2B) project "mTMS-TUTLI" is also ongoing and is funded by Business Finland. During the C2B project, mTMS prototypes are built and deployed to clinical research settings for demonstrating feasibility. There is an incentive to outsource the time-consuming assembly of the prototypes to release research personnel for technology-improving activities. To achieve this, comprehensive documentation of the current mTMS system and its assembly is needed. Furthermore, all design documentation produced in the prototyping phase lays a foundation for faster market entry and regulatory approvals.

In this thesis, the cabling design of the 5-channel mTMS prototype was implemented in the existing 3D computer-aided design (CAD) model and cabling documentation was created to describe the internal connectivity of the device. The documentation contains connectivity diagrams, reports, terminal drawings, and routing track documents. The CAD model describes the connectivity of the mTMS system in 3D. The outputs of this thesis are intended to support the outsourcing of the assembly process of future mTMS device prototypes as well as contribute to the post-C2B commercialization processes.

Keywords TMS, mTMS, computer-aided design

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Työn nimi: Tietokoneavusteisen suunnittelun hyödyntäminen viisi-kanavaisen mTMS prototyypin kaapeloinnin mallintamisessa ja dokumentoimisessa.

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Tiivistelmä

Transkraniaalinen magneettistimulaatio (TMS) on aivojen toiminnan tutkimiseen käytetty menetelmä. Monen paikan TMS (mTMS) vähentää TMS:n spatiotemporaalisia rajoitteita yhdistämällä useamman stimulointikelan. Teknologia mahdollistaa vierekkäisten aivoalueiden nopean perättäisen stimuloinnin. Lisäksi stimuloinnin paikkaa, orientaatiota ja intensiteettiä voidaan säätää elektronisesti.

Closed-loop mTMS -teknologiaa kehitetään tällä hetkellä Aalto yliopiston johtamassa Euroopan tutkimusneuvoston rahoittamassa ConnectToBrain (C2B) synergiaprojektissa yhteistyössä Tübingenin yliopiston ja Chieti-Pescaran yliopiston kanssa. Projektin päätyttyä kehitetty teknologia voidaan kaupallistaa, minkä vuoksi Business Finlandin rahoittama research-to-business (R2B) projekti mTMS-TUTLI perustettiin. C2B-projektin aikana rakennetaan mTMS-prototyyppejä, jotka otetaan käyttöön kliinisissä tutkimusympäristöissä. Prototyyppien kokoonpano vie tutkimushenkilöstön voimavaroja ja siksi olisi hyödyllistä ulkoistaa tulevien prototyyppien kokoaminen. Ulkoistaminen vaatii kattavan dokumentoinnin nykyisestä mTMS-systeemistä ja sen kokoamisesta. Lisäksi prototyyppivaiheessa tuotettu dokumentaatio edesauttaa pääsyä tiukasti reguloidulle lääkinnällisten laitteiden markkinoille.

Tässä diplomityössä kaapelointi mallinnettiin viisikanavaisen mTMS-prototyypin kolmiulotteiseen malliin tietokoneavusteisella suunnittelulla (CAD) ja laitteen sisäinen liitännäisyys dokumentoitiin. Dokumentit sisältävät liitännäisyyskaavioita ja -raportteja, komponenttien terminaalipiirroksia sekä reititysratoja kuvailevia dokumentteja. CAD-malli puolestaan visualisoi liitännäisyyden kolmiulotteisessa tilassa. Liitännäisyysdokumentoinnin ja CAD-mallin on tarkoitus edesauttaa tulevien prototyyppien kokoonpanon ulkoistamista sekä edistää C2B:n jälkeistä kaupallistamisprosessia.

Avainsanat TMS, mTMS, tietokoneavusteinen suunnittelu

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Preface

This thesis was produced while working for the TMS group of Aalto University Department of Neuroscience and Biomedical Engineering.

I want to thank the supervisor of this thesis, Risto Ilmoniemi, for allowing me to spend the last few years as part of the TMS group. I would also like to thank the advisor of this thesis, Dubravko Kicic, for guiding me through this jungle of writing as well as Jaakko Nieminen and Heikki Sinisalo for providing connectivity information whenever needed.

Otaniemi, 16/5/2022
Pekko Kauppila

Abbreviations

CAD	Computer-aided design
CAE	Computer-aided engineering
CAM	Computer-aided manufacturing
CE	Conformité Européenne
C2B	ConnectToBrain
EEG	Electroencephalography
FDA	Food and Drug Administration
FPGA	Field-programmable gate array
IGBT	Insulated gate bipolar transistor
mTMS	Multi-locus TMS
PCB	Printed circuit board
PMA	Premarket approval
rTMS	Repetitive TMS
R2B	Research-to-business
TMS	Transcranial magnetic stimulation
V&V	Verification and Validation
510(k)	Premarket notification

1 Introduction

Transcranial magnetic stimulation (TMS) is a non-invasive brain stimulation method used for studying brain functionality. Repetitive TMS (rTMS) refers to a form of TMS in which multiple stimulation pulses are generated in succession. rTMS can produce long-lasting effects in the brain, *i.e.,* inducing "plastic" changes. The ability to induce plasticity gives rise to extensive potential in the treatment of neurological disorders and diseases (Klomjai, Katz and Lackmy-Vallée, 2015).

Traditionally, a TMS system contains one coil and can stimulate a single cortical locus at a time. If stimulation of multiple locations is required, the coil needs to be physically moved. Furthermore, if the stimulation on different cortical targets needs to be done in rapid succession, separate coils (and separate stimulators) are needed. However, due to the size of TMS coils, the number of utilized coils is physically limited (Ziemann, Rothwell and Ridding, 1996). Rapid stimulation of different cortical sites would enable a more comprehensive study of causal interactions in the brain. In addition, this would introduce personalized and more accurate treatment methods for neurological disorders (Horn and Fox, 2020). Multi-locus TMS (mTMS) aims to overcome these limitations by providing rapid stimulation of nearby sites with electronic targeting based on real-time recorded physiological feedback. Stimulation of nearby sites with electronic targeting is achieved by implementing multiple coils to a single transducer. The stimulation site can be moved by individually adjusting the currents in each coil of the transducer (Koponen, Nieminen and Ilmoniemi, 2018). Real-time physiological feedback can be obtained by implementing an electroencephalography (EEG) loop in the system, which allows personalized optimization of the TMS stimulus (Tervo *et al.*, 2021).

Closed-loop mTMS technology is currently developed by the European Research Council (ERC) Synergy project ConnectToBrain (C2B) managed by Aalto University in collaboration with the University of Tübingen in Germany and the University of Chieti-Pescara in Italy. During the project, prototypes are built and deployed to clinical research settings for demonstrating feasibility. The technological outputs of C2B hold the potential to be commercialized. The pre-commercialization activities are managed by the research-to-business (R2B) project mTMS-TUTLI financed by Business Finland.

There are short-term and long-term benefits to utilizing computer-aided design (CAD) and documentation for the current mTMS prototypes. First, outsourcing the assembly of the prototypes would release research personnel for technology-improving activities. To achieve this, comprehensive

documentation of the current mTMS system and its assembly needs to be produced; CAD is a useful tool for this purpose. Second, to commercialize the mTMS technology after the C2B, one needs to gain market entry with regulatory approvals. All design documentation gathered during the prototyping phase serves as a foundation for the later quality and regulatory assurance. In this thesis, the cabling of the 5-channel mTMS system was modeled in 3D and documented in 2D in form of line diagrams and connectivity reports. The aims of the thesis are the following:

1. Demonstrating the utilization of CAD for modeling the cabling of the mTMS system in 3D:
    a. for determining cabling tracks
    b. as a basis for later design (changes)
2. Interpretation and evaluation of produced documentation (2D line diagrams, connectivity reports, and routing track documents) for:
    a. outsourcing of prototype assembly and production
    b. as a basis for later design (changes)
3. Evaluation of the usefulness of this process for university-based medical device development.

Chapter 2 introduces the relevant background of the function of TMS and mTMS. Furthermore, Chapter 2 includes the fundamentals of general product development and medical device development and clarifies the role of CAD in the design processes. Chapter 3 presents the used tools and methods, and Chapter 4 contains the results of the thesis. Finally, Chapter 5 contains the discussion, and conclusions are presented in Chapter 6.

2 Project background

This chapter presents relevant background information on topics addressed in the thesis. First, Section 2.1 presents the fundamentals of TMS in general and contains subsections concentrating on mTMS technology. Section 2.2 presents the basics of product development, which includes generic processes as well as an introduction to prototyping and CAD. Section 2.3 moves toward medical device development and addresses classification and regulation. Furthermore, the product development processes, management models, and procedures are now viewed in the scope of medical device development.

2.1 Transcranial Magnetic Stimulation

TMS is a non-invasive brain stimulation method, first introduced by Barker *et al.* (1985). In this initial study, the primary motor cortex was stimulated with a single-pulse TMS and the response was recorded from the peripheral nervous system as a motor evoked potential (MEP). For more focal stimulation of the brain, Ueno *et al.* (1988) proposed a new figure-of-eight coil design to replace the circular coil introduced by the study of Barker *et al.* three years earlier. One of the first clinical applications of TMS was introduced by Krings *et al.* (1977), who studied whether the accuracy of TMS would be sufficient for presurgical mapping of the brain. In their study, two patients with brain tumors near the central sulcus had their motor cortex mapped with TMS prior to the surgery and with direct electrical stimulation (DES) during the surgery. It was discovered that TMS and DES maps of the motor cortex correlated well. At present, presurgical mapping of the brain is still one of the main clinical applications of TMS (Klomjai, Katz and Lackmy-Vallée, 2015).

rTMS (pulses delivered in succession in the time scale of milliseconds to about a second) can cause long-lasting modulatory effects on brain excitability, and thus the method has a great clinical and therapeutic potential. It has been commonly thought that rTMS stimulation frequencies of 1 Hz and below have an inhibitory effect on the neuronal tracts (Rossini *et al.*, 2015). On the other hand, most high-frequency rTMS stimulation studies with a stimulation frequency ranging from 2 to 20 Hz or above have reported an excitatory effect on the neuronal tracts (Fitzgerald, Fountain and Daskalakis, 2006). The ability to produce changes in the cortical excitability outlasting the stimulation session has made TMS a tempting option for the treatment of neurological diseases and disorders. Lefaucheur *et al.* (2020) published guidelines for the therapeutic use of rTMS based on studies before 2018. It was concluded that a level "A" definite efficacy was granted for rTMS

treatment of major depressive disorder and neuropathic pain. Furthermore, a level "B" probable efficacy was granted for rTMS treatment of fibromyalgia, Parkinson's disease, motor stroke, post-stroke aphasia, and post-traumatic stress disorder.

2.1.1 Multi-locus TMS

TMS has been commonly used as a single-channel device, which can stimulate one cortical site at a time. If multiple sites need to be stimulated simultaneously or within a short time interval, one must utilize as many stimulation coils as there are stimulation targets. However, with this approach, spatial and temporal limitations may occur. Modern rTMS coils are quite large, and thus the number of used stimulation coils is limited simply by the area of the cortex (Koponen, Nieminen and Ilmoniemi, 2018). Furthermore, the TMS-induced activation volleys propagate to adjacent cortical areas in 5–10 ms and to the other hemisphere in 20 ms (Ilmoniemi *et al.*, 1997), which excludes the option of moving one stimulation coil to different cortical sites before the initial TMS-induced activation has reached the latter stimulation sites. Novel mTMS devices developed at Aalto University Department of Neuroscience and Biomedical Engineering (NBE) aim to overcome these limitations by implementing multiple coils to the same system and controlling the stimulation locus, intensity, and orientation electronically. In the design, a traditional single stimulation coil is replaced by a transducer consisting of multiple coils. The current in each coil can be adjusted individually, which allows modifying the spatial features of the induced electric field electronically without moving the transducer (Koponen, Nieminen and Ilmoniemi, 2018). The stimulation of multiple cortical areas in rapid succession would allow studying causal relationships between neural networks. Furthermore, it would contribute to the development of personalized treatment methods for neurological disorders (Horn and Fox, 2020).

2.1.2 mTMS over the years

The first steps in mTMS development were made in the 1990s. In 1996, Ruohonen and Ilmoniemi proposed an mTMS device that utilized small circular coils in an array. After the initial steps in multi-coil array development in the 1990s, multiple versions of coil arrays were proposed. In 2004, Han *et al.* proposed a rectangular array of coils in two layers. In this system, the second layer had an offset from the first layer that was half of the used coil diameter. In 2005, Wang *et al.* introduced an mTMS device with 119 small coils. However, the stimulation output was not enough for TMS applications. In the following years, Im and Lee (2006) and Lee *et al.* (2007) studied arrays that had three orthogonal circular coils as individual elements

of the array for improving stimulation location control. In 2009, Lu *et al.* moved onwards from planar arrays and modeled an array that followed the geometry of the head. In the years from 2012 to 2014, replacing arrays with line current elements was studied (Ge *et al.*, 2012, 2014; Jiang *et al.*, 2013). The systems described between 2004 and 2014 were mostly simulations and lacked evaluation of realistic power requirements and coil currents (Koponen, 2017). In 2021, Souza *et al.* introduced a two-coil mTMS system capable of controlling the electric field orientation in millisecond-scale intervals and without rotating the transducer.

The method for electronic control of stimulation intensity of individual channels was invented in 1993 by Ilmoniemi and Grandori. In general, the electronic control of stimulation locus refers to adjusting the desired currents to each channel of the mTMS system independently. Optimizing the currents of the coils is crucial in terms of the focality of the stimulation output. In 1996, Ilmoniemi proposed a least-squares solution for the current optimization. The resulting solution was focal but the array of coils was not yet energy-optimized. In 2010, Cao *et al.* proposed a genetic algorithm for optimizing the coil currents and five years later, in 2015, Laudani *et al.* proposed a particle swarm optimization for the same purpose. In 2017, Koponen *et al.* proposed a method for obtaining the most energy-efficient solution for the coil shapes when a given focality is to be achieved.

2.1.3 mTMS at Aalto University

Currently, mTMS devices with a varying number of channels are being developed in the C2B project. The project aims to develop mTMS coil arrays covering the majority of the cortical mantle, capable of real-time temporal control of stimulation intensity, induced current direction, and locus. Furthermore, recorded EEG data will be used for determining the stimulation targets so that a closed-loop will be formed. In other words, the stimulation will not be performed without feedback, but the pulse parameters and targets will be defined by individual responses of the subject's brain.

Regarding the electronics of the system, the main functional elements are H-bridge circuits (Koponen, Nieminen and Ilmoniemi, 2018). In general, the electronics of the system may be divided into five larger modules: control unit, charger unit, auxiliary electronics, channels, and coils. The charger unit, channels, and coils form the electronics related to stimulation. The control unit consists of a field-programmable gate array (FPGA) and a custom-made LabVIEW program, and it manages the low-level operation of the system. The charging unit contains a capacitor charger which is responsible for charging each high-voltage capacitor of the five channels. The auxiliary

electronics consist of various components participating in ensuring normal and safe operation of the device. The channel electronics contain the majority of the total electronics. Each channel consists of a pulse module and a discharge controller. Furthermore, each channel is connected to a coil when the device is operational. The pulse module includes the high voltage capacitor and the H-bridge circuit in parallel. Insulated gate bipolar transistors (IGBTs) serve as switching elements in the H-bridges and the switching is controlled by custom-made driver printed circuit boards (PCBs). The discharge controller is responsible for monitoring the capacitor voltage and reporting it back to the control unit. Furthermore, it controls the discharge resistor, which is connected in series with the capacitor (Nieminen *et al.*, 2022). An illustration of the device modules is presented in Fig. 1.

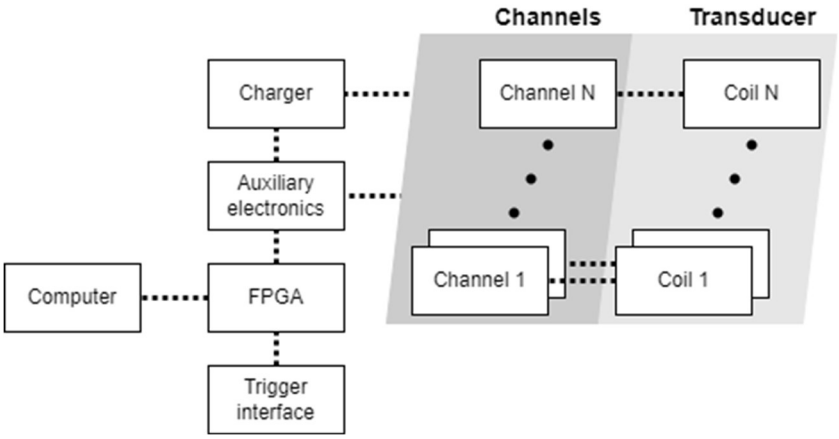


Figure 1. mTMS electronics modules. Modified from (Nieminen et al., 2022).

The increased number of channels is what distinguishes mTMS device operation from regular TMS. The transducer consists of five coils and can control the induced electric field maximum location, orientation, and intensity in a cortical region of 30-mm diameter around the center of the transducer by means of electric field superposition. The total transducer output is determined by adjusting the rate of change of the current, which is proportional to the capacitor voltage, for each channel. The resulting total induced electrical field is a vector sum of the electric field of individual coils (Ruohonen and Ilmoniemi, 1998; Koponen, Nieminen and Ilmoniemi, 2018). The windings and order of the coils were optimized to the following structure: an oval coil at the top of the transducer, two figure-of-eight coils in the middle, and two four-leaf-clover coils at the bottom (Nieminen *et al.*, 2022). The coil windings and corresponding electric field distributions are shown in Fig. 2.

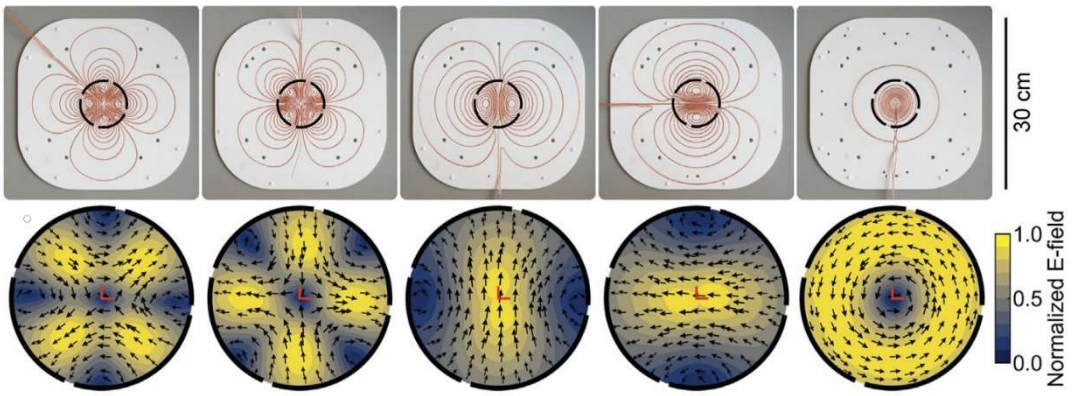


Figure 2. Coil windings and corresponding electric field profiles. The upper images show the windings of each coil of the transducer. The top-most coil is on the right and the bottom coil is on the left. The lower images present the individual electric field profiles of each coil. Image from (Nieminen et al., 2022).

The operation of the mTMS system is a result of the function of individual channels. The output of a single channel is managed by adjusting the electrical topologies of the H-bridges. The four IGBTs in the H-bridge determine whether the high-voltage capacitor is connected in series with the coil. As in typical TMS circuits, the series connection results in a damped oscillatory circuit, which is the stimulation-intent state of the circuit. The millisecond-scale oscillatory effect of the capacitor–coil configuration is disposed by cutting the capacitor from the coil in tens of microseconds, which results in nearly linear current ramps. The capacitor–coil configuration is shown in Fig. 3A and B. In turn, the non-stimulation-intent state called coil-short configuration is achieved by cutting the capacitor out of the circuit and by letting the residue current decay in the coil. The produced magnetic field and induced electric field due to the decay are of negligible magnitude (Nieminen *et al.*, 2022). The coil-short configuration is presented in Fig. 3C.

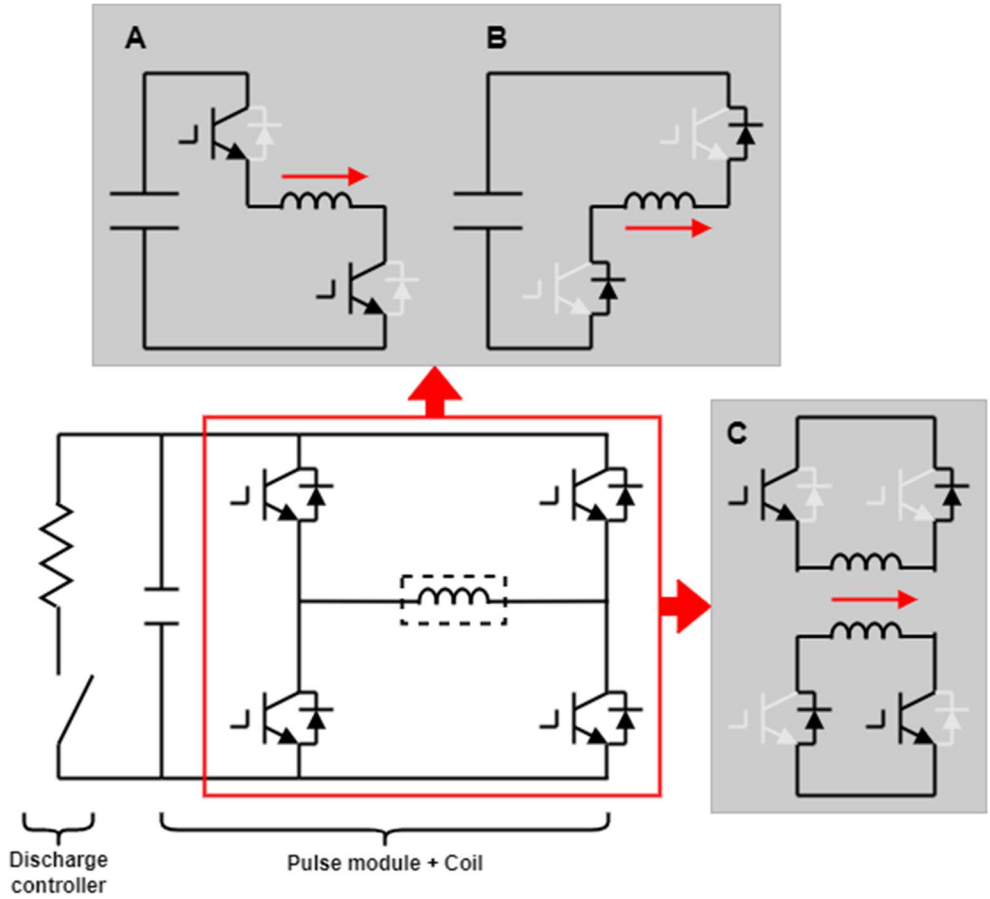


Figure 3. H-bridge configurations. (A, B) Capacitor–coil configuration. (C) Coil-short configuration. The pulse module consists of the capacitor and the H-bridge. The discharge controller is used to reduce the voltage from the capacitor. In the H-bridge topologies, the red arrows indicate which way the current flows through the coil. In the capacitor–coil configuration, the current flows through two IGBTs (A) or two flyback diodes (B). In the coil-short configuration, the current flows through one IGBT and flyback diode (C). Modified from (Nieminen et al., 2022).

2.2 Product development basics

This section addresses the general nature of modern product development and prototyping as well as CAD. Section 2.2.1 presents product development processes from a generic perspective. Section 2.2.2 presents the types, applications, and benefits of prototyping. Finally, Section 2.2.3 addresses CAD and its applications.

In the product development of medical devices, both hardware and software must be engineered. This thesis concentrates on the engineering side of product development, and particularly, on the design processes (Ogrodnik, 2019). The engineering side of product development consists roughly of design and manufacturing (Ulrich and Eppinger, 2012). In general, design is a process that creates a solution for a specified need. In the medical device industry, the needs are, of course, health-related. In any design process, there is a start and eventually the end of product life. Traditionally, the product life cycle is prolonged by revising the product design and by implementing enhancements to maintain sales. This way the product life cycle can be viewed as a constant process of adaptation and in a sense, the design is never finished (Ogrodnik, 2019).

The design process may be divided into:

- engineering design, which contains mechanical, electrical, software, and regulatory-related implementation, and
- industrial design, which addresses aesthetics and ergonomics as well as user interfaces.

In its entirety, the function of the design process is to output the physical form of the product. The manufacturing, in turn, relates to the production of the chosen design (Ulrich and Eppinger, 2012).

2.2.1 Generic processes

There are various definitions of the main processes in generic product development. Ogot and Kremer (2004) specify five steps: problem definition, conceptualization, preliminary design and evaluation, detailed design and testing, and production. Kamrani and Nasr (2010) divide the total process into six smaller entities: needs recognition, design specifications, conceptual design, detail design, production, and marketing. In this chapter, the generic model proposed by Ulrich and Eppinger (2012) is used for describing the general product development processes as this source appears frequently in the literature and divides the total development into quite easily distinguishable sub-processes. Later, Section 2.3 focuses on design processes and procedures in the scope of medical devices.

Ulrich and Eppinger define six larger processes shown in Fig. 4. The processes are (1) planning, (2) concept development, (3) system-level design, (4) detail design, (5) testing and refinement, and (6) production ramp-up. Each process is described in more detail in the following sections. In addition, Fig. 4. presents the rough timing of larger design process entireties, such as prototyping, with respect to the six design processes.

(0) Planning

The product planning phase precedes other major product development processes as it occurs before the official approval of the project. The product planning process may be divided into five consecutive sections: (1) identifying opportunities, (2) evaluating and prioritizing projects, (3) allocating resources and timing planning, (4) complete pre-project planning, and (5) reflection on the process and results. The main aim of the product planning process is to create a comprehensive mission statement, which contains a description of the following: business goals, target market, stakeholders, benefit proposition, critical assumptions, and the product itself (Ulrich and Eppinger, 2012).

(1) Concept Development

In general, a concept is defined as a description of the main features, functions, and form of the product. Furthermore, a concept typically includes an economic justification for the development project, an analysis of competitive products in the market, and major specifications regarding the concept. Concept development contains creative work where one produces multiple potential solutions to the identified problem. All concept options are evaluated and the best few are brought forward for further testing. The concept development phase can be further divided into three parts: concept generation, concept selection, and concept testing (Ulrich and Eppinger, 2012).

(2) System-Level Design

System-level design mainly addresses the components and subsystems of the product. Some sources name this phase embodiment design (Cascini and Rotini, 2011; Ogrodnik, 2019). This term will also appear later in this thesis when the design process is viewed specifically for medical device development. The system-level design includes creating a product architecture, defining the components and subsystems, designing an outline of the final assembly, and planning the future production system. Furthermore, the key components of the product may already be given a preliminary design. Typically, the outcome of this product development phase is a layout of the total product, specifications describing the functions

of each subsystem and component, and a process flow proposal for assembling the final product.

A central concept of this process development phase is the product architecture scheme that illustrates the main functional elements of the product and the relationship between those elements. In the product architecture, the physical parts and subassemblies of the product are divided into building blocks called chunks. Creating a product architecture can be divided into four steps: designing a schematic, clustering elements, designing an illustrative geometric layout, and determining primary and secondary interactions. The architectures can be roughly divided into two categories: modular and integral. In modular architectures, each chunk implements only a few functionalities, and the relationship between chunks is defined quite well. In integral architectures, a functional element of the product is implemented by multiple chunks. Furthermore, one chunk may implement multiple functional elements. This results in more complex interactions between the chunks. In general, a product architecture is rarely distinguished completely as modular or integral. Regarding the mTMS device, a single chunk may implement functional elements in a well-defined manner. However, there are many chunks, and the connectivity is quite complex making the architecture sway towards integral. The product architecture builds a foundation for later product design of increased detail (Ulrich and Eppinger, 2012).

(3) Detail Design

As the process name suggests, detail design proceeds deeper into the details. This phase aims to produce a comprehensive description of all unique and standard parts used in the product. The unique parts need a description of the geometric appearance, used materials, and allowed tolerances. The standard parts must be specified, and the supplier determined. By the end of this phase, the aim is to have sufficient control documentation that includes drawings and models representing the geometric appearance of the components and parts, detailed information of the purchased components and parts, and a process plan for the assembly of the product. In addition, by this stage of the total product development process, the specification of materials, cost of production, and robust performance should be determined. The detail design process also includes subcategories of environmental, robust, and manufacturing design. The environmental design aims to minimize the negative environmental impact on the product during its life cycle. Robust design refers to ensuring that the product performs as intended even in presence of noise. Design for manufacturing begins during the concept development and system-level design phases and it evaluates the costs of manufacturing and the implications of the cost-evaluations to product design choices (Ulrich and Eppinger, 2012). The detail design

process is central for this thesis as the cabling design and documentation are the details added to the system.

(4) Testing and Refinement

The testing and refinement process mainly addresses prototyping and developing the designed product into a production product. This process includes testing the performance, durability, and reliability of the product as well as assessing the environmental impact. Furthermore, the matter of regulatory approvals, which is especially relevant for medical devices, becomes essential in this phase (Ulrich and Eppinger, 2012). Prototyping is described in more detail in Section 2.2.2.

(5) Production Ramp-up

The last product development process is the production ramp-up, where the product is manufactured using a proper production system. This phase no longer focuses on the design features of the product but emphasizes the evaluation of the production processes. The workforce is trained, and the remaining production challenges are assessed. Typically, the transition from this phase to the actual continuous production occurs gradually (Ulrich and Eppinger, 2012).

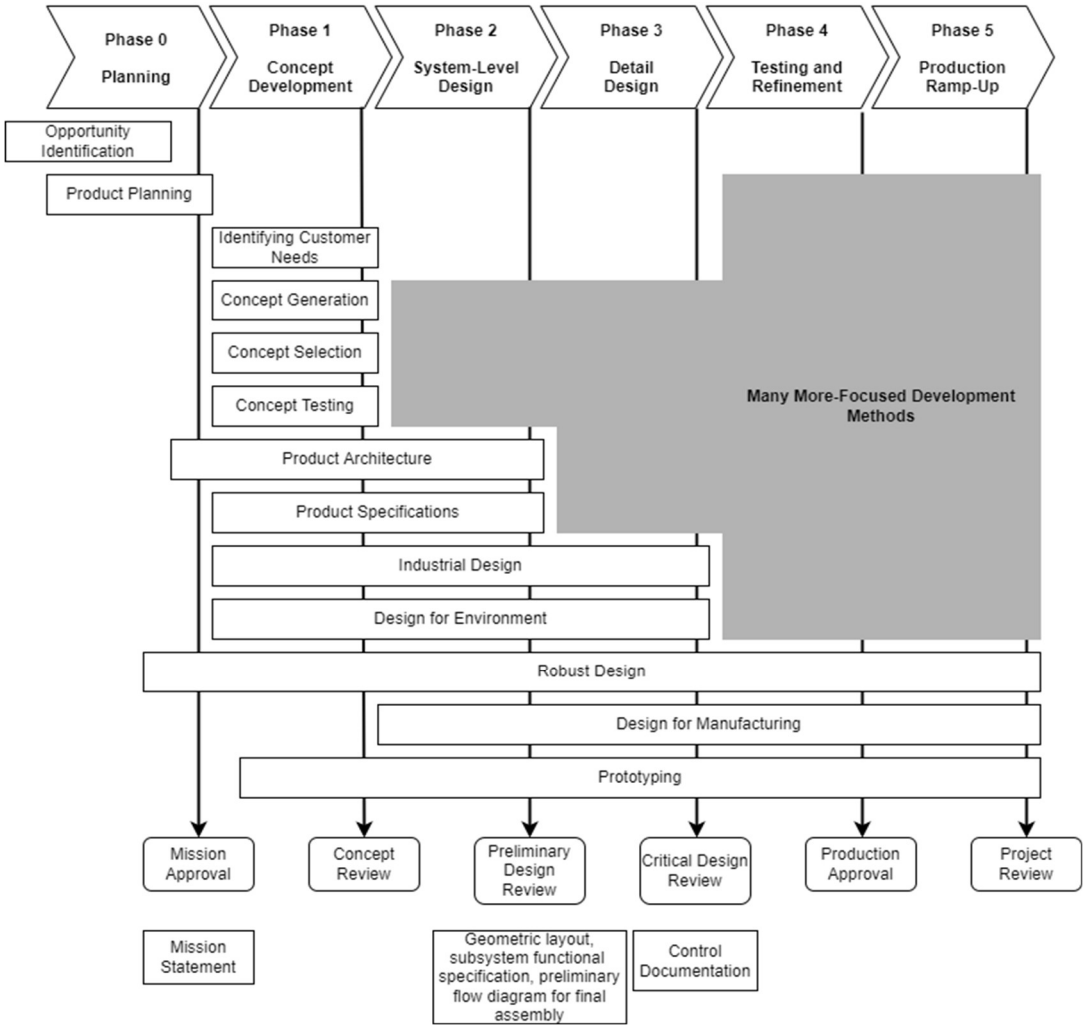


Figure 4. Generic product development process flow diagram and associated integrative methods. The uppermost structure presents six generic product development processes. Associated integrative methods and their rough timing are shown in the rectangular structures below. The arrows between processes indicate review structures, in which it is determined whether the project is ready to proceed. Some typical outputs for the processes are listed below the review structures. Modified from (Ulrich and Eppinger, 2012) exhibits 1–4 and 2–5.

The overall generic process flow diagram illustrated in Fig. 4 shows how different integrative methods approximately occur during the total project. Many of the methods are considered early in the total development process even if they are mainly associated with later development processes. The product planning phase is preceded by opportunity identification, and it finishes at the mission approval. A typical output for this phase is the mission statement. Identifying customer needs and concept generation, selection, and testing are distinctive methods for the concept development process. Product architecture is mostly associated with the system-level design and

product specifications with both the concept development and system-level design. Typical outputs for system-level design include a geometric layout of the product, functional specifications for subsystems, and a preliminary process flow plan for the final assembly. Industrial design reaches from concept development to detail design. Environmental, robust, and manufacturing design are mainly related to the detail design process. Control documentation is an important output of the detail design process, and it contains accurate information on the geometry, tooling, fabrication, and assembly of subsystems and the total product. The emphasis of the testing and refinement process is on prototyping. However, especially for medical device development, prototyping is already essential in the earlier design processes (Ulrich and Eppinger, 2012). In the scope of this thesis, the most relevant product development process is the detail design followed by system-level design, and testing and refinement.

2.2.2 Prototyping

Prototyping is a common procedure in product development. Ulrich and Eppinger (2012) define a prototype as an approximation of the actual product in one or more dimensions. Correspondingly, prototyping is defined as the process of producing the prototype. Typically, prototypes are evaluated using two dimensions: physical–analytical and comprehensive–focused. This section first addresses the types of prototypes, then the usage and applications, and finally the benefits of prototyping.

Naturally, a physical prototype refers to a concrete approximation of the product whereas an analytical prototype serves as an intangible representation of the product. Physical prototypes are also utilized to identify unexpected phenomena, which are not addressed with analytical prototypes. Analytical models aim to create, for instance, a mathematical or visual model of the product, and they are considered to be more flexible than physical prototypes. Comprehensive prototypes implement the majority of the features of the product. On the other hand, focused prototypes implement only a few features and study the function of those features in a precise manner. That is, focused prototypes represent smaller key features of the product. A 3D CAD model is an example of a focused prototype as it aims for an accurate representation of the geometric dimensions of the product. Comprehensive prototypes are fairly accurate representations of the product; they may be sent to customers for testing and determining whether design deficits can be identified in the product. The aim is to obtain valuable information on the performance and reliability of the product in its intended environment and assess whether modifications are required (Ulrich and Eppinger, 2012). This is what is also performed in the C2B project, where

comprehensive prototypes are sent from Aalto University to collaborating universities in Tübingen and Chieti-Pescara.

Prototypes may also be categorized by their level of detail and timing during the total product design. First prototypes, also known as *alpha prototypes*, are built, tested, and evaluated in terms of performance and customer need satisfaction. These initial preproduction versions are built with production-intent parts and lay on the physical and comprehensive section of the two-dimensional prototype categorization. That is, the features of the parts are the same as those of the future production version, but the production custom may differ. Primarily, the alpha prototypes are essential for determining whether the product design is functional. Later prototypes, also known as *beta prototypes*, are built based on the feedback of the previous ones—design deficits are remodeled. Furthermore, the beta prototypes contain an increasing number of parts that are supplied using the intended final production process. However, these prototypes may yet be assembled differently. The beta prototypes undergo extensive evaluations, where flaws are identified. Typically, the beta prototypes tend to be located near the comprehensive end of the evaluation dimension. *Preproduction prototypes* are the first prototypes that are produced completely by using the intended production process. That is, the prototype building is performed with all intended methods and processes (Ulrich and Eppinger, 2012). Regarding the mTMS development, these prototypes would occur after the device assembly has been outsourced and the manufacturing process determined and implemented. Fig. 5 below presents how alpha, beta, preproduction, and 3D CAD prototypes are placed along the two evaluation dimensions.

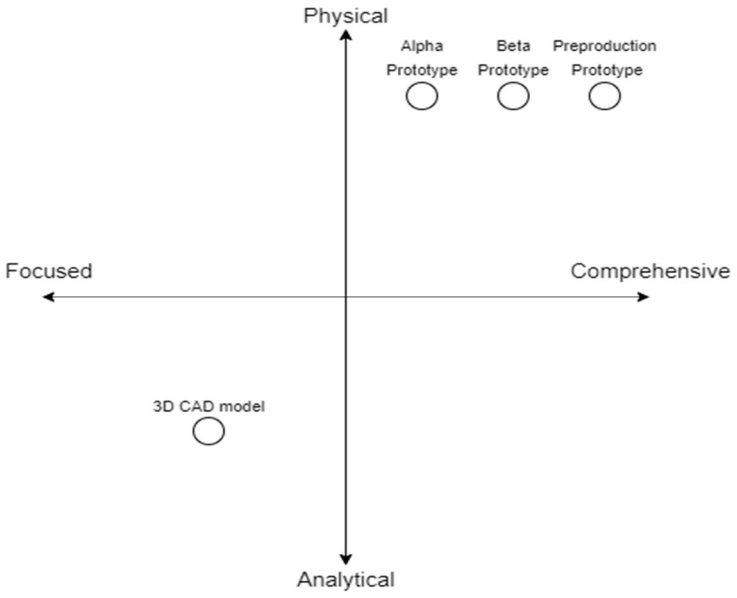


Figure 5. Two-dimensional categorization of different prototypes. Modified from (Ulrich and Eppinger, 2012).

Prototype usage within a project can be divided into four categories: (1) learning, (2) communication, (3) integration, and (4) milestones. Learning is typically achieved with any prototype of quality that is considered to be either comprehensive or focused. Physical focused and comprehensive prototypes are more appropriate for easing communication with other parties involved in the product development. Integration refers to ensuring that the components and subsystems of the product cooperate as intended. Integrational benefits are mainly achieved with physical comprehensive prototypes. However, one could argue that communicational and integrational benefits could also be achieved with focused analytical prototypes, such as precise 3D CAD models of the complete product. Milestones refer to stages of product development where prototypes are used to demonstrate progression. Physical comprehensive prototypes are best applied for this purpose (Ulrich and Eppinger, 2012).

Often, the prototyping phase eliminates the need for additional design costs. Building and testing a prototype can be viewed as insurance against additional costs. One allocates part of the funds for building the prototype, which is then intended to detect possible costly problems in the design. Thus, the probability of iteration is reduced. The method is illustrated in Fig. 6.

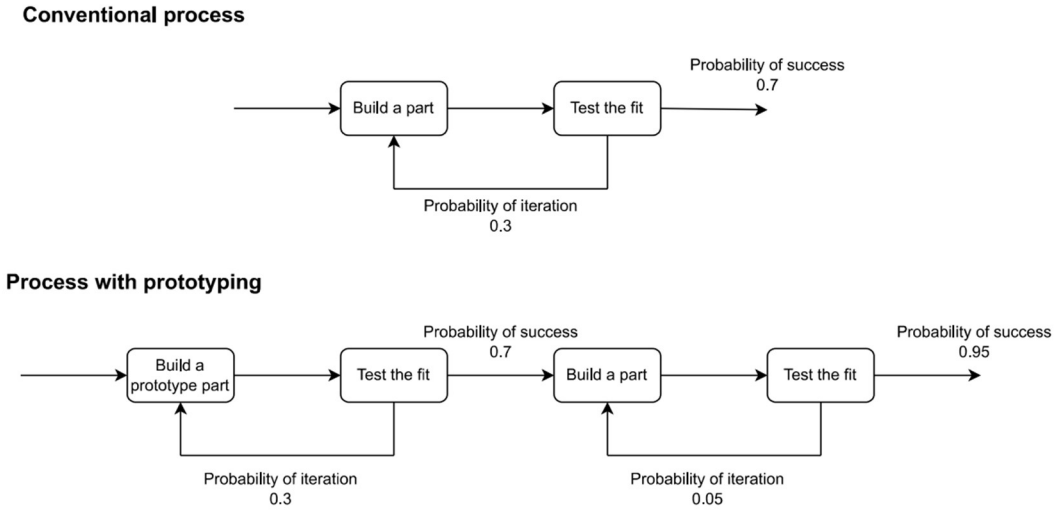


Figure 6. The effect of prototyping on the probability of iteration. Modified from (Ulrich and Eppinger, 2012).

Comprehensive prototypes are most useful for products that have a high probability of failure. For instance, a new technology, such as mTMS, has an elevated risk of failure as the design team is operating in unknown territory. In general, the use of comprehensive prototypes depends on the risk of failure and the cost of building the prototype. Regarding the mTMS, the products have both an elevated risk of failure and a high cost of prototyping.

For these types of comprehensive prototypes, extensive use of analytical prototypes is common (Ulrich and Eppinger, 2012). An essential analytical prototyping tool, 3D CAD modeling, is described in the next section.

2.2.3 Computer-aided design

Vendor-based manufacturing is widely used by modern companies to minimize time-to-market. This collaboration with other parties requires the use of CAD, computer-aided manufacturing (CAM), and computer-aided engineering (CAE) systems. CAD produces a virtual representation of the assembly and individual parts. Furthermore, it provides detailed technical information on the dimensions and has in-built mechanisms to produce technical drawings. CAM focuses on manufacturing automation as it enables transforming CAD designs into instructions for manufacturing machines. CAE software is utilized to simulate, for instance, kinematic and dynamic motion of the components of the model, thermal flow, and stress-related phenomena (Kamrani and Nasr, 2010).

The operation of CAD can be divided roughly into five larger elements: modeling kernel, user interface, graphics, applications, and databases. The geometric modeling kernel is the central element of a CAD system, and it is the software component enabling the 3D modeling features of the CAD system. The user interface is typically an interactive graphic communication window. The system includes dynamic and static graphics. Dynamic graphics form the shape of the parts. Static graphics are utilized in the creation of engineering drawings. Applications widen the features of CAD and include, for instance, CAE software. Databases store the information on the design (Stroud and Nagy, 2011).

Typically, CAD software requires a specialized computer to operate. The mTMS CAD model described in this thesis is a large assembly that takes several minutes to open on a regular computer. After realizing that a normal laptop was not sufficient for managing the model, a desktop with improved specific components was assembled. *Solidworks* provides hardware recommendations on its website (https://www.solidworks.com/support/system-requirements). These recommendations include a 3.3 GHz processor or higher, 16 GB minimum of random-access memory (RAM), solid state drive (SSD), and a list of adequate graphics processing units (GPUs). The assembled desktop used for this thesis had the following features: a 3.9-GHz processor, 32 GB of RAM, an SSD, and an NVIDIA Quadro P1000 GPU. This constellation performed well.

CAD, CAM, and CAE are mainly involved in the embodiment design, detail design, and manufacturing processes of the product design. Traditionally,

the CAD process is quite reactive, meaning that first a model is designed, and afterward, it is analyzed and corrected. Proactivity can be increased by involving the design team in early concept development phases, which may contribute to avoiding costly iterations in the detail design phase (Stroud and Nagy, 2011). Typically, the use of CAD begins after the concept development phase and is busiest in the detail design phase. The same applies to the timing of CAE except it stretches further. CAM is naturally related to the manufacturing process although manufacturing constraints must be considered already in earlier design processes (Cascini and Rotini, 2011). Currently, CAD is the main tool utilized in mTMS prototyping. However, CAM is used in the manufacturing of the coil connectors, side rails, busbars, and plates of the cabinet. The typical timing of CAD, CAM, and CAE usage over product design processes is illustrated in Fig. 7.

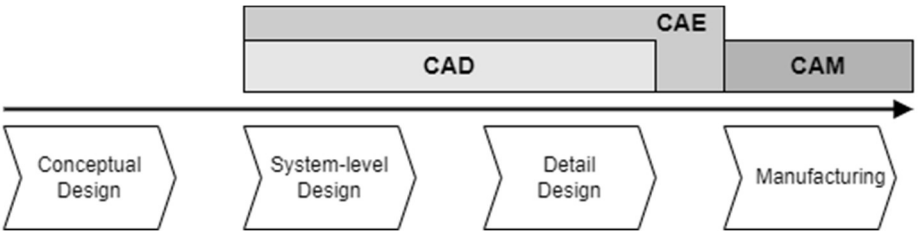


Figure 7. Timing of CAD, CAM, and CAE over product design processes. Modified from (Cascini and Rotini, 2011).

Before the 1990s, the main method of design representation was creating descriptive drawings. Currently, models are displayed with three-dimensional solid entities, and with an increasing amount of detail, these models have begun to represent products as analytical prototypes. Ulrich and Eppinger (2012) define the main benefits of CAD modeling for product development as the following: an easier method for producing a three-dimensional representation of the product, the ability to produce realistic images of the final appearance of the product, the ability to determine physical properties of the product without assembling a prototype, and the ability to produce one design from which information may be drawn for describing components and subsystems of the product. In general, utilizing CAD increases the efficiency of a designer as the software deals with time-consuming processes. Furthermore, CAD improves the quality of the design and documentation (Kamrani and Nasr, 2010). Overall, modeling precise CAD representations of the product may decrease the number of physical prototypes needed (Ulrich and Eppinger, 2012). Utilizing CAD for a university-based medical device development project brings the product closer to industry standards and shortens the time-to-market.

The cabling design lies in between mechanical and electrical design. Traditionally, mechanical design has been implemented in a 3D environment

and electrical in 2D. However, current CAD software includes cabling modules where the 2D design can be realized into 3D space. Typically, the cabling design has been involved in the later phases of product development. Furthermore, in the scope of CAD design, the cables are modeled in later phases as modeling the cables is troublesome without having the origin and destination parts well-defined. In general, the connectivity information is first created in 2D and then brought to the 3D space. This includes associating the 2D representations of the electrical components with their 3D CAD models. Some of the cables may be auto-routed, which expedites the modeling process, but the success of it is case-specific (Lindfors *et al.*, 2003). Integration of mechanical and electrical design and fluent information transfer between the two is crucial for effective concurrent engineering. Utilizing CAD in the cabling process may decrease the probability of costly iteration loops in the design process (Ruotsalainen and Kuosmanen, 2000).

2.3 Medical device development

The development process of medical devices follows the same basic principles as other products—defining a need, finding and implementing a solution, and satisfying customers. Earlier, the product development model of Ulrich and Eppinger (2012) was used to describe generic product development phases. This section focuses on the design process and aims to present the concepts in the scope of medical device development and the mTMS system. To understand medical device development, one needs to understand the definition, classification, and regulation of medical devices. These concepts are addressed in Sections 2.3.1 and 2.3.2. Section 0 presents a design process model in the scope of medical device development. Next, Section 2.3.4 describes typical design management models for low-volume product development, which apply to medical devices, and finally, Section 0 addresses the procedures related to those models and their processes.

2.3.1 Definition and classification

To study the product development processes of the medical device industry, one needs a clear definition of a medical device. The definition varies slightly among continents and contains a few sub-sections, but a summarized general description of a medical device declares that if a device is used on humans in any clinical environment, it is considered a medical device. All medical devices are classified to determine the level of regulation and control required. As the classification level gets higher, the associated risk also increases. Fig. 8 shows the main risk-based classification of medical devices in the USA and Europe. As seen, the required design control increases with class number and is highest for class III devices. Conversely, the proportion

of self-regulation decreases with class number and is highest for class I devices (Ogrodnik, 2019).

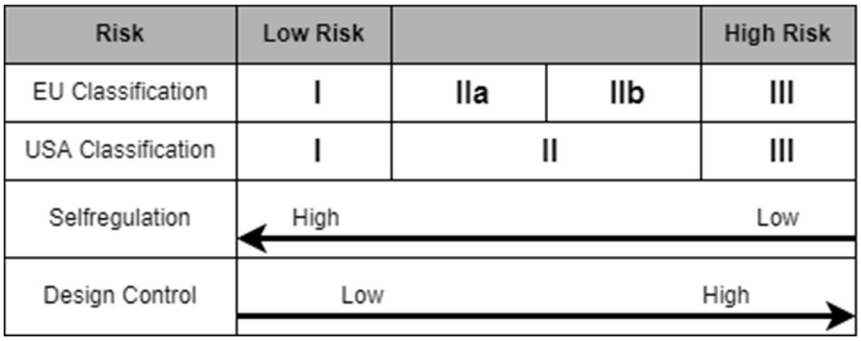


Figure 8. Medical device classification in EU and USA. Modified from (Ogrodnik, 2019).

Class I devices are largely self-regulated as external regulation is low. For these devices, internal control within a company or institution plays a significant role. For class II devices, the amount of internal and external control rises. For class III devices, the amount of external control may surpass that of internal and the design decisions need full justifications. Fig. 9 presents design effort, internal, and external control as a function of regulation class. As seen, both internal and external control increase with respect to regulation class, and similarly, the overall design effort increases. The curves of internal and external control as well as the linear design effort line are produced solely for illustration purposes, and thus their relationships are not accurate in the figure.

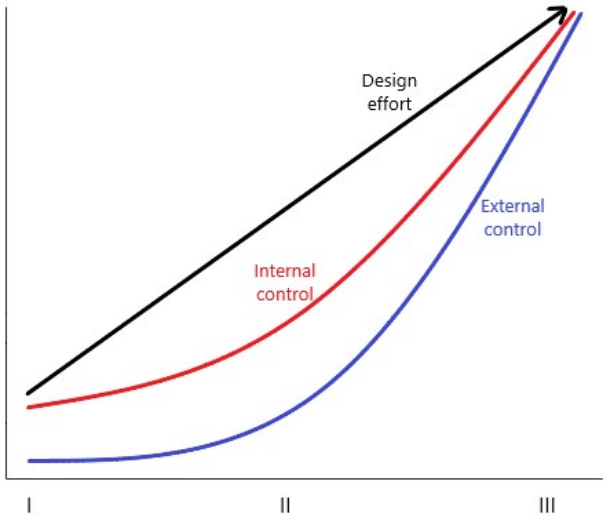


Figure 9. Design effort for regulatory classes. The regulatory classes are presented on the x-axis and the amount of required effort on the y-axis. Both the internal and external control as well as the overall design effort increase as a function of regulation class. Modified from (Ogrodnik, 2019).

2.3.2 Regulation

What distinguishes medical device development from most other commercial product development are the extensive regulatory requirements (Medina, Kremer and Wysk, 2013; Ogrodnik, 2019). These regulations invoke an increased need for design control. The benefits of adequate design control in medical device design are fairly intuitive—decreased overall costs and shorter time-to-market (Ogrodnik, 2019). In the USA, medical device regulation is governed by the Food and Drug Administration (FDA). The approval from the FDA is obtained by demonstrating reasonable assurance of the safety and effectiveness of the device. In Europe, the regulation is governed by Notified Bodies, which are private organizations authorized for assessing medical devices that intend to enter the market. The approval results in a Conformité Européenne (CE) marking, which signifies that the device is safe and functions as intended. Once the CE marking is obtained, market entry is guaranteed in all member states of the European Union as well (Sorenson and Drummond, 2014).

In the USA, in general, low-risk medical devices are subject to general controls, medium-risk devices to premarket notification (510(k)), and high-risk devices to premarket approval (PMA) (The FDA, 2020a). The 510(k) review process leads to demonstrating substantial equivalence (SE) for a legally marketed predicate device. In other words, it is not demonstrated that the device is safe and effective—merely that it is as safe and as effective as a similar device already on the market (The FDA, 2020b). Furthermore, these devices are typically subject to general and special controls (Ogrodnik, 2019). The PMA is the most stringent pathway designed for high-risk devices and it requires demonstrating safety and effectiveness through clinical studies. In addition, a new device without a predicate is classified directly as a high-risk device. However, one may apply for recategorization to low and moderate-risk classes through the de novo program, in which it is demonstrated that the associated risk level is only low or moderate (The FDA, 2019).

In the EU conformity assessment, the devices are classified into three classes as in the USA. Non-invasive low-risk devices are placed into class I, which are subject to general controls. Class II has two subclasses: IIa for low to medium-risk devices that are used for less than 30 days, and IIb for medium to high-risk devices that are used for more than 30 days. Devices in this class include an assessment from a Notified Body (NB). Furthermore, class IIb devices are subject to slightly more stringent procedures than IIa devices. Finally, high-risk devices are placed in class III (French-Mowat and Burnett, 2012).

2.3.3 Design processes

Ogrodnik (2019) introduces a divergent–convergent model based on Pugh's (1990) model of product design phases. This medical device design model is shown in Fig. 10 and consists of four larger phases: clarification, conceptual design, embodiment, and detailed design. The whole process can be considered a roughly linear beginning from establishing a need and finishing at final documentation. In the clarification phase, designers deepen their knowledge of the need and associated environment, and the output of this phase is a full product design specification of the product. The product design specification is highly detailed and produced based on comprehensive discussion with customers, end-users, subcontractors, etc. In the conceptual design phase, ideas are produced, and finally, a candidate is chosen for the embodiment phase, in which a final prototype is produced. Next, the model proceeds to the detailed design, which prepares the design for manufacture and finally to the documentation phase.

In the generic product development model of Ulrich and Eppinger (2012), the number of options peaks at the concept development phase. Likewise, the divergent–convergent model peaks during concept development. The divergent open phase of the design consists of clarification and conceptual design phases, in which multiple ideas are produced and analyzed. In this phase, creative thinking is at its maximum and potential solutions for the product design specification are created. The selection phase is located between the widening and narrowing sections of the model. In this phase, the best idea is chosen. The third phase is the convergent selective phase, in which the use of creative thinking decreases and the use of methods for undertaking tasks increases (Ogrodnik, 2019).

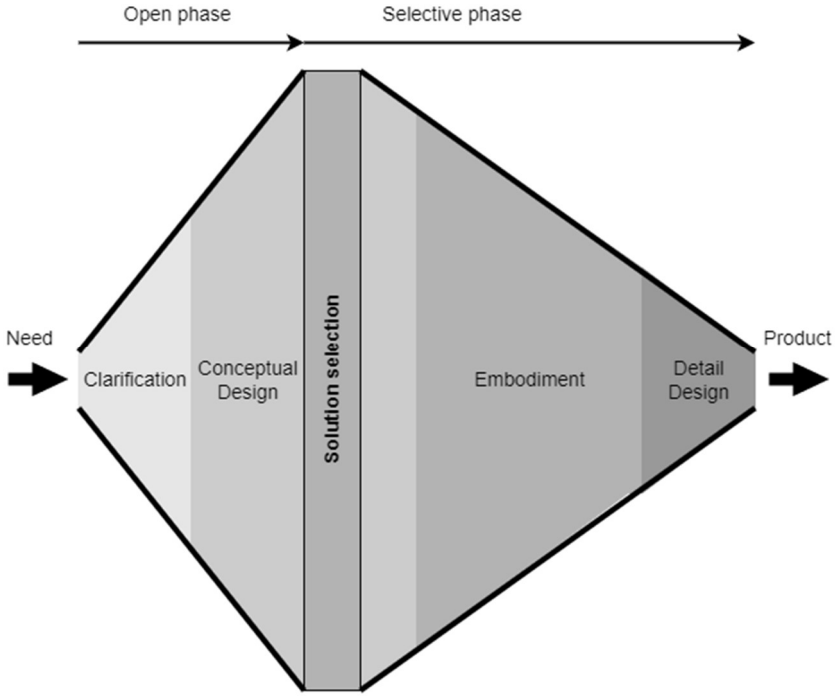


Figure 10. Divergent–convergent design model for medical devices. Modified from (Ogrodnik, 2019)

2.3.4 Management models

In this chapter, serial, concurrent, collaborative, and holistic management models are reviewed to produce a general descriptive design process model for medical devices.

The serial design model or waterfall model is maybe the simplest example, and it consists of successive tasks. A specific task cannot begin before the previous has been completed. The serial model was the standard design process structure before concurrent engineering appeared. This model is not optimal for larger projects with many team members as the lead times would increase excessively (Kamrani and Nasr, 2010; Ogrodnik, 2019).

Concurrent engineering or concurrent design model is fundamentally serial but enhances many aspects of the serial design model. As indicated by the name, this model divides serial tasks into smaller processes that may be implemented concurrently. That is, the design process is divided among smaller teams. Previously, design processes propagated in a purely linear fashion Concurrent engineering introduced iteration to the design process, which enabled going backward and forward in the design process and fixing problems that would potentially grow to substantial (Ogrodnik, 2019). Another characteristic feature of concurrent engineering is considering multiple product life cycle elements early in the design. An increased forward

planning is noticed to ease the flow of the total process as more unforeseen design complications are addressed early in the conceptual design phase (Kamrani and Nasr, 2010). In this model, high-quality project management and efficient communication are essential as without them the model will almost inevitably revert to the serial model. Time-consuming individual products are typically produced by utilizing concurrent engineering at least in some form (Ogrodnik, 2019). Fig. 11 below shows the main concept of the concurrent engineering model in the scope of mTMS design. Communication is marked with dashed grey lines.

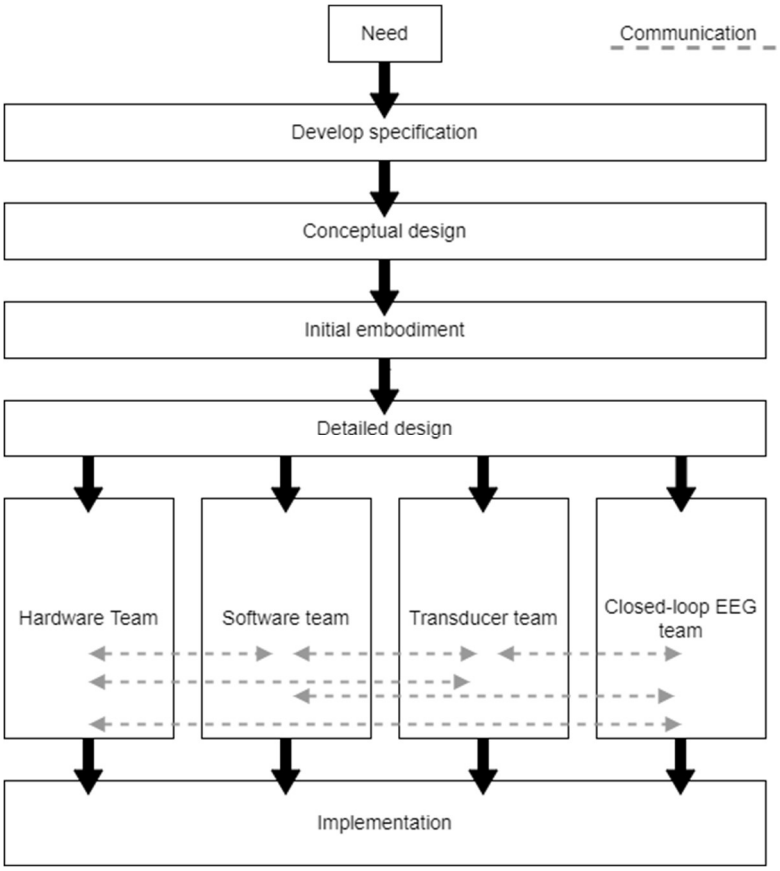


Figure 11. Concurrent design model. Modified from (Ogrodnik, 2019). The teams are used as an example.

Collaborative and holistic models can be viewed as extensions of the concurrent engineering model. Both address the information flow internally within the project and externally with customers and other relevant parties aiming to enhance information flow. The collaborative model introduces web-based repositories, which centralize information flow to a specified location. Without it, the risk of unsuccessful communication increases. For instance, when a team faces an error, it must inform all other teams directly. Utilizing the collaborative model transforms the communication between teams into communication between the data store and each individual team.

Furthermore, the collaborative model enables the cooperation of distant teams as the data can be accessed from all around the world and with various devices. For instance, modern CAD viewer software has allowed everyone to check on CAD models without acquiring expensive modeling software and equipment. This further eases involving the customer in the design process (Ogrodnik, 2019). Fig. 12 merges collaborative and holistic models and presents them in the scope of mTMS design. In the figure, the collaborative model contributes by transforming the communication structure.

The holistic model expands the reach of the teams in the development chain. The aim is to involve the teams already in the early stages of the product development starting from the specification. This allows valuable experience and knowledge to affect the design from the start while decreasing the probability of a single person being responsible for a specification (Ogrodnik, 2019). In Fig. 12, the holistic model contributes by expanding the reach of design teams to early processes.

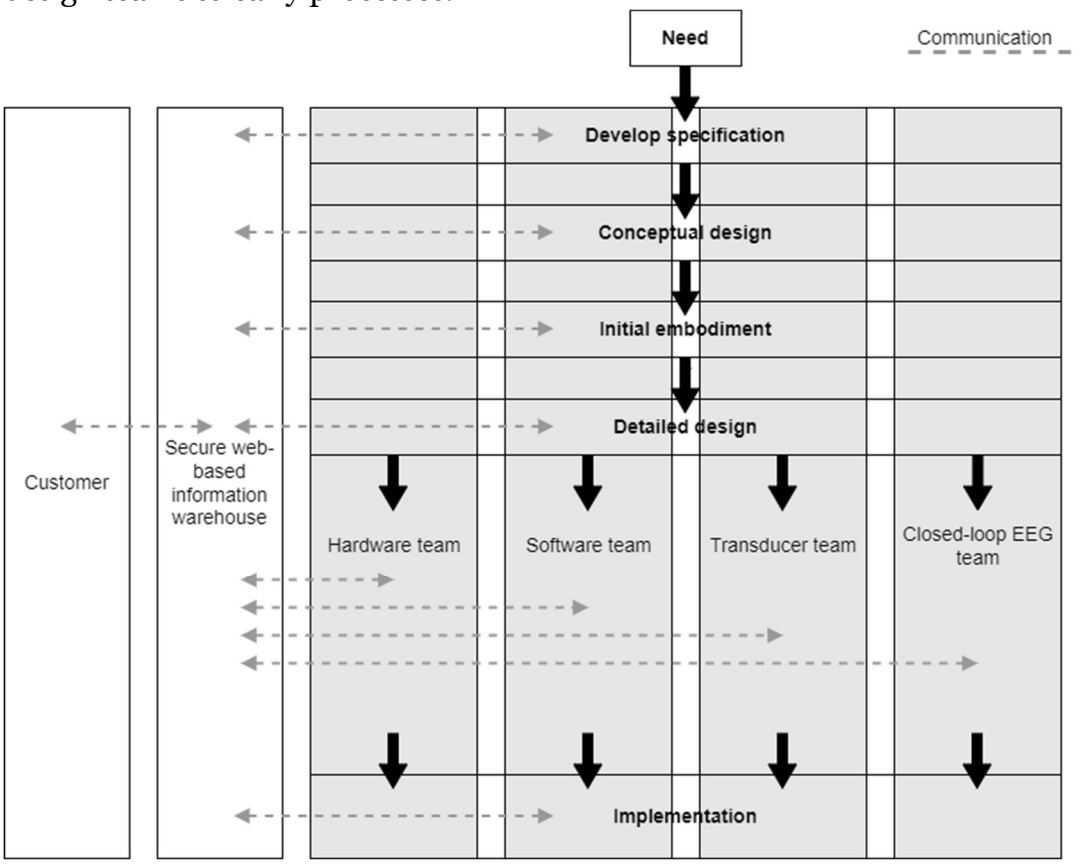


Figure 12. Holistic design model. Modified from (Ogrodnik, 2019). The teams are used as an example.

2.3.5 Procedures

To comply with the regulatory requirements of medical device design, adequate control needs to be established. This control may be demonstrated utilizing procedures. Overall, the idea of procedures is to manoeuvre through the design phases described in the previous chapters and the main function of design procedures, notably, is to demonstrate conformity to regulations and standards as well as ensuring sufficient design documentation. Regarding the regulations of the FDA and medical device standards, the design control is addressed in FDA CFR 21 and ISO 13485. This section of the thesis describes some relevant design procedures on a general level to elaborate the contents and requirements in the design processes. The procedures are illustrated with flowcharts, which typically have a waterfall-like structure. However, it is worth noticing that the flowcharts do not consider the information flow in the project, which was described in the previous section (Ogrodnik, 2019).

The total procedure is best summarized by the new product procedure, which is presented in Fig. 13. The elements with a grey background represent larger procedures, which are described in more detail in the following text. Conceptual design is included in the detail design procedure. The rounded box elements represent the outputs of the procedures. Turquoise diamond elements represent central decision nodes where it is determined whether the design is adequate for proceeding. *Conducting a risk analysis review during each of these approval stages is also recommended to support decision-making*. The turquoise circle elements indicate updating the Design History File (DHF), which is an essential document for eventually gaining a market entry. The DHF should be frequently updated along the total design process. In the flowchart, whenever approval is denied, one must decide at which point of the procedure the feedback applies and return accordingly (Ogrodnik, 2019).

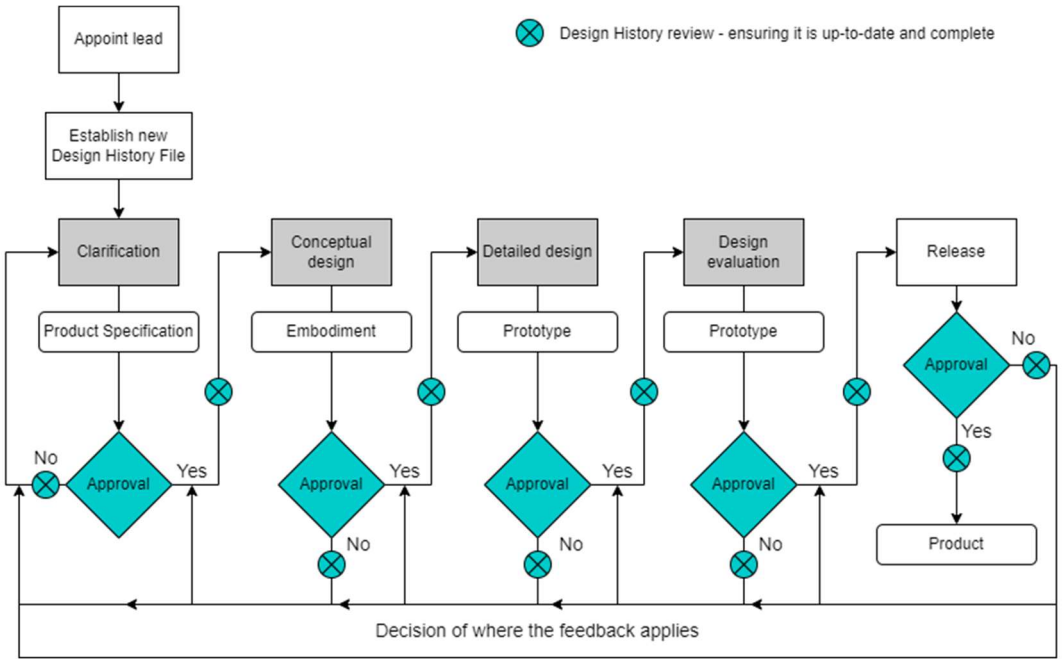


Figure 13. New product procedure. Modified from (Ogrodnik, 2019) figure 4.4.

Clarification Procedure or Product Specification procedure outputs, naturally, the product specification. The development contains various inputs that need to be considered in the light of FDA guidelines and ISO 13485, which addresses medical device regulatory requirements of quality management. Furthermore, feedback from customers, patients, and end-users is essential for the development process. The procedure is quite case-specific but generally contains multiple iterations as one produces the specification, checks with sources, and redrafts when necessary. Each iteration should be properly documented (Ogrodnik, 2019). The clarification procedure is shown in Fig. 14.

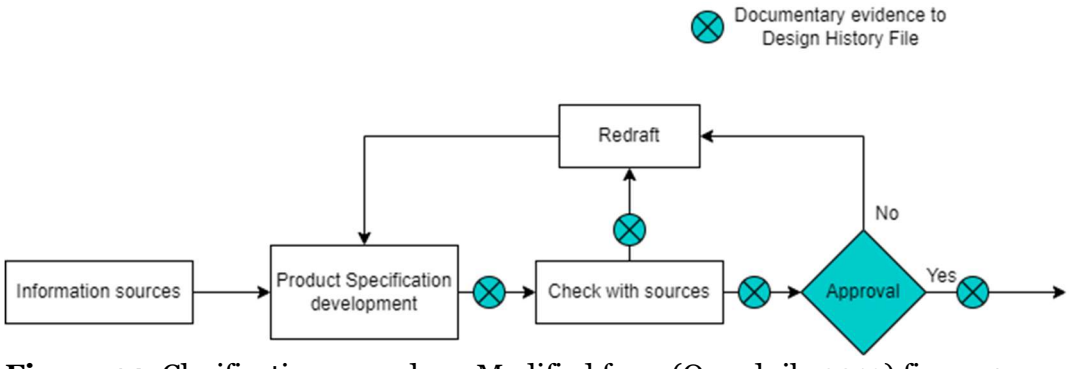


Figure 14. Clarification procedure. Modified from (Ogrodnik, 2019) figure 4.5.

Detailed Design procedure can be thought of as a two-phase procedure consisting of the creative conceptual development phase and the actualizing detailed phase even though conceptual and detail design are generally

separate processes. A flowchart of the total detail design procedure is shown in Fig. 15. The conceptual section consists of iterations of idea generation until a concept is approved. The detail design phase begins with forming of project teams and determining milestones. Next, the actual design activities are addressed. This includes, for instance, the selection of components and materials, performing design calculations and dimension analyses as well as conducting a risk analysis, failure mode and effects analysis, and quality function deployment method. After this, a prototype is produced and evaluated. If approved, required documentation is created, assessed, and finally approved when deemed sufficient. The procedure contains iteration loops and DHF documentation after each progressive step. Risk analysis should be conducted at each of the approval nodes. The procedure may be applied to any embodiment phase of the total design–be it designing an alpha prototype or a final design for manufacturing (Ogrodnik, 2019).

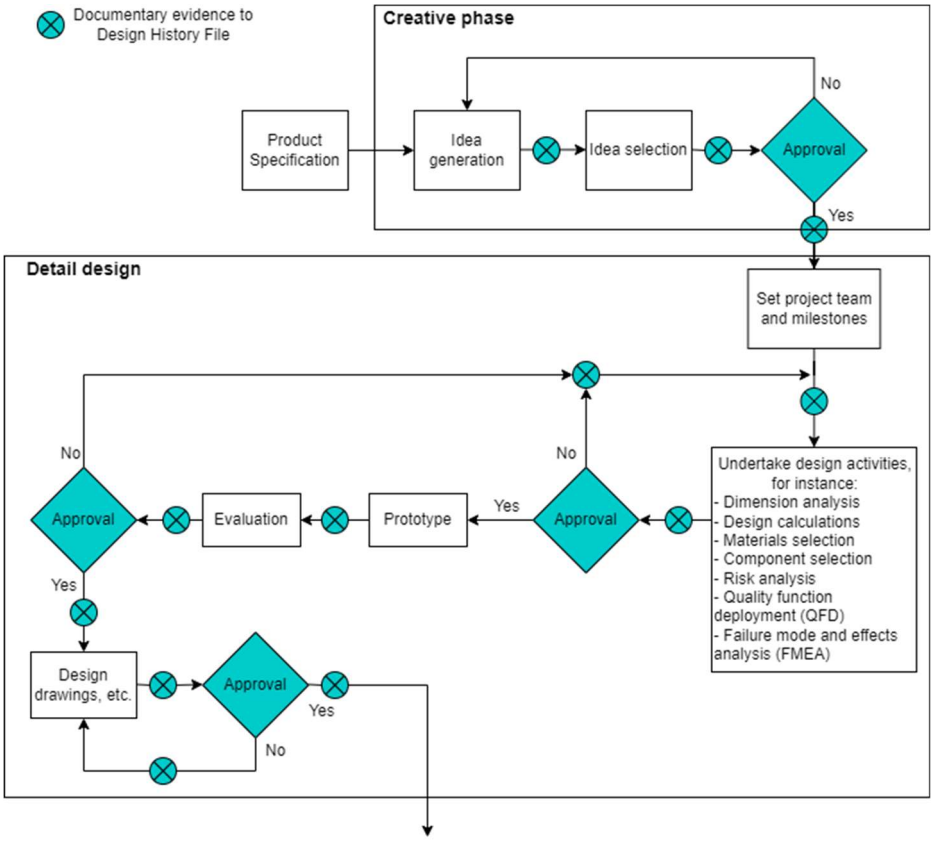


Figure 15. Detail Design procedure flow chart. Modified from (Ogrodnik, 2019) figure 4.6.

Design Verification and Validation (V&V) procedure requires considering FDA 21 CFR 820.30 sections F and G, which address verification and validation requirements. The same concepts are addressed in ISO 13485 sections 7.3.5 and 7.3.6. *Verifying refers to assuring that the inputs of the*

process meet the outputs. That is, the product complies with relevant regulations and specifications, and performs as it is supposed to. Verification activities mainly consist of tests, trials, inspections, and analyses. *Validation refers to assuring that the output works as intended in the clinical setup*. That is, the product meets the requirements of customers, patients, end-users, etc., and the total design is suitable for the intended use. Testing conducted in this phase should be performed in an environment that resembles the true usage environment of a finished product. Validation testing includes, for instance, clinical trials, labeling reviews, human factor testing, and stability testing. Overall, this procedure requires that evaluation criteria are specified, against which the V&V are conducted (Ogrodnik, 2019; Teixeira, 2019). Fig. 16 shows the main idea of the evaluation procedure, which applies to both verification and validation.

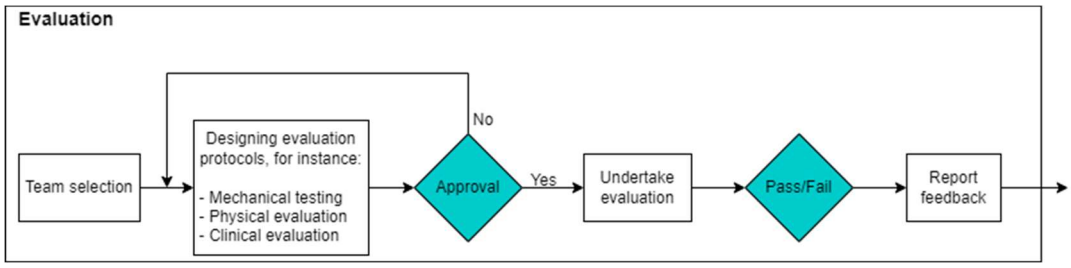


Figure 16. Design evaluation procedure. Modified from (Ogrodnik, 2019) figure 4.7.

Risk analysis and management are essential in medical device development, and they follow the requirements of ISO 14971:2019 – Application of risk management to medical devices. *The aim of Risk Analysis is to ensure that design changes or completely new configurations do not induce hazardous events*. That is, identifying the possible hazards, evaluating the risks associated, implementing risk control, and monitoring the efficacy of those controls. The total risk management process may be troublesome to present utilizing a single procedure as it consists of larger separate entities–analysis, evaluation, and control. Thus, individual procedures are not introduced here. Fig. 17 shows the main structure of the total risk management process as an adaptation from ISO 14971 (ISO 14971:2019; Ogrodnik, 2019).

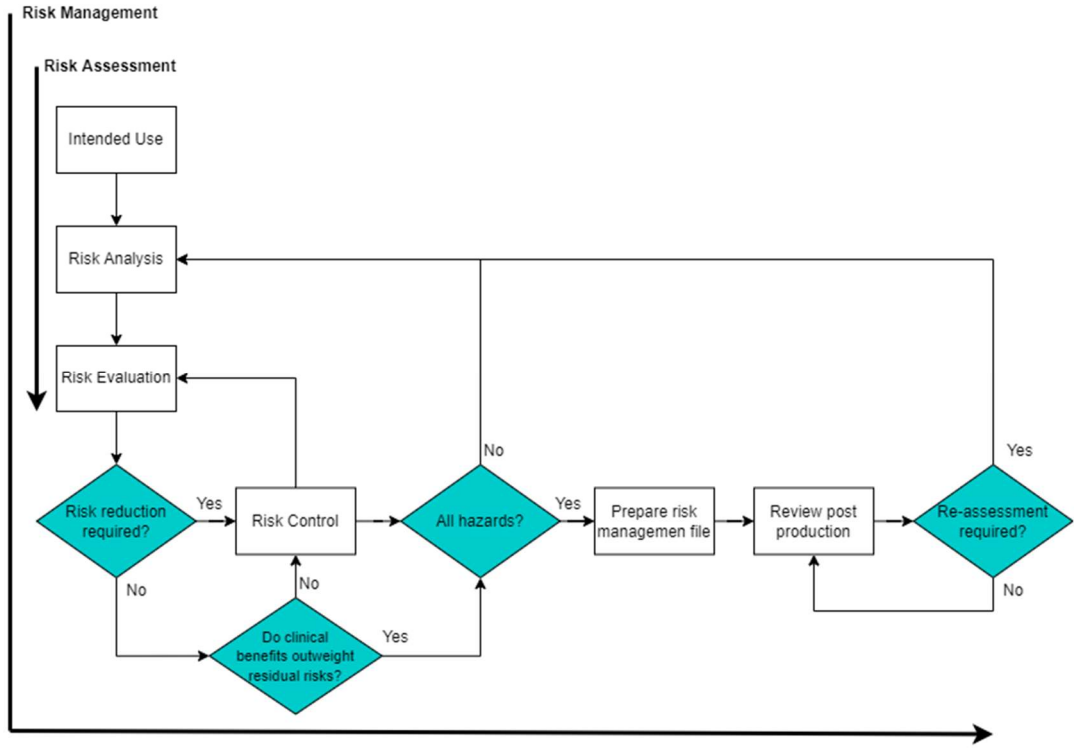


Figure 17. Risk management process. Modified from (Ogrodnik, 2019) figures 9.1 and 9.2.

The flowchart begins from intended use and proceeds to the risk assessment phase, which consists of risk analysis and risk evaluation. The analysis phase specifies potential hazards, and the evaluation phase assesses the level of risk associated with those hazards. *Typically, the risk level is defined as a product of severity and likelihood and presented in a tabular form*. Next, the total risk management loops around risk control until it is determined that clinical benefits outweigh the residual risks and that all hazardous events are addressed. After the control is deemed sufficient, the risk management file is prepared or modified. *The file is an essential component of the CE Technical File in Europe, and FDA's DHF in the USA, which are demanded to gain market entry*. The preparation of the risk management file is presented in the flowchart as a separate step. However, it may be beneficial to update during the risk assessment phase as well. Finally, the flowchart proceeds to the re-assessment stage where it is determined whether the total risk assessment is sufficient for market approval or if iterations are in place. *Overall, risk management should be conducted multiple times during the product development and after it*. This is demonstrated by the cyclic structure of the flowchart (Ogrodnik, 2019).

3 Methods and tools

This chapter addresses the process of producing all 2D documentation as well as the 3D CAD model of the cabling. Section 3.1 briefly describes the *Solidworks* software used in this project. Section 3.2 describes populating the manufacturer libraries with the component, connector, and cable data. Section 3.3 address the creation of line diagrams and connectivity reports. Section 3.4 describes the process of designing the 3D CAD model of the cabling, which includes transferring connectivity data to 3D space and the actual routing of the cables.

3.1 Solidworks Electrical

Solidworks Electrical is an electrical CAD package released from Dassault System integrating information from 2D schematics and 3D models in real-time. The line diagrams of this thesis containing the connectivity information of the 5-channel mTMS system were produced with *Solidworks Electrical Schematic* package. The line diagrams present the cabling of the system using single lines between component symbols. These diagrams are simplified representations of the complete system clarifying high-level connectivity (Verma and Weber, 2021). *Solidworks Electrical Schematic* contains a large database of symbols and manufacturer parts and allows adding new data. *Solidworks Electrical 3D* serves as a pathway between 2D schematics and 3D CAD model and brings electrical components to real-life imitating environments. Furthermore, the software allows modeling wires, cables, and harnesses of the system, which greatly eases cabling design and design for manufacturing in the latter phases of total product design. Electrical Schematic and 3D collaborate bidirectionally associating modifications in 2D environment to 3D, and vice versa. Aalto University provides free *Solidworks* licenses for students and personnel, and thus the software was used for this project.

3.2 Populating manufacturer libraries

Before producing the cabling documentation, information on the following was needed: electrical components, connectors, cables, wires, PCBs, and connectivity. Information on these was obtained largely from Dr. Jaakko Nieminen and Mr. Heikki Sinisalo. The connectivity of each component as well as used connectors, cables, and wires was then discussed in various meetings with both. Occasionally, an electrical component or a connector was discovered to be inadequate for 3D modeling purposes or the accurate model could not be obtained from the manufacturer. In these cases, a replica

was designed with *Solidworks*, with realistic dimensions, mounting options, and connectors' locations.

The first step in *Solidworks* software was to populate the manufacturer parts library of *Solidworks Electrical Schematics* with the used components. In this library, each component was given the following information: reference, manufacturer, line diagram symbol as well as possible circuits and terminals if deemed necessary. In most cases, the circuits and terminals of the electrical components themselves were neglected if any connectors were utilized. Only when a cable or wire was to originate directly from the electrical component or a PCB, for instance with a screw terminal, the component itself was supplemented with circuits and terminals. This simplification could be introduced as there was no interest to produce detailed electrical schematics of the connectivity. All electrical components that were added are found under miscellaneous class in the classification tree and by setting the library to USER. The view of the manufacturer parts manager is shown below inFig. 18. After the electrical components were successfully added to the manufacturer parts library, the same process was performed for the connectors and the PCBs used in the device. In addition to the previous data, information on the circuits and terminals was added for each connector according to the manufacturer's datasheets. The connectors can be found under the connectors class and the PCBs under the printed circuit board class by setting the library to USER.

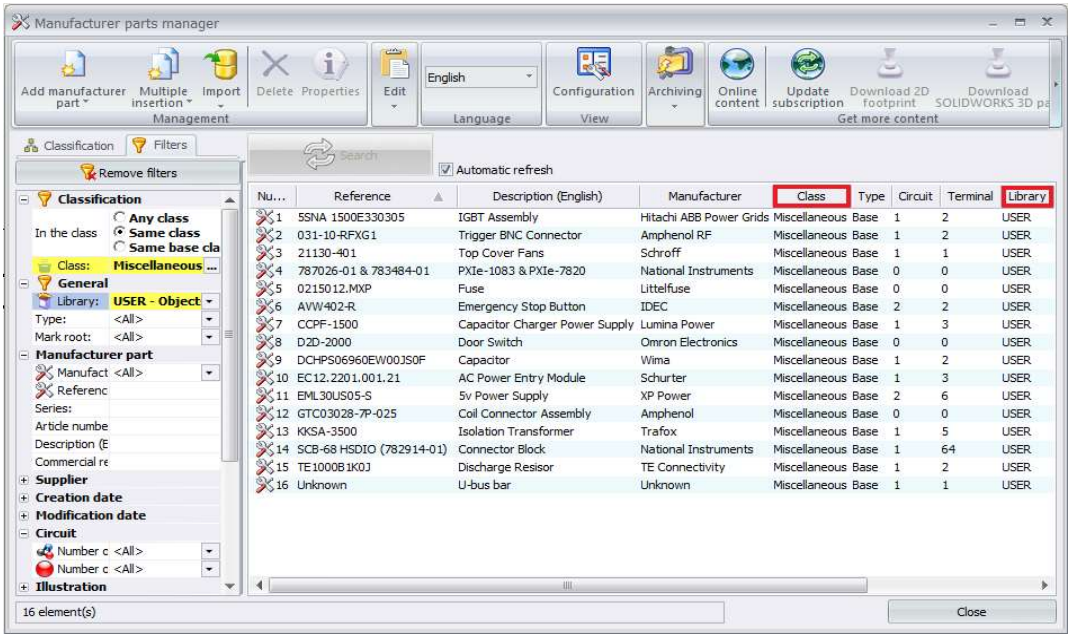


Figure 18. View of the manufacturer parts manager. To find the component data used in this project, one needs to navigate to the miscellaneous class and set the library to USER.

To connect the electrical components, PCBs, and connectors of the device, the terminals had to be named. Terminal drawings indicating the names were produced for each component and PCB. These drawings contain 2D representations of the components and PCBs where the names of the terminals are pointed with arrows. The connectors did not have their own terminals named. Instead, the connectors were named according to the function they had. For instance, the discharge controller (DC) PCB has a terminal for a 15V power supply. Therefore, the connector connected to this terminal was named "15V" and consequently, its marking in the connectivity reports "DC – 15V". The aim was to name the terminals as clearly as possible so that each terminal/connector would have a name indicating its function or the name of the destination it connects to. However, it is worth mentioning that utilizing these terminal names is not compulsory–they are simply the ones appearing in the connectivity reports introduced later.

Populating the manufacturer parts library with electrical components and connectors was not sufficient as information on the links between them was still absent. The cables were added to their own library using the cable references manager of *Solidworks Electrical Schematics*. Each cable was given the following information: reference, manufacturer, number of conductors as well as the gauge and color of both the cables and conductors. Whenever the manufacturer did not provide information on the diameters of cables or conductors, an approximation was used. All connected cables of the project were added under _AWG class and to the USER library. The view of the cable references manager is shown below in Fig. 19.

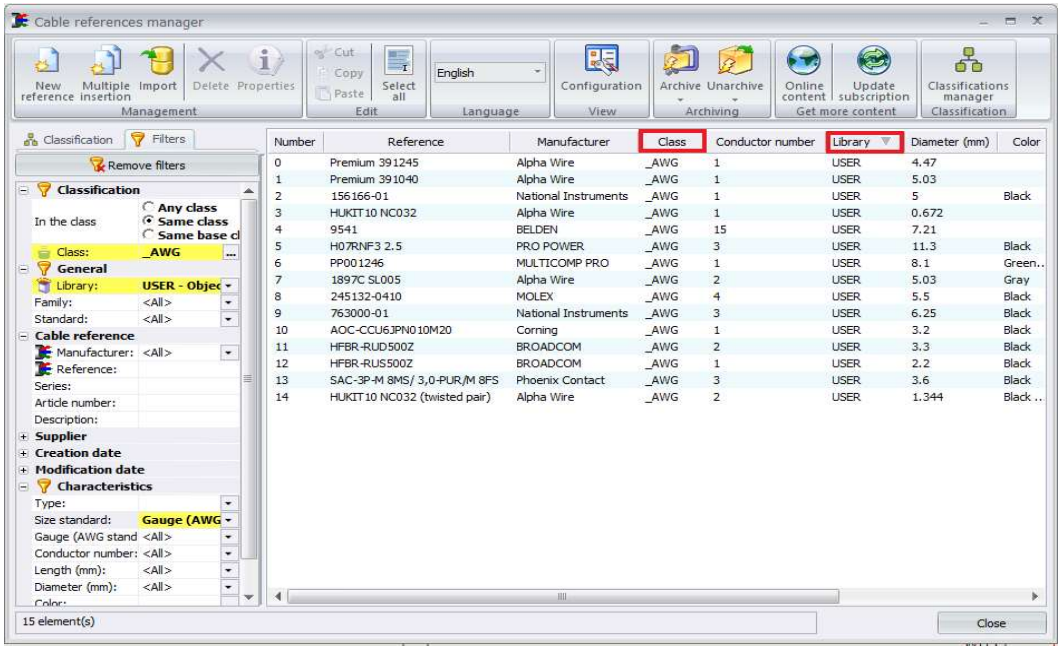


Figure 19. View of the cable references manager. To find the cable data used in this project, one needs to navigate to the _AWG class and set the library to USER.

3.3 2D documentation

All data needed for creating the 2D representation of the system was now added to the libraries. Next, the symbols for the line diagrams had to be designed. This was achieved with the symbols manager of *Solidworks Electrical Schematics*. In this environment, one may choose the visualizations for the line diagram symbols and define which information is visible in the box elements. In this project, the line diagram symbols of electrical components and PCBs were equipped with a tag, reference, manufacturer, and a description when deemed necessary. The CAD model of the component was used as an image for each box element. The connectors were also given their own line diagram symbols to increase the clarity of the whole diagram. By adding the connectors, lines could be drawn directly from connector to connector, which eases the perceiving of the diagram. Each connector box element was equipped with a tag and a black-and-white transparent CAD model image. After all the symbols were created and added to the symbols manager, the electrical components and connectors were assigned their own line diagram symbol in the manufacturer parts manager. Now when placing a symbol to the line diagram canvas, the associated manufacturer info fills the reference, manufacturer, and description fields in the box element. Furthermore, all circuits and terminals are now accessible for creating the connections between box elements.

The creation of the actual line diagrams was fairly simple after all relevant data was added to the libraries and each component was assigned its own line diagram symbol. First, the symbols involved in a connection were chosen from the *Symbols Manager* and placed on the canvas. Second, a cable was drawn between the symbols with the draw cable command. Third, the cable was defined first by double-clicking the drawn line and then the empty white space between the components in the detailed cabling window. This allows assigning a cable for this connection from the cable references library. One may also add multiple cables in this view. This allows representing multiple cables with a single line in the line diagram. Once a cable has its reference, it also appears in the cables manager, which contains information on all cables used in the project. Cables manager can be found under the project tab in *Solidworks Electrical Schematics*. Finally, the conductors of the cable are connected to the terminals of the electrical components and connectors by drag and drop. The view of the detailed cabling window is shown below in Fig. 20.

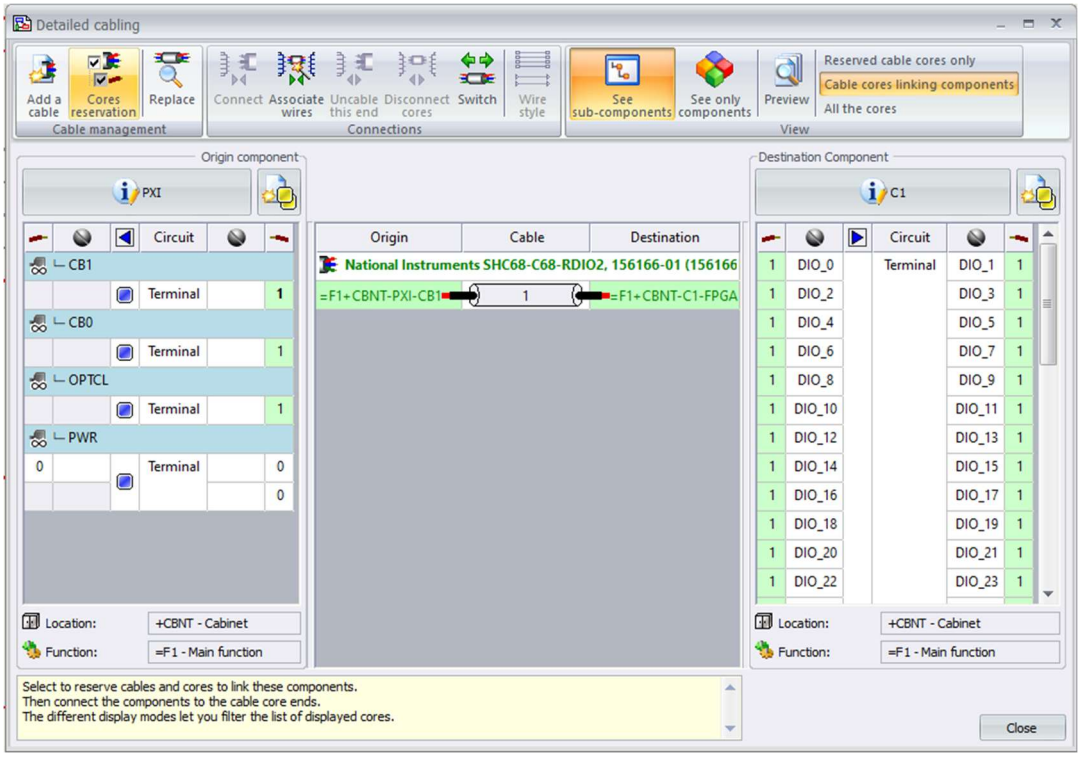


Figure 20. View of the detailed cabling window**.** The connected components are on the right and left sides of the window. In between is the cable that was chosen by double-clicking the initially empty space between the origin and destination components. The conductors of the cable are associated with their appropriate terminals by drag and drop. After this, the associated terminal appears at the end of the cable on a green background. The number one on a green background under the origin and destination components indicates the number of conductors assigned for a particular terminal.

The connectors in the line diagrams were associated with the components and PCBs that they were connected to. This was performed by left-clicking the connector symbol and using the *Assign Component* command. After this, the tag of the connector line diagram symbol changes to match that of the component/PCB. At the same time, however, the connector lost its circuit and terminal information. This was corrected by adding the connector under its parent component in the component tree. In the component tree, each component and PCB already have their own line diagram symbol as well as the line diagram symbols of the connectors associated with them visible. By left-clicking the component/PCB in the component tree and choosing new – connector, one may add connectors. After this, one specifies the connector by opening the manufacturer part and circuits tab and by searching for the appropriate connector from the manufacturer parts library. In the mark and data tab, one also identifies the mark of the connector, which should be the same as in the terminal drawings. All this allows having the connector line diagram symbols present in the line diagrams while also maintaining their circuit and terminal data. Now when the terminals are connected to cable

cores in the detailed cabling window, the terminals of each connector appear under the parent component/PCB and are available for connecting. For instance, the connectors named CB0, CB1, OPTCL, and PWR of component PXI are visible as separate sections on the left side of Fig. 20 above.

Once the wiring diagrams were finished, the information they held could be extracted into various reports. Three report types were chosen for this project: a list of cables, a bill of materials sorted by mark, and a list of connections. The list of cables report was grouped by cable description, which consists of cable manufacturer followed by its reference. The cables are in numerical order within each group. Furthermore, some of the cables have an approximation of their length in the system, which is based on the cable lengths in the 3D model. However, the length of the cable could not be determined correctly for most of the routed cables, and thus the lengths were omitted (for the prototype device, the lengths of cables will be determined during the cable production process). The bill of materials sorted by mark report indicates what each mark stands for in the list of connection lists. The reports first go through the electrical components and PCBs in the system presenting the mark, reference, description, and manufacturer for each. Then, the report lists the same information for each connector in the system. The list of connections contains the most important information from the reports. This is where each connection is described in detail. The same information can be found in the *Solidworks Electrical Schematics* environment, but this section of the reports allows presenting the connectivity without the use of the software. The list of connection report follows the same order as the bill of materials sorted by mark list: first it goes through the electrical components and PCBs of the system one by one and then reviews the same data for the connectors. The first column indicates the mark of the origin component/PCB/connector and the second indicates the used terminal. Correspondingly, the third column indicates the mark of the destination component/PCB/connector. In addition to the destination information, this column contains the terminal information as well. The fourth and fifth columns describe the used cable and cable core. The list of connection report reviews the connections in the system for each origin independently. Thus, every connection is represented twice in the lists. However, as the list is generated in alphabetical order, it is beneficial to have each component/PCB/connector as the origin at least once. This eases the browsing for a specified connection.

3.4 3D CAD model of the cabling

All relevant connectivity data was created in the 2D environment. Switching to the 3D space meant implementing this information and visualizing it. This process consisted roughly of four parts: creating the connector models and

transforming each component/PCB/connector CAD model into electrically intelligent elements, populating the whole cabinet with the connectors, designing routing tracks, and routing the cables, and producing descriptive visualizations of the routing tracks.

Initially, the CAD model of the device had, in practice, no connectors. The first step was to download the connector CAD models from the manufacturers, which turned out to be a troublesome task. Some connector manufacturers provided CAD models, but most did not or did not reply to the inquiries. Luckily, websites, such as GrabCAD (https://grabcad.com/library) and 3D ContentCentral (https://www.3dcontentcentral.com/) provide CAD models of various components created by their users. Often, a replica of sufficient accuracy could be found, and the insufficient ones could be modified into useful units. Once every connector of the project had a 3D CAD representation, it was time to turn these connectors as well as other electrical components and PCBs having cabling connection points into electrically intelligent elements. This was performed with *Electrical Component Wizard* of *Solidworks Electrical 3D*. In this environment, each component, PCB, and connector were equipped with necessary connection points, which were then associated with those of the manufacturer parts. This was performed by adding a connection point with the point type set as "CPoint from manufacturer part" under the routing functionality points in the wizard. A view opens allowing the choice of a manufacturer part.

The electrical components and PCBs of the device with connection points were relatively few, but the number of connectors was large. Therefore, it was not practical to create the connection points for each connector separately. Luckily, the software allowed one to save the CAD model with its newly created connection points and linked manufacturer part data to a design library at the end of the steps in the *Electrical Component Wizard*. Once a connector was saved to this library, it could be inserted into the CAD model of the device by drag and drop. Furthermore, if proper mate references were added to the connector during the steps of the *Electrical Component Wizard*, the connector also snapped into its intended place. This property accelerated the connector populating process although not all added mate references obeyed as planned. When all connectors were added to the CAD model of the device and all CAD models of the electrical components and PCBs were given their routing connection points, it was time to associate each component/PCB/connector to their representation in the 2D line diagrams of the project. This was performed by first opening the *Solidworks Electrical* project in the 3D space and then by associating 2D elements to their 3D CAD models one by one. The project could be opened by clicking *Electrical Project Documents* on the right side of the *Solidworks* window, right-clicking the empty space, choosing *Project Manager*, and then opening the correct

project. This opens a new tab to the left side of the *Solidworks* window named *Electrical Manager*, which contains the same component tree that may be viewed in the *Solidworks Electrical Schematics* environment. Each component linked with a manufacturer part had a 3D part icon under it. By right-clicking the icon and selecting Associate, the chosen component/PCB/connector was linked with its representation in the CAD assembly.

The 3D routing process was performed both automatically and manually. All the relevant data for the automatic routing was already entered into the system except for the routing guidelines. *Solidworks Electrical 3D* offers the option to draw 3D sketches that serve as guidance for automatic routing. However, this was discovered to be impractical for a device with so many connections and many tight spaces. The best practice proved to be utilizing cable ties as guidance. Furthermore, this was the way most of the cables of the previous physical prototype were routed with. The routing steps proceeded as follows: first, the auto-routing was performed for each of the roughly 230 cables of the system. The system created each cable with its correct characteristics unless there were disagreements with the manufacturer data and the associated 3D component. Simultaneously, the system informed of all errors in the routing process. Some of the errors were for a clear cause but some stayed in each routing round no matter the actions. The cables that were not successfully created appeared as stubs in the origin and destination. Eventually, these connections had to be routed manually. The cables that were successfully modeled had their correct visual appearance, but the track of the cables was nowhere near realistic as they did not notice any obstacles, therefore, piercing other components and solids. The re-routing of these cables was achieved with the cable ties that were attached to the cabinet walls, side rails, and other locations. Overlapping was reduced wherever deemed necessary by manually moving the splines of the cables. Overlapping was ignored in and near the cable bundles formed with the cable ties. The final step was to re-color the modeled cable as they tended to lose their assigned colors if the route in question was modified.

Finally, routing track documents containing images and descriptions of the tracks were produced. The designed routing tracks were highlighted, and descriptive images were produced. These images serve as a rough outline of each track and should be examined shortly after beginning the cabling process. Each track is colored in bright red and when deemed necessary, the display state was set to transparent black and white. All components, PCBs, and connectors, besides those connected to the studied track, were hidden. The documents are described in more detail in Section 0.

4 Results

This chapter describes the outputs of the total cabling design and documentation process. This includes connectivity documents and other illustrations as well as 3D CAD representations of the total cabling. Section 4.1 introduces the connectivity of the mTMS system on a general and detailed level. First, the connectivity is described without utilizing specialized software. This includes connectivity matrices and connectivity graphs. These demonstrate that the general-level connectivity of a complex electro-mechanical system can be described without using highly sophisticated software, however, a comprehensive understanding requires more. The latter sections of the chapter present 2D documentation produced with *Solidworks* and *Solidworks Electrical Schematics*. Section 0 switches to 3D space and describes the CAD model and routing track documents of the cabling. Finally, Section 0 presents how all the documentation can be used for cabling the device in the form of an example.

4.1 Connectivity documentation

Currently, the mTMS CAD model consists of roughly 80 components that have cable connections, 290 connectors, and 230 cables. The number of connected components, connectors, and cables varies slightly depending on the definition. A connector may be in contact with more than one component, which affects determining the total number of cable-connected components in the model. Furthermore, sometimes a component comes with its own connectors intact, or a component is, in principle, a connector itself, which affects determining the total number of connectors in the model. The cables of the model consist of either one wire or multiple. Thus, the number of cables depends on the grouping method.

The connectivity of the total system can be presented using a simple two-dimensional connectivity matrix presented in Appendix A. The first row and column of the matrix contain a list of components and the elements of the matrix indicate whether a link exists between the components. The number of links between the components can be expressed by assigning a weight for each link. The matrix of Appendix A contains all currently defined connections of the device. The weights have been slightly adjusted for connections between Connector Blocks and E2O PCBs to not overemphasize their role. The matrix is used to plot the connectivity graphs presented later in Fig. 22.

The matrix expression can be used to plot simplified graphs of the connectivity. Fig. 21 resents a circular layout graph of the connectivity based

on a complete unweighted connectivity matrix of the mTMS system. The graph is unweighted to improve the clarity of the connections. Component name–abbreviation pairs are presented in the connectivity matrix. Fig. 22 presents location outline graphs of the mTMS system in 2D, which illustrate the centrality of each component. The node diameters are determined by degree, that is, the number of connections for each node. The width of the edges corresponds to the number of cables between components. The graphs are based on a weighted version of the connectivity matrix presented in Appendix A, where the weight of each link corresponds to the number of cables between the specific components. As mentioned, the weights of some connections are mitigated. For instance, connector blocks and electrical-to-optical boards have multiple small cables connecting the components. In the device, the cables will be bundled so it is left for interpretation whether the connections are indeed small individual cables or larger cables consisting of multiple wires. Regardless, the weight of this link was mitigated to avoid overemphasizing the role of the two component groups in the centrality graphs. The components are organized to mimic their real location in the mTMS cabinet in 2D when viewed from the backside of the cabinet. The color of the nodes indicates the centrality scores of the components using four different measures. Without going into details, these scores and node degrees indicate the most central and widely connected components of the system.

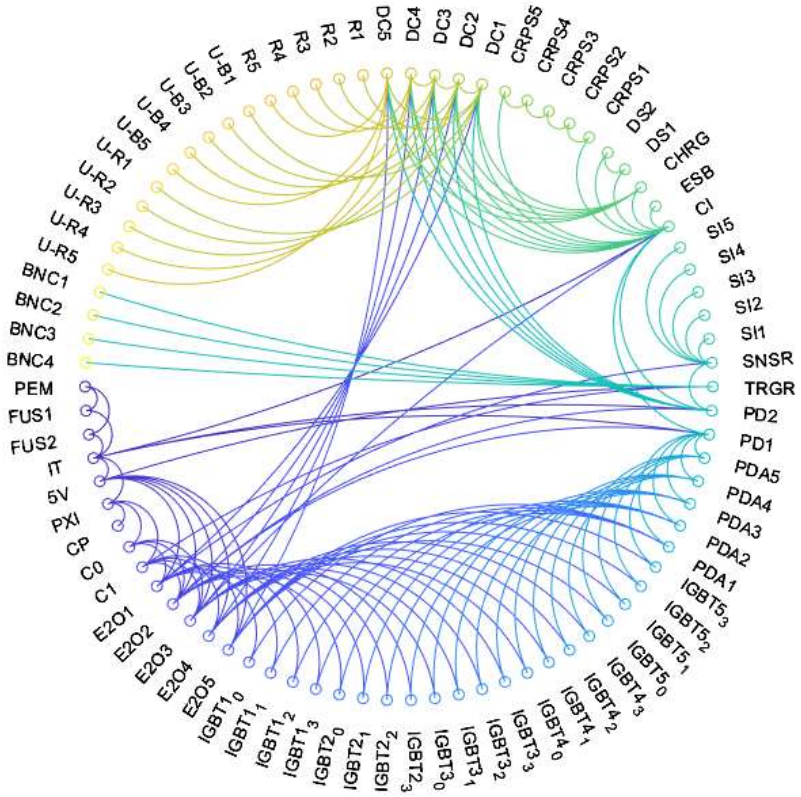


Figure 21. Unweighted circular connectivity graph. The graph does not consider multiple connections between specific components.

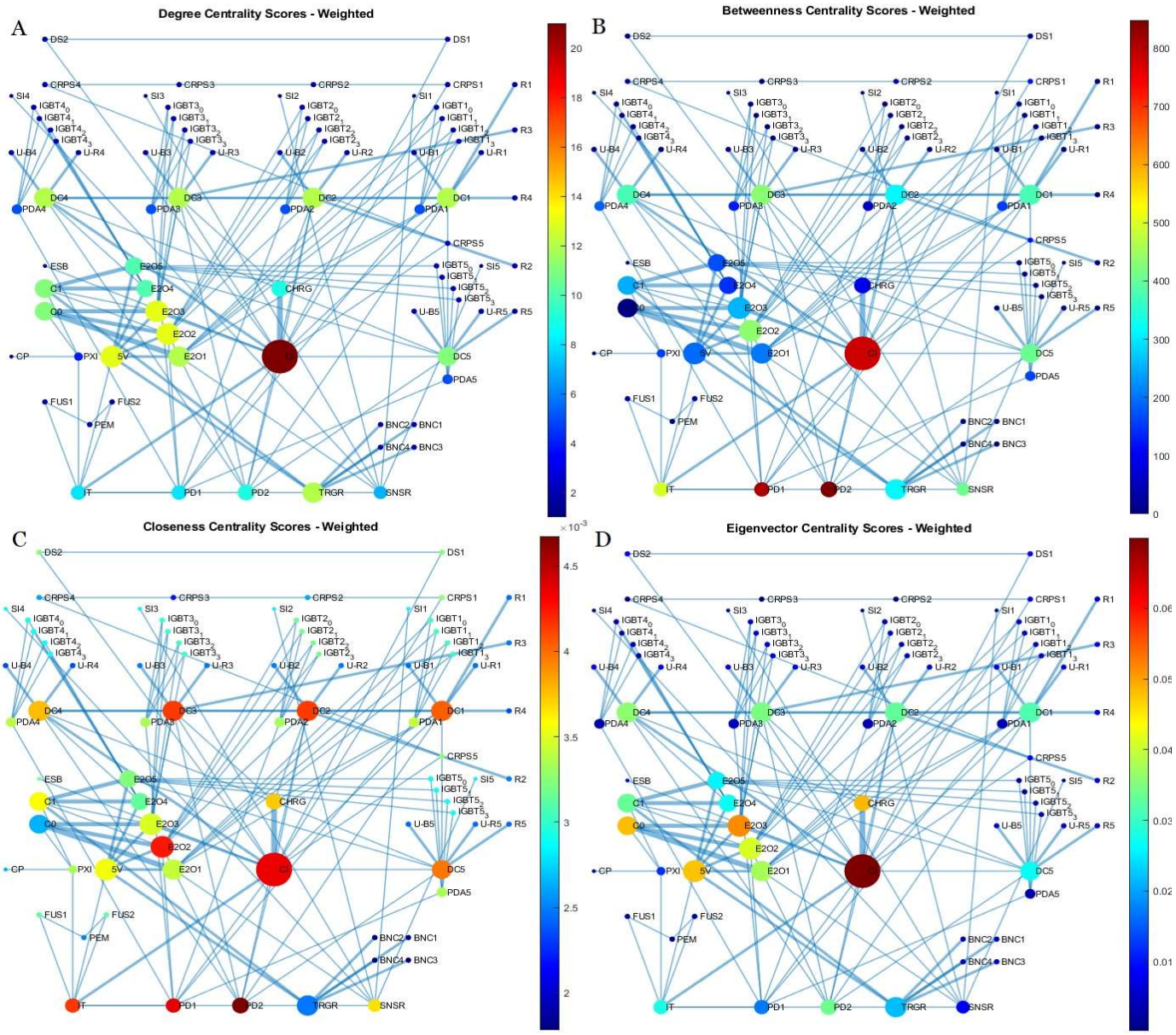


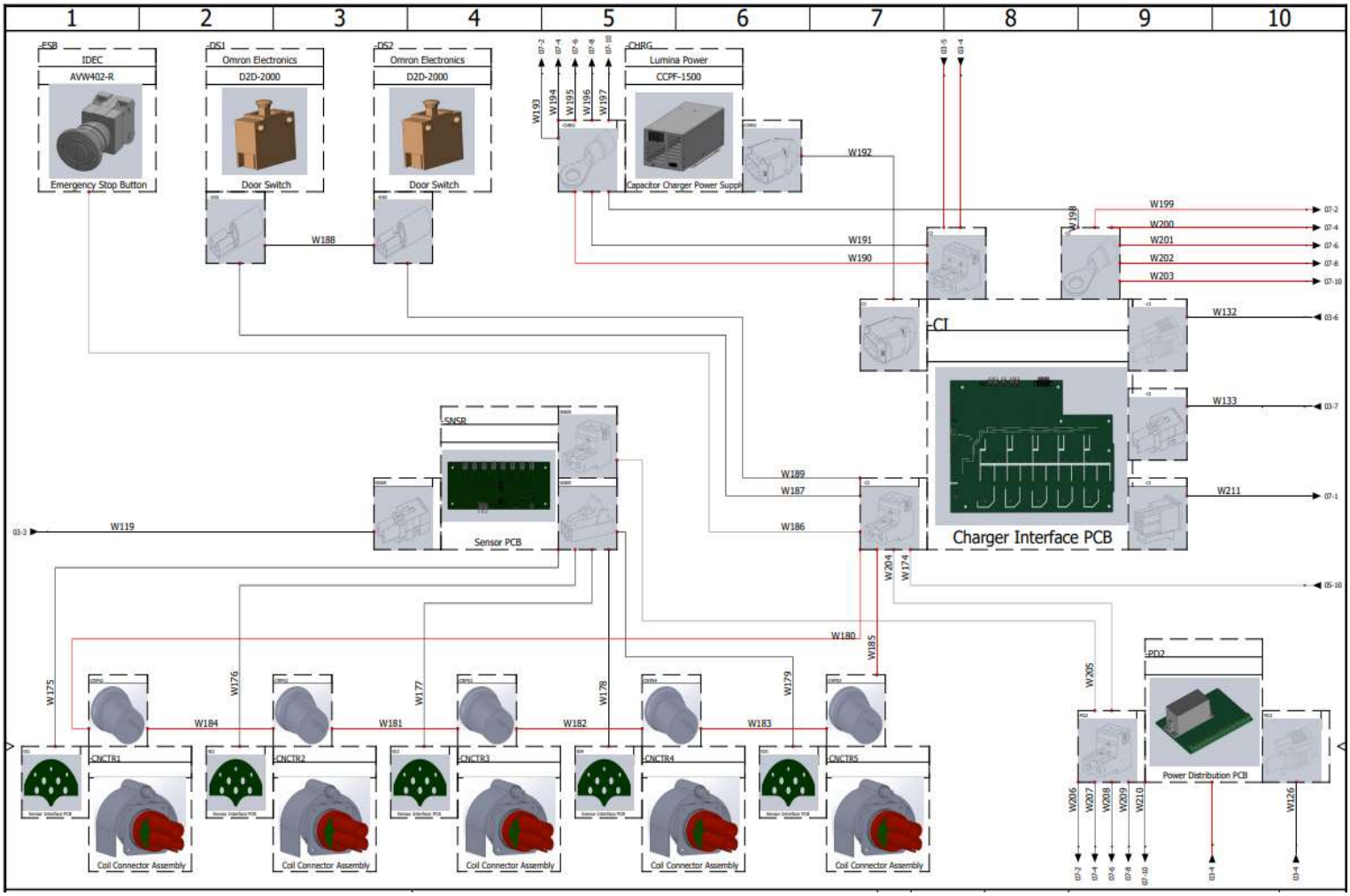
Figure 22. (A) Degree centrality, (B) Betweenness centrality, (C) Closeness centrality, and (D) eigenvector centrality of mTMS components in a weighted location outline connectivity graph. The structure of each graph is the same – node diameter is proportional to the number of connections for each component and edge width to the number of connections between two specific components. The weight of edges between connector blocks and electrical-to-optical PCBs has been mitigated. The color of nodes corresponds to their centrality score with the four measures.

The matrix expression and corresponding network graphs present general information of the device connectivity but lack much of relevant information for documentation and assembly. Furthermore, the definition complications regarding components, connectors, cables, and wires complicate producing a comprehensive weighted connectivity matrix. Overall, for a functionally complex system, such as the mTMS, more comprehensive connectivity

documentation is needed, which in this case was produced with *Solidworks Electrical Schematics*.

Solidworks Electrical Schematics was used for creating line diagrams of the system, which illustrate the connectivity and contain sufficient information on the components, connectors, and cables to aid in the assembly of the device. The whole device was described by four line diagram pages, one of which is presented as an example in Fig. 23. The large box elements represent the components of the system, and they display the reference and the manufacturer. High voltage capacitors are not directly involved in cable connections in the diagrams but are still represented with a box element to indicate their location among other components. Similarly, coil connector assemblies do not have cable connections, but they are included in the diagrams as their subcomponents are involved. The smaller box elements with transparent images represent the connectors. Each connector type is presented only once next to its component to free space. Typically, the connections are drawn from connector icon to connector icon to indicate the types of connectors involved in the link. Connections that do not originate from a connector icon indicate that the cable is connected directly to the component with a screw terminal or that the component has a suitable terminal by default. The links represent the cables of the system, and they are numbered. Multiple cable numbers for a single link indicate that the link consists of more than one cable. If the cables have different connectors or terminals, the links are not grouped under the same line. Currently, the non-numbered links do not have a designated cable yet. The link colors are set to mimic those of the cables. However, applying heat shrinks to the system may alter the coloring. The links leading to the edges of the document page are leading to other line diagram document pages.

After adding components, associating their connectors, defining terminals, and connecting all box elements, three report types were chosen for describing the connectivity. Bill of materials sorted by mark links each component mark used in the system to component information, such as part reference, manufacturer, and description. Similarly, the list of cables links each cable mark to cable information, which contains a reference and a description. The most important report is the list of connections as it disentangles detailed information on the connections. That is, the report describes which component and connector marks link together and what cable mark is used for the link. Sections of each three reports are shown in Fig. 24. The use of connectivity reports is not mandatory as all mentioned connectivity information of the components, connectors, cables, and connections can be viewed in the *Solidworks Electrical Schematics* environment as well.



***F*igure 23.** Line diagram document. The box elements represent components and connectors, and the lines between boxes consist of cables.

A

Mark: Component / Component-Connector	Reference	Description	Manufacturer
-CI-PD2	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT
-CI-RX/TX3	HFBR-4506Z	Fiber Optic Connector Duplex	BROADCOM
-CI-ESB	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT

B

-CI-PD2

Origin: Component / Component-Connector	Terminal	Destination: Component / Component-Connector / Component:Terminal	Cable	Cable wire
-CI-PD2	(0-0)	-PD2-PD3	W204	1
-CI-PD2	(1-0)	-PD2-PD3	W204	2

-CI-RX/TX3

Origin: Component / Component-Connector	Terminal	Destination: Component / Component-Connector / Component:Terminal	Cable	Cable wire
-CI-RX/TX3	TX	-E2O3-RX/TX6:RX	W133	2
-CI-RX/TX3	RX	-E2O3-RX/TX6:TX	W133	1

-> -CI-ESB

Origin: Component / Component-Connector	Terminal	Destination: Component / Component-Connector / Component:Terminal	Cable	Cable wire
-CI-ESB	(0-0)	-ESB:NC1	W186	1
-CI-ESB	(1-0)	-ESB:NC2	W186	2

C

Wire number	Description	Reference
W133	Fibre Optic Cable (two fibres)	HFBR-RUD500Z
W186	Alpha Wire, 1897C SL005	1897C SL005
W204	Alpha Wire, 1897C SL005	1897C SL005

Figure 24. Line diagram reports. (A) Bill of materials sorted by mark report for some Charger Interface PCB connectors. (B) List of connection report for three Charger Interface PCB connectors. (C) List of cables report for three cables used to connect Charger Interface PCB.

Although the reports describe the origin and destination component and connector as well as the used cable, one still needs information on the connector locations within components. For instance, the Charger Interface PCB has 19 connector terminals and thus knowing which connector mark represents which terminal is difficult. As a result, descriptive terminal drawings were produced for each component. In the drawings, each terminal is linked with its connector mark used in the reports. The naming of the terminals does not have to be official nor final–these marks are simply used in the connectivity reports. The terminal drawing document for Charger Interface PCB is shown in Fig. 25.

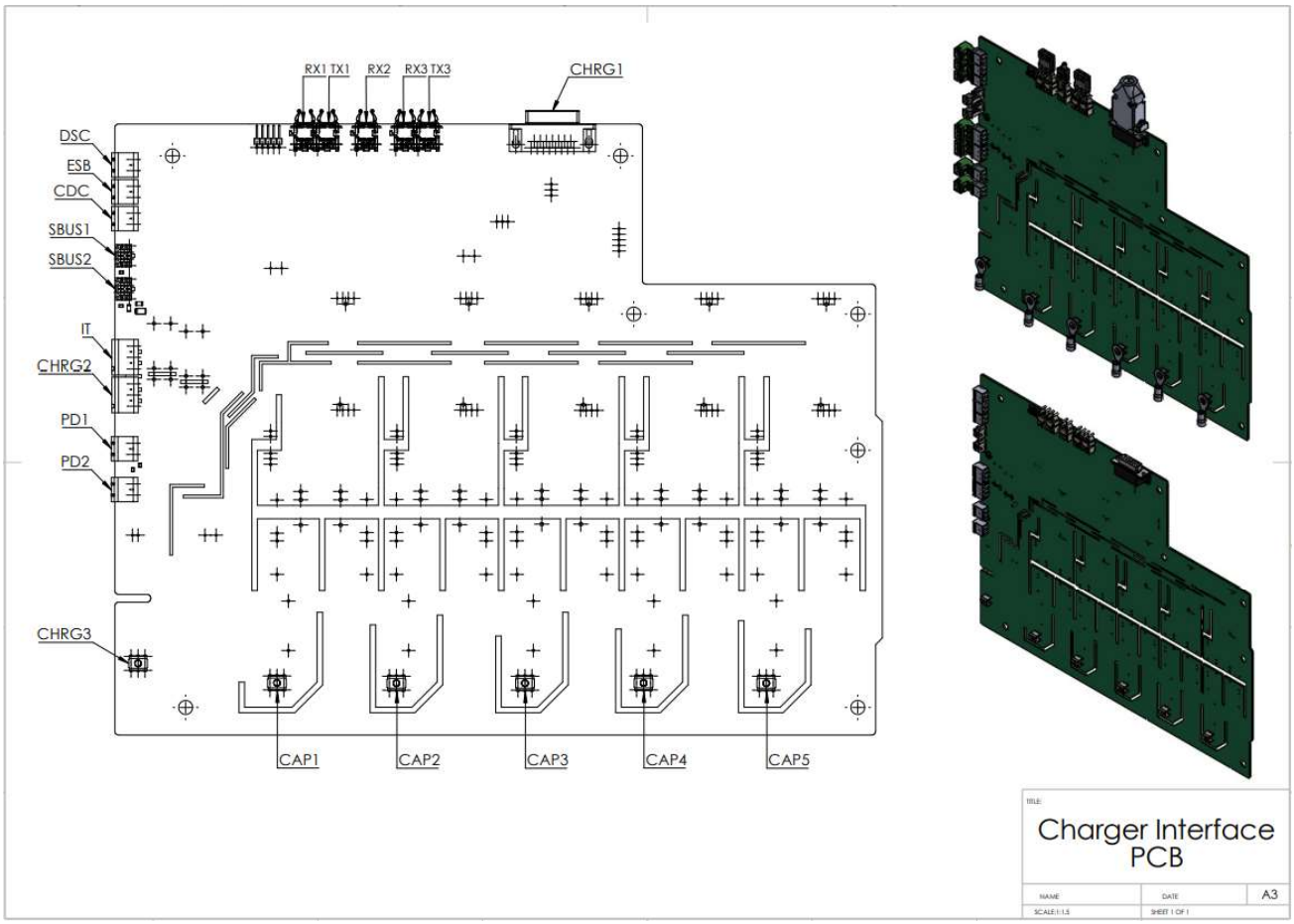


Figure 25. Component terminal drawing document. The terminal tags indicate the names of the connectors that are plugged to them. If a connector is not used, the tag indicates the name of the component terminal.

4.2 Routing track design

After all 2D documentation, what remains is designing the tracks in 3D. This design was performed in *Solidworks Electrical 3D*. By the time of writing, cabling has not been performed for the 5-channel mTMS system. Thus, this model stands as a proposition and a basis for later modification. Before the cabling, the total mTMS CAD model was already modeled per IEC60601 (https://www.iso.org/standard/65529.html), which is a medical device safety standard. Slight changes were made whenever the existing component models proved to be impractical for cabling. All components with cable connections were turned electrically intelligent. That is, terminals and connection points were produced for each component. Furthermore, connector CAD models were added to the total model. The main guidelines for determining the routing tracks were to avoid high voltage components to comply with medical device regulations and standards and to utilize the side rails and cabinet pillars as much as possible. The routing was performed by utilizing cable ties, which is how the cables are routed in the real-life system as well. The resulting total CAD model is shown in Fig. 26 and closer views in Fig. 27.

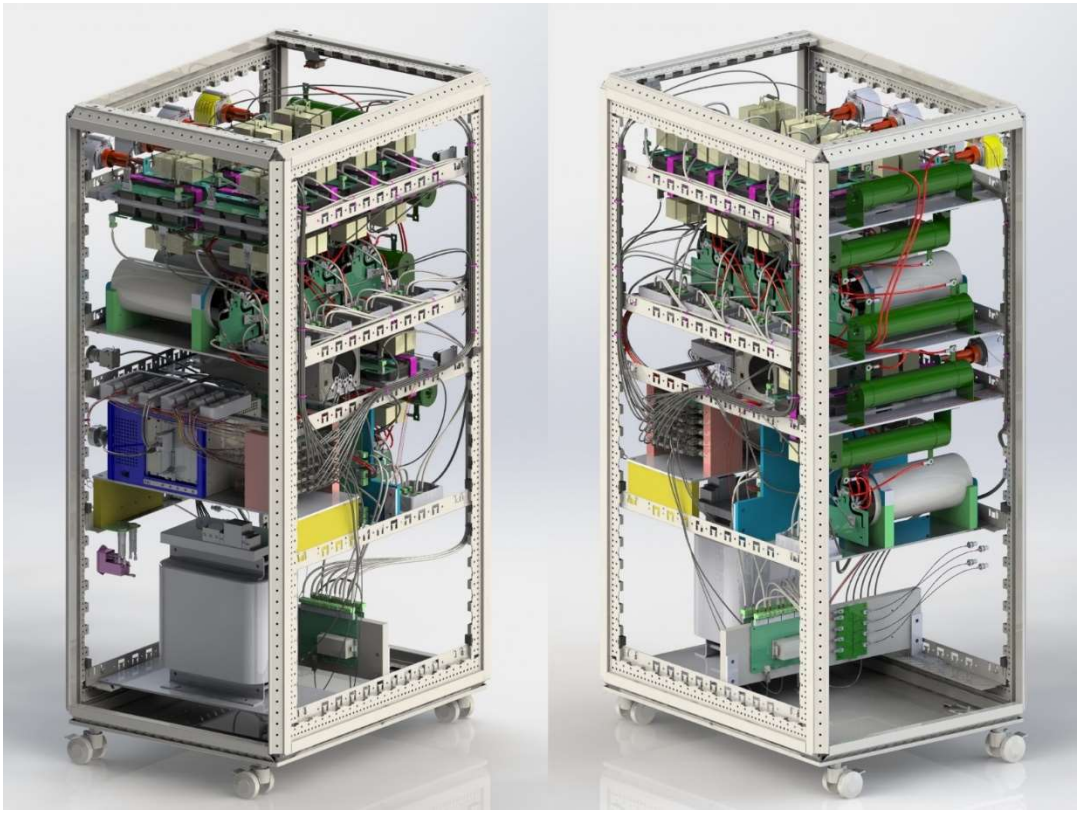


Figure 26. 5-channel mTMS system CAD model. The side panels, doors, and top are hidden in the image.

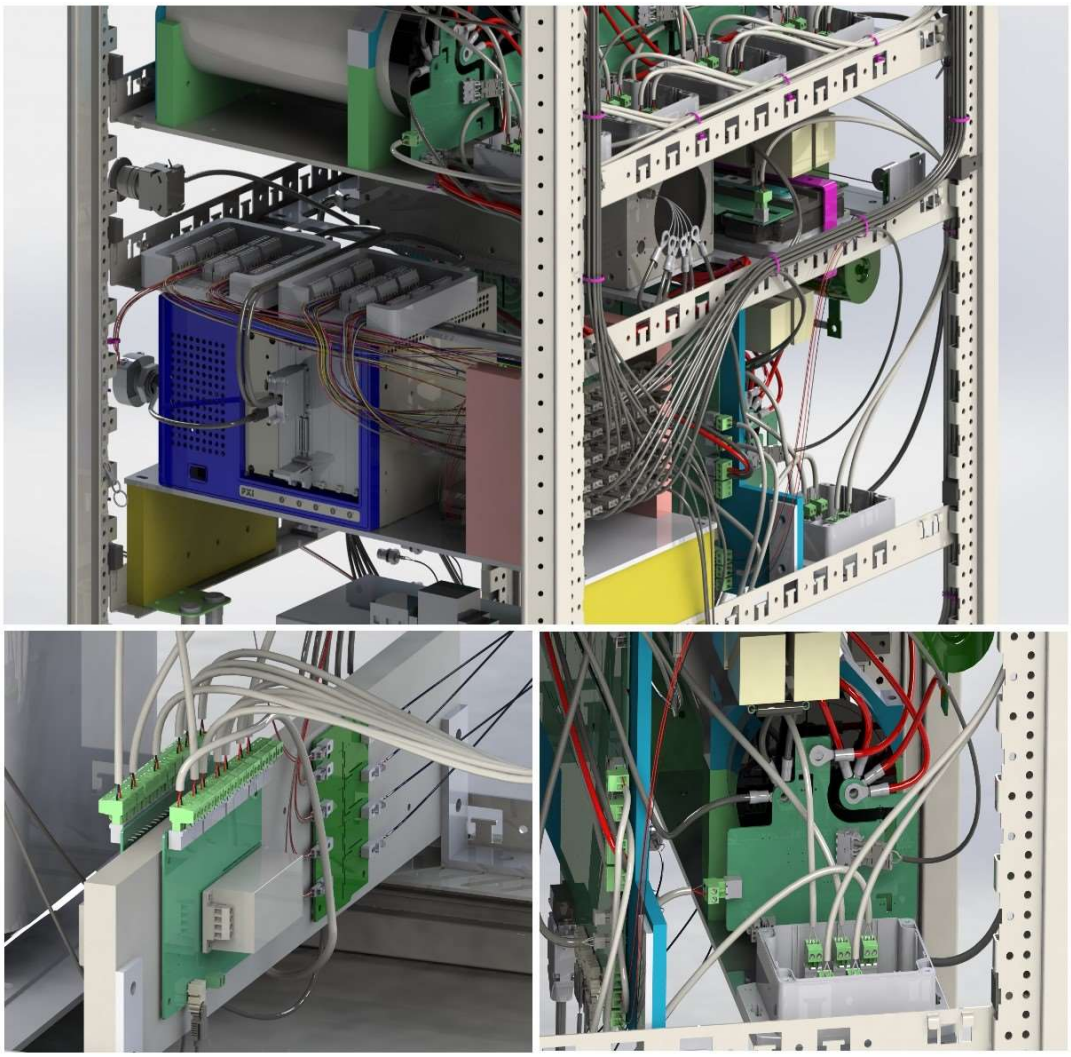


Figure 27. 5-channel mTMS system CAD model detailed views.

The CAD model and together with the 2D documentation contain, in theory, enough information for outsourcing the assembly task. However, a step-by-step manual of the cabling that describes used screws, nuts, washers, tools, etc. is still needed. To aid in the perceiving of the routing tracks, routing track documents were created. These documents are compact files that illustrate and describe the routing tracks for major connections in the cabinet. In addition, relevant connectivity reports are added to the document. The documents do not have duplicate connections. That is, each connection is described once–either in the document of the origin or destination component. An example document is shown in Appendices B and C.

4.3 Interpretation of the documentation

Next, the use of the previously described connectivity documentation for the cabling of the device is demonstrated. As an example, one connection from the Charger Interface PCB to Power Distribution PCB is drawn using the documents shown in the figures above. Fig. 28 below combines the process flow into one image. First, the cable mark is obtained from the line diagram and the cable characteristics are checked from the list of cables report. In our example, the cable is W204. Then, the list of connection report is browsed for the correct cable mark. The browsing process can be expedited by searching for connections for the specific component as the list of connection report is grouped by components and their connectors. The correct cable is found by searching the list of connection for connectors under CI and the origin and destination connectors are discovered to be CI-PD2 and PD2-PD3. If it is unclear what the component marks (CI & PD2) stand for, one may check the bill of materials sorted by mark. In our example, the connectors are PD2 connector of Charger Interface PCB (CI) and PD3 connector of Power Distribution PCB 2 (PD2). This example connection is chosen to demonstrate that the components and connectors do not have unique marks. For instance, the PD2 connector of CI is named according to its connection destination– the second Power Distribution PCB. On the other hand, the second Power Distribution PCB has 12 similar terminals and the connection order of those is flexible. Thus, the terminals, and correspondingly the connectors, are marked simply from PD1 to PD12. Finally, the component terminal drawing documents are studied to clarify the location of the connectors in their parent components. As a result, one has discovered the correct cable, components, connectors, and the location of those connectors with respect to the parent components. The routing track for the described connection is discovered by viewing the 3D model. Furthermore, the routing track documents serve as additional support for determining the correct tracks. The interpretation process for the 2D documentation and the corresponding 3D view is shown in Fig. 28.

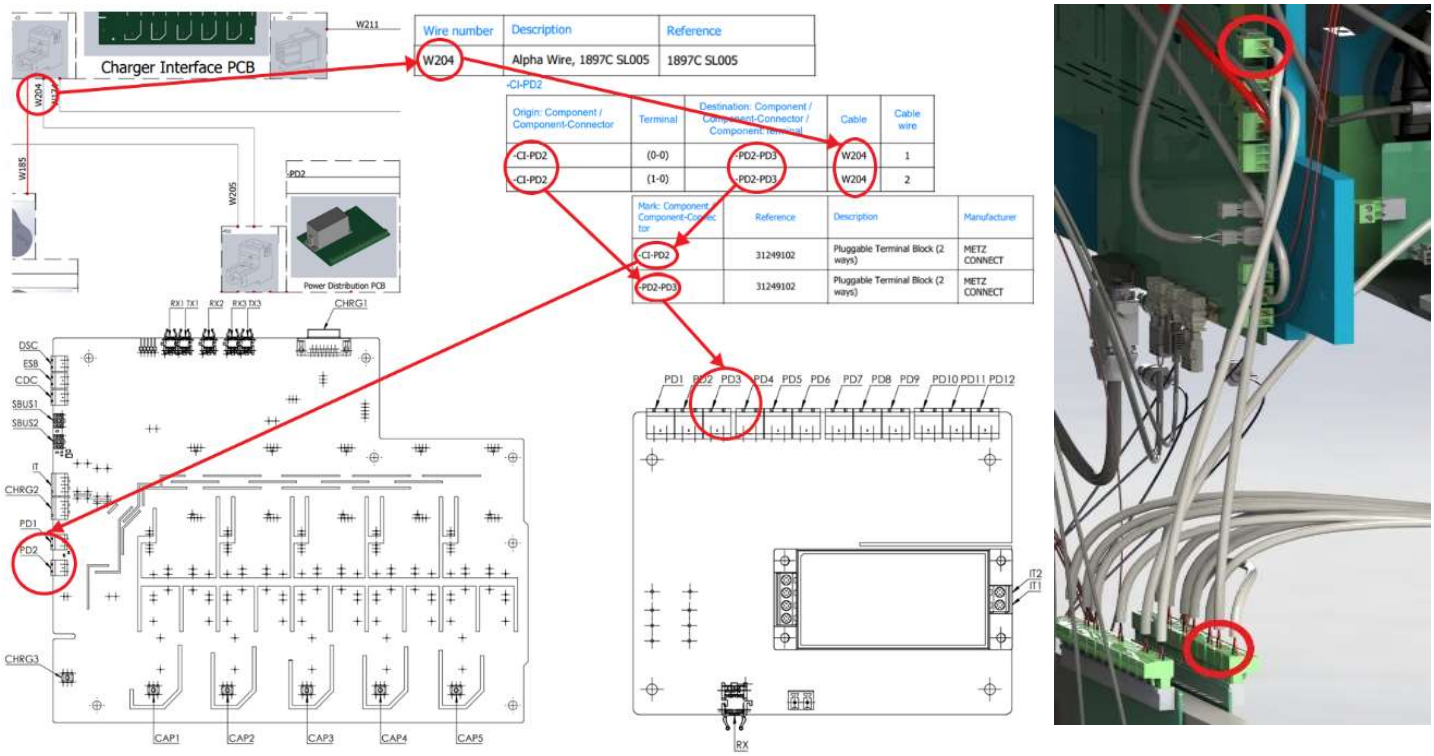


Figure 28. Interpretation of the 2D connectivity documentation and a 3D view of the described connection.

5 Discussion

This thesis relates to a specific design segment of the product development process for mTMS technology, namely, modeling and documentation of the device cabling. This thesis introduces a model of the cabling of the 5-channel mTMS prototype, documentation of the device connectivity, and evaluates the usefulness of the contents for a university-based medical device development project. The CAD model and the documentation are designed to guide and support an outside party in the assembly of the device as outsourcing the assembly of future prototypes releases workforce for other activities. Furthermore, the CAD model of the cabling and the connectivity documentation serve as a foundation for later design modifications.

The produced connectivity documentation includes the following: single line connectivity diagrams, connectivity reports, and component terminal drawings. The connectivity diagrams and reports were produced with *Solidworks Electrical Schematics*. The line diagram presents the whole connectivity of the system with block elements and visualizes which connectors are used for each connection. Furthermore, this diagram has been fed with all relevant manufacturer information. That is, the manufacturer and reference have been defined for each component, connector, and cable in the system. The diagrams are great for providing an overview of the total connectivity of the system. The connectivity reports could be created directly from the software once the line diagrams were complete. These reports present detailed information on each connection in the system by using predetermined component, connector, and cable marks. In practice, the reports contain the connectivity information of the line diagrams in a printed form allowing the utilization of the diagrams without access to the *Solidworks Electrical* software. Together with the line diagram images and terminal drawings, the reports should be sufficient for cabling the device.

Although the connectivity reports contain information on all components, connectors, and cables of the device as well as on the connectivity, perhaps one cannot see the forest for the trees. That is, it is difficult to form a holistic perception of the connectivity of the device solely based on the reports. On the other hand, by only viewing the 3D model of the cabling one can easily see the forest, but individual trees are left in the background. Regarding the cabling of the device, the line diagrams combine the best of the 3D model and the connectivity reports–one may easily obtain an overview of the total connectivity, and by clicking individual links in the *Solidworks Electrical* environment, the component, connector, and cable information are accessible. Based on my work on this thesis, cabling the device by utilizing the diagrams inside the *Solidworks Electrical* software is much easier and straightforward than cabling solely based on connectivity reports.

The component terminal drawings were produced with *Solidworks*, and their function is to illustrate the position of each connector/terminal in their parent component. Furthermore, each connector and terminal are assigned with tags, which are used in the line diagrams and reports. This way the origin and destination terminals and connectors linked in the line diagrams and connectivity reports are given a location within their parent component. The terminal drawings are useful for interpreting both the 2D documentation and the 3D model. Currently, the naming of the terminals has some inconsistencies between the real-world PCBs and the PCBs of the line diagrams.

No matter how accurate and comprehensive, the 2D connectivity documentation remains difficult to implement into the device without visual cues. The 3D model is great for providing spatial information about the connections. Furthermore, the CAD model provides a safe and cheap environment for implementing design changes as well as testing alternative solutions. In this thesis, the routing tracks of the device were designed in the *Solidworks Electrical 3D* software, which takes the 2D connectivity information simply into 3D space. *Solidworks Electrical 3D* contains auto-routing features, which route the cables automatically once the 2D line diagram elements have been associated with 3D representations of the components and connectors. However, due to connection point issues or maybe tight spaces inside the cabinet, the routing process was somewhat troublesome. Whenever I wanted to route a specific group of cables, I had to route all cables and delete the doubles afterward. Otherwise, the software would output a load of errors and only route stubs of the cables. Furthermore, after auto-routing, all cables would take the shortest possible path to their destination while piercing all physical objects on the way. *Solidworks Electrical 3D* has a mechanism for defining a routing track in 3D space before auto-routing. However, the routing sketch would have had to be enormous to be sufficient for the mTMS system. Thus, the feature was not utilized. These obstacles should be considered by future users of the model as utilizing *Solidworks Electrical 3D* together with *Electrical Schematics* was not completely effortless.

After all, cable ties proved to be most practical for routing track design. First, the cable ties were added to the model to guide the desired track for the cables, and then, the chosen group of cables was auto-routed and re-routed through the cable ties. Finally, routing track documents were created to clarify how the cable tracks between components are routed. These documents contain images of the CAD model highlighting the specific connections as well as descriptions of how the cables are routed.

The documentation and the 3D model contain some deficits. First, the current model is outdated as design changes were implemented during the cabling of the physical prototype. Some cables were routed using shorter paths, some cables were unnecessarily of differing lengths, and some cables were grouped together in a new way. Furthermore, in both the line diagrams and the 3D model, the connections of the isolation transformer remain undefined, the third and fourth power distribution PCBs are missing, and coil connector audio jack connectors are outdated. Also, grounding cables have not been implemented at all. These issues will be solved through a Design Request Procedure and the CAD model will be updated. In addition, the diameters of the CAD model cables are smaller than in the actual device due to heat shrinking and overlapping cables. In the physical prototype, most of the cables were overlaid with heat shrinks to provide additional insulation, which increases the diameter of the cables. The overlapping of the cables was avoided manually in the CAD model. Nevertheless, overlapping still occurs especially in the cable bundles. Finally, the lengths of the cables proved to be unreliable. *Solidworks Electrical* provides an option to print out the length of each routed cable in the connectivity reports. However, it was discovered that the reported lengths were those of the initially auto-routed cables and the length increase due to re-routing was not considered. Thus, the lengths appearing in the routing track documents are residue and not valid.

The discussed documentation has described the connectivity of the system comprehensively. The 3D CAD model of the mTMS cabling was created to support the assembly process of future prototypes and to serve as a virtual representation of the most up-to-date prototype. Recently, the design of the latest prototype was enhanced by compressing the components into an overall smaller space, and by considering medical device regulatory restrictions. The design modifications were first implemented in the CAD environment and then brought to the real world, which functioned well. The same method applies to the cabling of the device–well-documented cabling eases the assembly process, especially, if the assembly process is outsourced. In the previous prototypes, the cabling of the device was performed without many guidelines and as the completed prototypes are, in practice, shipped away soon after completion, little support remains for repeating the process. Inventing the wheel again for each prototype iteration is inefficient, and thus updating design modifications to the virtual CAD prototype improves the efficiency of assembling future prototypes.

The described documentation and the 3D CAD model together serve as a foundation for later prototypes and support in the outsourcing of the prototype assembly process. It is likely, that the outsourcing process eventually needs even more detailed assembly instructions. Nevertheless, the CAD model and connectivity documentation introduced in this thesis should

provide satisfactory support. When frequently updated, the CAD model is also a competent representation of the physical prototype and in many locations, the CAD model serves as the most up-to-date version of the device as built prototypes are shipped away quickly after completion. For instance, the 5-channel mTMS system described in this thesis will be shipped to Tübingen quickly after the device is fully assembled and tested. Thus, the CAD prototype may often be the fastest accessible version of the prototype as physical prototypes with the latest design modifications are absent. Overall, the CAD model co-operates with physical prototypes bidirectionally. Some features can be designed and tested in the CAD environment and then implemented into the real-world device. On the other hand, sometimes better solutions are discovered while working on the real-world device, and in these cases, the design modifications are updated to the CAD model, which serves as version control. In this project, the modeled cabling tracks serve as a suggestion and after the cabling is finished, the model should be updated to correspond to the real-world device.

Based on my work on this thesis, maintaining the produced CAD models with cabling design requires a little more than regular CAD modeling. However, CAD expertise together with presented contents of this thesis (especially chapter 3) should be enough to operate the model. In the beginning of this project, I had no experience on electrical CAD design nor modeling cables with *Solidworks*. Thus, even without guidance, one may learn to utilize the *Solidworks Electrical* packages quite quickly.

The CAD model cabling should be updated immediately as some components, connections, and routing tracks have been changed. The missing and modified connections should be added to the 2D and 3D environments. Furthermore, the *Solidworks* projects should be brought from the 2018 version to 2021 as Aalto University no longer provides licenses to the 2018 version easily.

6 Conclusions

This thesis aimed to produce 2D documentation and a 3D CAD model of the 5-channel mTMS prototype cabling as a basis for further design modifications and to support the outsourcing of future prototypes. The outsourcing of future prototype assembly would be beneficial as it would release workforce of the C2B project for other technology-improving activities.

2D documentation of the device connectivity was produced with *Solidworks Electrical Schematics*. The documentation includes line diagrams and connectivity reports, with all relevant information on the components, connectors, and cables as well as the connections. In addition, terminal drawings were produced to indicate the locations of origin and destination connectors and terminals in their parent components. The line diagrams contain all information of used components, connectors, cables, and the connections. The connectivity reports contain the same information but in a printed form. My experience indicates that interpreting the connectivity of the system with the line diagrams inside the *Solidworks Electrical Schematics* software is easier than with the connectivity reports, and thus this is also recommended.

The connectivity data of the 2D environment was brought to 3D utilizing *Solidworks Electrical 3D*. First, CAD models of all connectors were added to the total CAD assembly and then the cables were routed between the origin and destination connectors. Finally, the routing tracks were set by moving and bundling the cables inside the CAD assembly. In addition, routing track documents with images of the cabling tracks in the CAD model were produced to ease the cabling process for a potential future collaborator or subcontractor.

Overall, the aims of the thesis were quite well achieved. The modeling of the cabling for determining routing tracks was nicely fulfilled. The produced 2D documentation together with the 3D model should also provide satisfactory support for outsourcing the assembly of future prototypes. The impact of routing track documents remains to be seen as these documents describe the overall cabling tracks well but do not contain detailed information of possible screws, nuts, washers etc. used in the assembly. Thus, it is likely that additional instructional documentation is needed. The basis for later design changes has been formed and the documents together with the CAD model serve as version control for the mTMS technology. For a university-based project of this magnitude, CAD version control and prototyping is valuable especially as prototypes with the latest design modifications are shipped away. Furthermore, to outsource the assembly, CAD modeling is practically mandatory as it is likely that an outside party would have difficulties assembling the device without proper visual cues.

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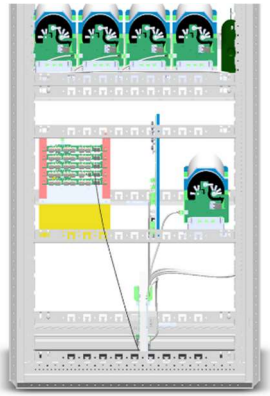
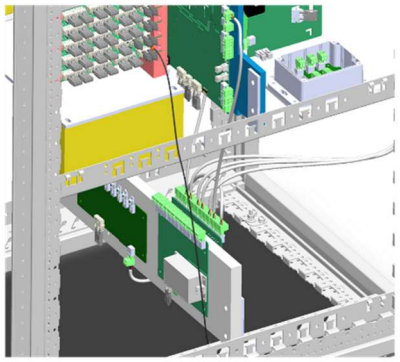
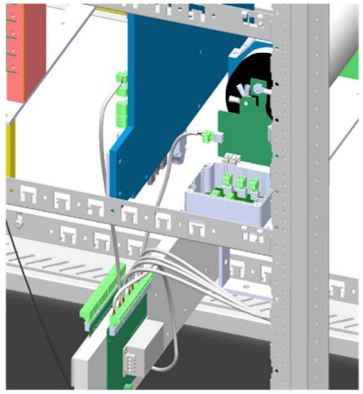
Appendix A



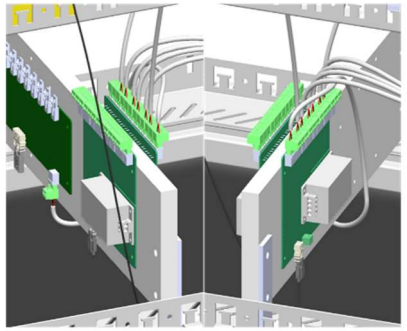
Connections to E2O board, Charger Interface PCB, Sensor PCB, and channel 5 Discharge Controller PCB can be routed directly. Connections to the Discharge Controller PCBs of channels 1-4 follow the left backside pillar of the cabinet (front right in this view). The cables are tied to the pillars and side rails with cable ties.



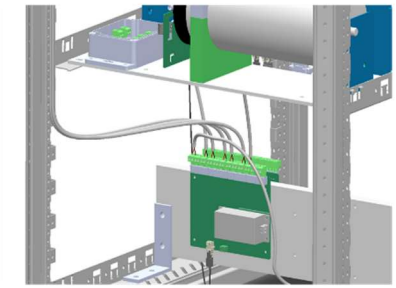
The optical connection originates from the second E2O board, follows the back wall of the cabinet, and dips under the PCB support.



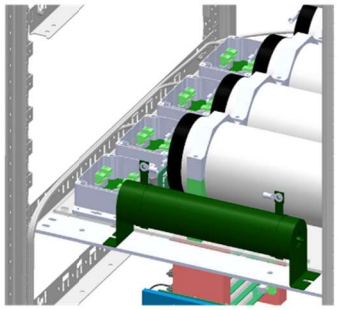
Connection to Charger Interface PCB can be routed directly. Connection to the channel 5 Discharge Controller PCB passes between the Charger Interface PCB and the channel 5 capacitor plate.



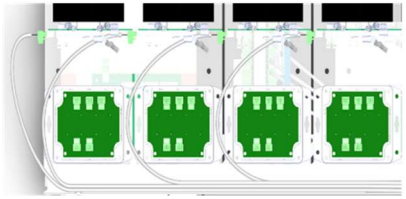
Connection to the Sensor PCB can be routed as seen fit. The 3D modelled track may not be the most effortless solution.



Connections to channels 1-4 follow the inside of the cabinets left backside pillar. The bundle is connected to the cabinet with cable ties as seen fitting.



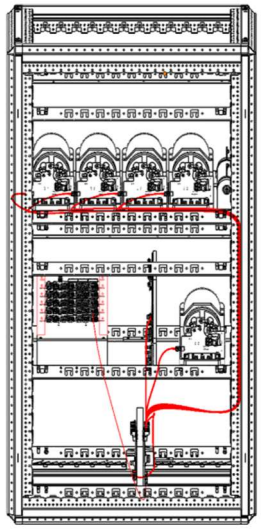
The bundle leads to the channel 1-4 capacitor plates where they connect to the Discharge Controller PCBs. The bundle can be tied to the side rail with cable ties to increase the clarity of the overall cabling.



The cables can be routed to pass between the Power Distribution Adapter PCBs.

Power Distribution PCB 2

- Tracks to Charger Interface PCB, E2O PCB block, Sensor PCB, and Discharge Controller PCB of each channel.
- Backside view of the cabinet



Cable reports

[Wire number | Description | Approximation of cable length (zero if unable to determine) | Reference]

W204	Alpha Wire, 1897C SL005	0.37	1897C SL005
W205	Alpha Wire, 1897C SL005	0.36	1897C SL005
W206	Alpha Wire, 1897C SL005	0.71	1897C SL005
W207	Alpha Wire, 1897C SL005	0.73	1897C SL005
W208	Alpha Wire, 1897C SL005	0.78	1897C SL005

W209	Alpha Wire, 1897C SL005	0.86	1897C SL005
W210	Alpha Wire, 1897C SL005	0.26	1897C SL005
W126	Fibre Optic Cable (one fibre)	0.69	HFBR-RUS500Z

Appendix C

Component reports

[Mark: Component/Component-Connector | Reference | Description | Manufacturer]

-PD2-PD1	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT
-PD2-PD2	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT
-PD2-PD3	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT
-PD2-PD4	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT
-PD2-PD5	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT
-PD2-PD6	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT

-PD2-PD7	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT
-PD2-PD8	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT
-PD2-PD9	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT
-PD2-PD10	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT
-PD2-PD11	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT
-PD2-PD12	31249102	Pluggable Terminal Block (2 ways)	METZ CONNECT

-PD2-RX	HFBR-4503Z	Fibre Optic Connector Simplex Latching	BROADCOM

Connectivity reports

-PD2-PD1

Origin: Component / Component-Connector	Terminal	Destination: Component / Component-Connector / Component-Terminal	Cable	Cable wire
-PD2-PD1	(0-0)	-SNSR-15V	W205	1
-PD2-PD1	(1-0)	-SNSR-15V	W205	2

-PD2-PD3

Origin: Component / Component-Connector	Terminal	Destination: Component / Component-Connector / Component-Terminal	Cable	Cable wire
-PD2-PD3	(0-0)	-CI-PD2	W204	1
-PD2-PD3	(1-0)	-CI-PD2	W204	2

-> -PD2-PD4

Origin: Component / Component-Connector	Terminal	Destination: Component / Component-Connector / Component-Terminal	Cable	Cable wire
-PD2-PD4	(0-0)	-DCI-15V	W206	1
-PD2-PD4	(1-0)	-DCI-15V	W206	2

-PD2-PD6

Origin: Component / Component-Connector	Terminal	Destination: Component / Component-Connector / Component-Terminal	Cable	Cable wire
-PD2-PD6	(0-0)	-DCI-15V	W207	1
-PD2-PD6	(1-0)	-DCI-15V	W207	2

-PD2-PD7

Origin: Component / Component-Connector	Terminal	Destination: Component / Component-Connector / Component-Terminal	Cable	Cable wire
-PD2-PD7	(0-0)	-DCI-15V	W208	1
-PD2-PD7	(1-0)	-DCI-15V	W208	2

-PD2-PD9

Origin: Component / Component-Connector	Terminal	Destination: Component / Component-Connector / Component-Terminal	Cable	Cable wire
-PD2-PD9	(0-0)	-DC4-15V	W209	1
-PD2-PD9	(1-0)	-DC4-15V	W209	2

-PD2-PD10

Origin: Component / Component-Connector	Terminal	Destination: Component / Component-Connector / Component-Terminal	Cable	Cable wire
-PD2-PD10	(0-0)	-DC5-15V	W210	1
-PD2-PD10	(1-0)	-DC5-15V	W210	2

-PD2-RX

Origin: Component / Component-Connector	Terminal	Destination: Component / Component-Connector / Component-Terminal	Cable	Cable wire
-PD2-RX	(0-0)	-E2O2-TX7	W126	1