CHALMERS
UNIVERSITY OF TECHNOLOGY

Intellectual Capital Management in Digital Healthcare

Intellectual Property Strategies for Smart Dressings

Master's Thesis in the Master's Programme
Entrepreneurship and Business Design

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CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden 2019
Report No. E 2019:118

MASTER'S THESIS E 2019:118

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Chalmers digitaltryck
Gothenburg, Sweden 2019

Abstract

Wound care is a segment in medical technology that is becoming increasingly important to improve as we are due to our modern lifestyle more prone to acquire wounds. An increased incidence of diabetes, obesity and cardiovascular diseases as well as an ageing population are factors increasing the risks. Today, five to seven million people in the US acquire chronic wounds annually, which corresponds to treatment costs up to $20 billion. Market trends implicate that the wound care segment will be impacted and innovated by digital transformation, just like any other segment in healthcare, and the technology of smart dressings could be the next innovation that addresses the difficult challenges in advanced wound care.

Smart dressings are wound dressings with the purpose to monitor certain wound characteristics, which will be processed to provide an output for treatment recommendations or actions. Smart dressings comprise the dressing as such, but is also connected to a network where data can be exchanged, processed and stored. The measured wound characteristics will thus be analyzed to either give an indication of the progression of the wound healing or provide for a treatment adapted to the wound characteristics.

This thesis investigates whether a global actor that operates within wound care has the intellectual assets and properties to create and control a smart dressing. The research focused on the current status of the market, which showed an immaturity with no launched products, and the patent landscape, that presented a scarcity of relevant patents, a majority of pending patents. The patent landscape could be seen as a field that combines two mature and dense patent fields - wound dressings and electronics. Therefore, it could be considered difficult to obtain patent protection as the threshold for genericity is low for both of the mature fields, hence, the technical scope needs specificity to achieve patent eligibility. A knowledge gap was discovered in the patent landscape that revealed an uncertainty of what wound characteristic to measure, which could be an opportunity to leverage on if one learn what parameter is the most crucial for wound healing progression.

The patent landscape was complemented by a value chain analysis to examine opportunities of value creation, which resulted in value propositions for patients of improved wound treatment and data generated value propositions of e.g. personalized care and product development opportunities. The current situation of the market and patent landscape together with the opportunities of value creation, could be leveraged on if the right capabilities are achieved in combination with suitable control mechanisms. An intellectual property strategy could and should include patent protection of the smart dressing system with physical components and software implemented functions. The functions enabling management of the generated data are eligible for other intellectual property rights, such as copyright, trademark, design and trade secrets.

Acknowledgements

This research study is the result of a master thesis work and presents the final work in the Master of Science programme Entrepreneurship and Business Design at Chalmers University of Technology. The master thesis work has been conducted during the spring of 2019 with the support from a global medical technology company.

The authors would like to thank the supervisors at medical technology company for always being supportive throughout the study and open minded to new approaches. Without your help and important input this study would not have been possible.

The authors would also like to thank the supervisors Anna Holmberg and Magnus Eriksson at Chalmers School of Entrepreneurship for the guidance and help with bringing this study to life. A thanks is also directed to the examiner and creator of the theoretical framework used in this study, Ulf Petrusson.

This study has given the authors great insights into the medical technology sector and motivation to proceed future work within this area as well. We believe that digitalization in medtech is and will play a significant role for an improved and more efficient healthcare. Our desire is to be a part of that development and implementation.

Lovisa Eriksson & Susanna Thunholm

2019-06-12, Gothenburg

1. Introduction

In this chapter, necessary background information is provided to describe the problem statement as well as giving an introduction to medical technology, wound care and connectivity in healthcare. Aim, delimitations and research questions are also presented in order for the reader to grasp the purpose with this study.

1.1 Definitions

- *Connectivity*: the ability of an electronic circuit or software to connect with other units or software (Nationalencyklopedin, 2019)
- *Smart*: designation of objects exchanging data through network infrastructure via connectivity (Stojkoska & Trivodaliev, 2017)
- *Internet of Things*: network of smart objects that enables data exchange through connectivity (Gartner, 2014)
- *Intangible Assets:* Intangible assets are the company's assets which are not physical, e.g. "the name of the company, product or service; the company's logotype, product or service; design and appearance; text, photo, music, films, computer programs, computer games, and apps; internal manuals and working methods; business concepts or business models, competence and specialist knowledge; customer databases; manufacturing processes; company databases; internal databases; inhouse-developed technology; research results; results of development work; certifications" (PRV, 2019)
- *Intellectual Assets*: Intellectual assets is referred to an transferable intangible knowledge asset with a business value e.g. an idea or design created by the human intellect (Teece, 2000)
- *Intellectual Property: "Intellectual property is an aspect of property rights which augments the importance of know-how assets. Knowledge assets are often inherently difficult to copy; moreover, like physical assets, some knowledge assets enjoy protection against theft under the intellectual property laws of individual nation states. In advanced nations, these laws typically embrace patents, trademarks, trade secrets, and copyright"* (Teece, 2000)

1.2 Background

1.2.1 Digital Health

In the age of digitalization, emerging technologies create new ways to connect with information, which are and could be applied for multiple areas within the healthcare sector to make care more integrated, value-based and with more emphasis on the patients (MedTech Europe, 2019). Digitization of healthcare plays an important role for empowering the

patients, increasing quality of life and relieving heavy workloads for the caregivers through usage of wireless, connected solutions that collect patient data and generate valuable and data-driven health information. Connectivity could provide the patient with better control over their health and support the caregiver in using health data more efficiently, thus contributing to better treatment for patients and less burden for the caregiver (Jabri, 2019).

According to Forbes (2018), key opinion leaders believe that innovations in digital health play a grand role in achieving proactive healthcare, but the adoption of emerging technologies of e.g. smartphones, sensors, data analytics and cloud storage, will require a high degree of coordination and cross-sectional operability by companies operating within the healthcare sector. One driving trend is the interaction between machine and human, where the interface is a crucial point in order for information, both clinical and advisory, to be distributed and interpreted correctly. There is a need to bridge the gap between the human abilities of improvisation, generalization and communication and the machinal abilities of repetition and prediction. The advisory service in digital health is considered a significant leap and is rather complex, since it demands larger collections of data from the same patients to be able to build correct patient profiles and provide customized options and better treatments (Medical-technology.nridigital.com, 2019).

Digital healthcare is expected to keep acquiring momentum in the upcoming years due to the short-term goal of big players in pharma and medical technology to reduce cost and increase customer engagement (Forbes, 2019). There is also an increasing demand from customers due to expectations driven by our contemporary digitization-influenced environment (McKinsey, 2017). However, there are implications that the medical technology sector is lagging behind other sectors in digital transformation.

1.2.2 Connectivity and Smart Objects

Connected solutions in the healthcare sector will enable collection, communication and generation of valuable data-driven health information. Here, connectivity is key since it could i.a. enable better control for both the patient and the caregiver by streamlining the communication of health data and treatment support (Jabri, 2019). Connectivity is the ability of an electronic circuit or software to connect with other units or software (Nationalencyklopedin, 2019) and the network of objects that enable communication via connectivity is called Internet of Things (IoT) (Gartner, 2014). IoT aims at facilitating autonomous smart decision making and is according to Van Kranenburg (2008) defined as

"*A dynamic global network infrastructure with self- configuring capabilities based on standard and interoperable communication protocols where physical and virtual 'Things' have identities, physical attributes, and virtual personalities and use intelligent interfaces, and are seamlessly integrated into the information network*"

The variation of objects that comprise the network of IoT are called by different terms, but could collectively be called smart objects. These cover a broad range from smartphones to sensors, and are considered smart due to their capabilities of communicating and computing

(Stojkoska & Trivodaliev, 2017). Beyond their ability to exchange data with other objects in the network, smart objects should have the ability to adapt to changing contexts, be compatible and provide for outputs based on operating conditions (Ray, 2016). To summarize the meaning of an object being smart, it should communicate via connectivity and be aware of and adaptable to the context. The use of IoT and smart objects is increasing in several sectors and creates opportunities and competitive markets globally, whereas the healthcare sector is one that benefits from this growth (Silverio-Fernández, Renukappa and Suresh, 2018).

1.2.3 Medical Technology

According to Medtech Europe (Medtech Europe, 2018), medical technology is defined as

"*...any technology used to save lives or transform the health of individuals suffering from a wide range of conditions. In its many forms, medical technology is already diagnosing, monitoring and treating virtually every disease or condition that affects us.*

[...] ...medical technology includes medical devices and in vitro diagnostic medical devices. Medical devices are products intended to perform a therapeutic or diagnostic action on human beings by physical means. In vitro diagnostic medical devices are products which provide medically useful diagnostic information by examination of a specimen derived from the human body."

Medical technology is highly driven by innovation and development even though the field has not been able to keep up the pace with digital transformation, e.g. a product generally has a life cycle less than two years before an improved product is launched. More than 12 200 patent filings were made with the European Patent Office in 2016, which is more than any other sector as it corresponds to almost 8% of the total amount of all patent applications made. The sectors of biotechnology and pharmaceuticals each file approximately half of that amount. European countries stand for 41% of the filings and the US 38% (MedTech Europe, 2019).

The European market is the second largest with 29% of the global medical technology market and has an estimated worth of 110 billion Euro. The US market is largest with its size of 43% of the global market (MedTech Europe, 2019).

Medical technology could be divided into three main categories: in vitro diagnostics, medical devices and digital solutions. With *in vitro* diagnostics information of patients' health will be provided through non-invasive tests of biological samples to support caregivers to make decisions. Medical devices are solutions for prevention, diagnosis, monitorization and treatment, among other appliances, implants, instruments, materials and software. Digital solutions are tools that generate data and utilize information and communication technologies to improve healthcare. According to Medtech Europe, digital solutions have potential to

innovate the healthcare sector by increasing the overall efficiency and precision, improve quality of life and access to treatments (MedTech Europe, 2019).

1.2.4 Wound Care

One application area of medical technology that is becoming increasingly important is wound care, as we are more prone to acquire wounds due to our contemporary life style with an increasing incidence of diabetes, obesity and cardiovascular diseases among others, but also a growth in ageing population (Medical technology, 2019).

Wound care products aim at treating both chronic and acute wounds, but chronic wounds take longer time to heal and require expensive treatment. Due to the high costs, there is a need for better and more efficient products, that enables advanced wound care and faster healing (Allied market research, 2019). According to Life Changing Innovation there is an annual prevalence of five to seven million episodes of chronic wounds in the US only, which requires approximately $20 billion in treatment cost (Life Changing Innovation, 2019).

The increased risks of acquiring wounds, the profound effect on life quality if treatment fails, the attempts to reduce duration of hospital stays as well as the need for cost efficient treatments are all drivers for the demand of better and advanced wound care (Medical technology, 2019). The segments of advanced wound care can be divided into therapy devices, exudate (wound fluid) management, infection management and active wound care (Allied market research, 2019), and one standard wound treatment applicable to all the segments that is becoming more of an advanced care is the use of the medical device dressing.

1.2.5 Premium Dressings - The Standard of Advanced Wound Care

According to Merriam Webster Dictionary, a dressing is a material applied to cover a wound or lesion (Merriam webster, 2019). According to Nationalencyklopedin a dressing, within medicine, is a material that protects wounded skin, exerts pressure on swellings or prevents injured body parts from exercising inconvenient movements (Nationalencyklopedin, 2019). In this study, it is therefore assumed that a dressing is a material applied to the skin to cover wounds or protect from injuries on skin.

As the demand for improved wound care increases, the development of dressings advance. Today, the traditional and simplistic dressings are replaced by so called premium dressings with advanced features and technologies that manage exudate, relief pressure and obtain a beneficial environment for the wound during healing (Life Changing Innovation, 2019). Depending on whether the dressing is used for treating acute or chronic wounds the dressing construction differ, but generally there are certain layers that are required to achieve the high standards of a premium dressing. The major players in advanced wound care include Smith & Nephew, Acelity, ConvaTec, BSN Medical, Mölnlycke Health Care and Coloplast (Allied

market research, 2019); according to one of them, a premium dressing has the following features (Molnlycke, 2019):

- A permeable top or backing film that allows for fluid and moisture from the wound and skin to evaporate
- Retention that hinders wound fluid to enter back into the wound
- Spreading that allows for wound fluid to spread out over a larger surface to prevent saturation, facilitate for evaporation and maintain beneficial environment for wound healing
- An absorbent layer that allows for wound fluid to be absorbed from the wound to facilitate for a beneficial environment for wound healing
- An adhesive contact layer that allows for the dressing to stick to the skin and maintain its position over the wound, but also allows removal of the dressing from the skin without causing further skin damage

Even though the features in premium dressings are constantly improved and provide for better wound care than before, there are indications that the shift in digitizing the healthcare sector will have an impact on dressings as well. Instead of relying on passive treatment by dressings and having a caregiver monitoring wounds, it is indicated that dressings will be driven by data and have an extra dimension enabled by connectivity.

1.2.6 Smart dressings – Next Generation of Wound Dressings

An area of interest to investigate is connected and data-driven wound dressings, so called *Smart Dressings*. This area is not researched to a large extent, hence the definition of a smart dressing is indefinite; but by compiling public sources of information, a preconception of a smart dressing could be defined accordingly in this report:

A wound dressing positioned over a wound surface that measures wound characteristics of said wound and via connectivity communicates the data measurements to a device or cloud (electronic component/module), upon which an output is executed as a response to the generated (input) data.

In order to be considered a smart dressing the dressing should be able to sense one or more wound characteristics and provide an output to the wound environment or communicate the wound status to the external environment from the wound dressing. To enable this the dressing should contain a wound contacting surface, a sensing element for one or more wound characteristics and a communicable and readable electronic module, controlling device, which can be remote or adjacent to the wound dressing.

The smart dressing can be seen as a smart wound dressing system, including the dressing with sensing element, e.g. sensor, a controlling device which receive signals from the dressing, processes the input and transmit a signal containing an output to the dressing or a display for human interpretation. The wound data from the wound dressing system transfers to a database or cloud storage. The definition of a smart dressing is based on the compilation

of sources (Tufts Now, 2019; Kassal et al., 2015; Pal et al., 2018; Brocklesby et al., 2013; Schrage, 2017), but an iteration of the definition is expected during the course of this study as it is a preconception as of now. The theoretical Smart Dressing System, which will be a used as a starting point for the study, is visualized in *Figure 1*.

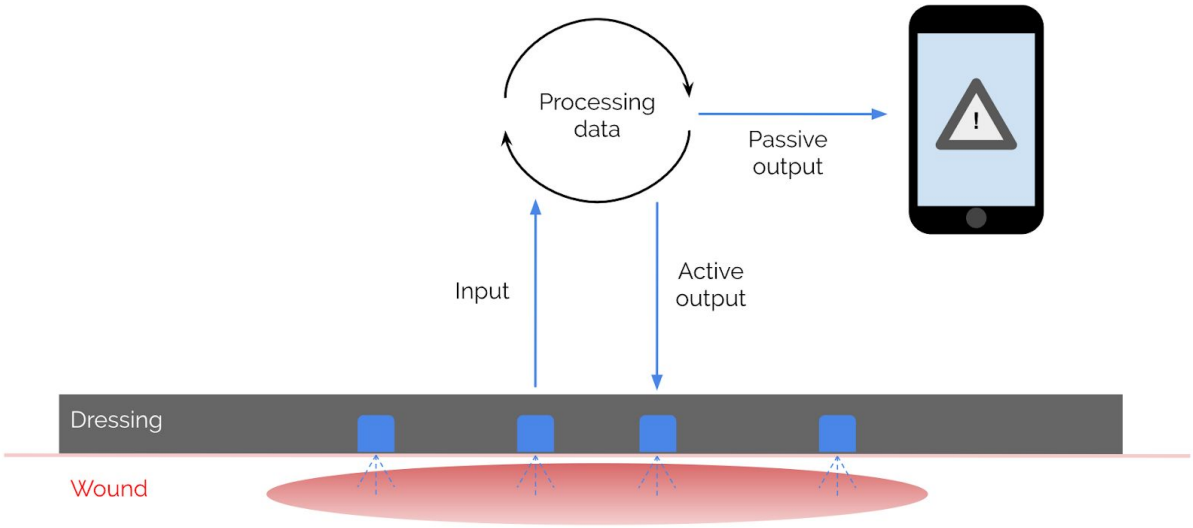

Figure 1. Visualization of a Smart dressing comprising a dressing in contact with a wound, measuring wound data and transmitting said wound data to a computing device. The computing device process the data and determines an appropriate output responsive to the processed data, upon which it will transmit an output signal in two pathways; the active output enables an action towards the wound surface by the dressing, meanwhile the active output alerts of an indicative value or recommends a clinical decision. The active output is instructed an action towards the wound surface, the passive output displays an alert or instructions of an action for execution by caregiver or patient.

The data storage from several smart dressing systems could enable data-driven wound care and could be used to improve the software in each smart dressing system as well as provide valuable insights for the progression of wound care.

1.2.7 Definitions of Dressings

The differences between the dressings defined in this study are summarized in *Table 1* below. Explained are the definitions of a *dressing* according to dictionaries, a *premium dressing* according to one of the big players in the field and a *smart dressing* as a preconception based on a compilation of sources.

Table 1. The definitions of a dressing, a premium dressing and a smart dressing are presented. The definitions are based on the material and sources provided in the Background.

Dressing	
material applied to the skin that covers wound or protects from injuries on skin	
Premium dressing	***Smart dressing***

same as *dressing*, but with features of permeable backing film, retention, spreading and absorbing abilities, adhesive contact layer damage free to skin	same as *dressing*, but with functions to measure wound characteristics, communicate with device computing measured data to generate an output

1.3 Purpose & Aim

There is reason to believe that there is a paradigm shift in the medical technology industry, from a traditional production-focus to value creation for patients and caregivers through data-driven value. Therefore, there is a need for companies within medical technology to keep up with the pace in the industry shift and meet the increasing demand for connected products from both caregivers and patients. Traditional medical technology companies stand before a challenge to ensure continued value creation in a new emerging market. The aim of this study is to provide recommendations to a traditional medical technology company entering the digital field of wound care. The recommendations will include intellectual property strategies with a focus on digital solutions in wound care dressings. In order to reach this recommendation, a case study of a medical technology company was executed to establish possible value creation opportunities and the obstacles that a traditional medical technology company within wound care is likely to face entering the digital field.

1.3.1 A Medical Technology Actor Aiming to Transform Digitally

A large global established medical technology company with many years in the industry, hereinafter called *the MedTech company,* has their main business activities in wound care and wound prevention, and is striving for pursuing their business within digital healthcare solutions. Their business covers activities from R&D to commercialization of healthcare solutions and they are very prominent within wound care dressings. The product portfolio comprises wound dressings for acute and chronic wounds, prevention dressings and post-op appliances, amongst other products. Currently, they have very few digital solutions implemented, but desires to enter the market of connected wound care. Their main area of expertise and knowledge lies in wound care, hence, connectivity in wound care could be considered to be suitable to evaluate when investigating opportunities to digitize. Their experience in wound care is revealing a need for improving the patients' possibilities to monitor their own wounds, but also a need to support caregivers with more valuable data of the patients' wounds in order to improve the treatment. The MedTech company believes that these needs can be met with digital solutions. However, there are certain aspects regarding intellectual property that needs to be considered when developing or implementing connectivity in wound care. Therefore, an investigation of how the intellectual property landscape looks as well as what intellectual property strategies could be suitable for the MedTech company, was requested.

The MedTech company is considered to be a traditional medical technology company due to the following parameters (Medpac, 2017; Medtech companies prepare for an innovation makeover, 2013):

- key player in the industry
- provide product units rather than service
- produce disposable one-time-use products
- incremental improvements for products
- sell conventional products

An investigation of the MedTech company was required to determine whether digital implementation or transformation in the product portfolio is possible and should be aimed at. The investigation was focused on what intellectual assets the MedTech company has, should acquire or create, to be able to apply or implement digital wound care solutions to their portfolio. An in-depth analysis of the internal intellectual assets in combination with an external market analysis comprising an extensive patent landscape analysis was performed to establish the current technological obstacles in the current market of smart dressing. The purpose was aligned with the MedTech company's mission to improve healthcare performance in wound care by supplying innovative medical solutions that make a difference.

1.4 Delimitations

This study was delimited to focus on wound dressings for the purpose of treating and/or monitoring wounds. Excluded were dressings that have technical functions of negative pressure wound therapy and surgical dressings. The dressings should have the application on existing wounds, and not have a preventive purpose.

The definitions of dressing, premium dressing and smart dressing in the background in *Table 1*, were providing the description of what the definitions were considered to be in this study.

The jurisdictions in market with respect to regulations and standards were limited to Europe and the USA; however, the patent landscape covered a global scope.

The study was partially based on a case study of one medical technology company within wound care. The case study covered phase I, which included internal intellectual assets that were identified only for this medical technology company. Hence, there were delimitations based on interviews from the case study that might not mirror medical technology companies in general, but it was assumed that the case study provided a truthful perception of an average global medical technology company that operates within wound care whose core business is in producing and distributing dressings. The interviews were limited to key personnel recommended by the IP Global director at the MedTech company. The key personnel were in

different technical areas within the company to provide a broad perspective on wound care and insight in their different scope of work.

The patent searches were limited to the usage of two databases: Orbit Intelligence and Derwent Innovation.

1.5 Research Questions & Research Area

Research Area: Digital healthcare

Defined area of knowledge: Smart dressings (for treating or monitoring wounds)

Selected research questions: The main research question and two sub research questions, are presented in *Table 2* below.

Table 2. The research questions are presented in the table, where the main research question is presented first with the two supportive sub research question presented underneath.

Main research question	What control positions are relevant to build to enable value creation in the defined area of knowledge?
Sub research question 1	What mature, in-house developed and controllable intellectual assets can be claimed in a traditional MedTech company in the defined area of knowledge?
Sub research question 2	What are the technical gaps in the patent landscape in the defined area of knowledge?

1.6 Thesis Outline

In order to provide the reader with a logic and clear structure throughout the thesis, this report is outlined in seven chapters, excluding the references and appendices, that cover the following topics

1. Introduction. Here, necessary background information is provided to describe the problem statement as well as an introduction to medical technology, wound care and connectivity in healthcare. Aim, delimitations and research questions are stated, and should be sufficient for the reader to grasp the purpose with this study.

2. Theory. In this chapter the IAM framework and different theories utilized throughout the study regarding dynamic capability, value chains and intellectual property rights amongst other, are presented. These are presented as in the literature and are not yet adapted to the methodology where they are applied.

3. Methodology. The method is presented here and provides the reader with research design and strategy of data collection and analysis of findings. Each research question is

dispositioned into a phase since they require different methods and applicable theories. The phases are *Claiming Intellectual Assets, Control Positioning* and *Utilization Opportunities*, which follow the structure presented in the IAM framework.

4. Findings & Analysis. This chapter includes both findings and analysis of said findings from the conducted study, as some of the findings are inseparable from the analysis. The three phases are separately presented to distinguish the analyses from each other and make each analysis easy to track back to the methods and research questions.

5. Discussion. Here, the analyses are discussed in relation to the research questions in an attempt to provide answers to them. In addition to discussing the research questions, the method and findings are discussed to criticize the accuracy of the methodology and the expectations of the findings.

6. Conclusion. In this chapter, the study is summarized and the discussion about the research questions is concluded to provide concise answers and key takeaways. An intellectual property strategy is provided along with reasoning on what the strategy is based on.

7. Continuation of Study. The authors' thoughts on the conducted study as well as considerations for future studies are presented in this chapter. Delimitations are criticized and suggestions on how to proceed with the study are discussed.

2. Theory

The section below will present the theoretical frameworks and models that underlie this research study. The IAM framework is the applicable theoretical framework that is the foundation for the methodology; the theories that follow the framework serve as basis for the analyses and are applied for that purpose. Some of the theories are considered necessary to present in order to provide a foundation for other theories, e.g. the material value chain is necessary to explain before the intellectual value chain.

2.1 IAM Framework

The Intellectual Asset Management framework, IAM framework, is constructed for utilization of academic research, where there is a clear need to know what assets, intellectual and knowledgeable, consist within the project and the requirements for further utilization (Petrusson, 2015). The IAM framework focuses on a proactive and reactive environment for utilization opportunities for an organization and approaches the challenge on constructing the intellectual assets in a communicative manner to external environments. The IAM framework is divided in four key processes for capturing and utilizing intellectual asset;

1. Claiming intellectual assets.

2. Evaluating and Positioning academic environments in relation to the outside world.

3. Making decisions about concrete ways of utilizing and implementing these in the university's operations.

4. Governance of knowledge assets, intellectual property rights and contracts within the university's organization.

The study will follow the IAM framework processes of Claim, Decide and Utilize, which will be presented in detail in the section 3. Methodology.

2.2 Resource-Based Theory

Resource-based theory (Penrose, 1959) show the importance of strategic resources for a company's competitive advantage and how the combination of common resources can create a strategic resource which are more valuable than the common resource alone. The resource-based theory also raises the question of the tangibility of a firm's resources. Tangible resources can be seen and quantified, e.g. physical assets as equipment or cash, meanwhile intangible resources are the contrary, e.g. knowledge and skills within employees or the reputation of the firm. Intangible resources are more likely to meet the criteria of strategic resources of being valuable, rare, inimitable and non-substitutable and therefore important for the sustainable competitive advantage of the firm (Barney, 1991).

For a intangible resource is to be perceived as an intellectual asset it needs to be transferable through documentation or similar objectification. Resources in the format of tacit knowledge do not fall under the definition of intellectual assets. These are difficult to capture or claim since these resources reside within individuals. Therefore, it is complex to create a control position around this kind of resources due to the inability to objectify and transfer them. These resources that are knowledge but fall outside the definition of intellectual assets, will hereinafter be referred to as intangible resources. A knowledge-based resource theory is derived from resource-based theory (Penrose, 1959) and states that sources of competitive advantage are internal resources in the form of intellectual assets, capabilities in the form of well performed intellectual value creating activities and finally, position effects given by the firm's technology market position (Teece, 2000).

2.3 Dynamic Capability Theory

A firm's capabilities relates to the ability to do, rather than what resource they own. In extension capabilities is what the company needs to have to execute the actions needed to be taken to extract value and build on strategic resources. Dynamic capability of a company refer to their ability to create new capabilities. The importance of a company's development of dynamic capability are increasing due the fact that the market are constantly changing through the fast technology development. The firm can therefore ensure competitive advantage by continually updating the firm's capabilities through adaptation, integration and reconfiguration of its present capabilities to keep up with the market changes (Teece, 2000).

2.4 The Value Chain

The value chain is a part of the tool box created by Porters (1985) for strategic business management. The value chain was presented in 1985 and often include both suppliers and distributors of a company to show where in the creation process a firm's activities are present. The purpose of the value chain is to separate and get an overview of the activities that a firm has to show where the firm's activities are cost related to suppliers or price related to the distributors, and which activities that are of highest relevance and serve as a basis for competitive advantage. The business strategy comes in at the different choices the company can take in the implementation of activities and how the activities are correlated to each other to enable value offerings to and of a final product or service. The traditional value chain was created during an industrial economy and focuses on the internal activities that a firm invest in to provide value to a final product that in in extension create a profit for the company. The internal activities can be value creating directly through primary activities as e.g. operations, outbound logistics, marketing and sales, or indirectly through support activities as e.g. human resources, firm infrastructure, procurements and technology (Harvard Business School, 2019). Porter's value chain are presented in the *Figure 2.*

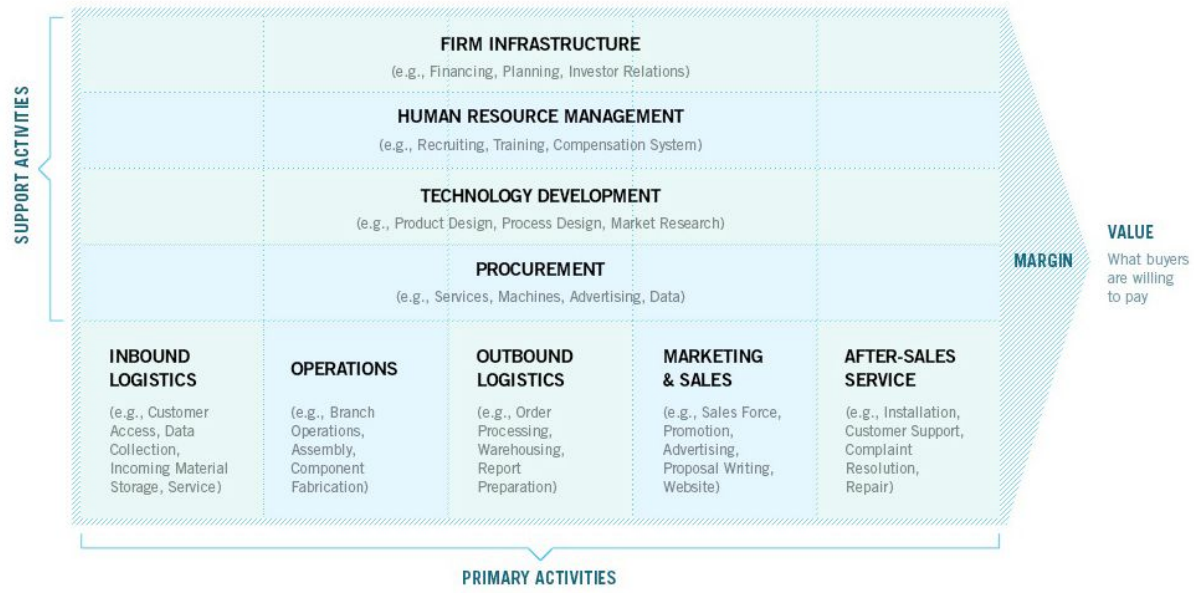

Figure 2. The traditional value chain created by Michael Porter is visualized in the figure. It presents the support activities a firm needs to have to enable the primary activities, which will build the value creating offerings (Harvard Business School -President & Fellows of Harvard College, 2019).

2.5 The Intellectual Value Chain

In business driven by knowledge as the core, the value is created by management and leverage of intangible resources, such as intellectual assets and property, rather than physical goods and means (Berman, 2009). The traditional value chain could still provide for viable business options, but it needs to be complemented by an intellectual value chain in order to present how and where value is created from a knowledge standpoint. The intellectual value is presented in *Figure 3* and is generated by the human intellect and take forms of know-how and relationships among others. Leverage of intellectual assets and property through services, license offers and virtual products, are only a few ways of creating value through the intellectual value chain, but production and manufacturing of physical goods also are based on management and leverage of intellectual assets and property in today's economy (Teece, 2000). The intellectual assets and property do constitute the prerequisites for commercialization, and the competitive advantage will rather be determined by the ability to recognize strategic options and management of value creating opportunities in the intellectual value chain.

One critical aspect of the intellectual value chain is being able to recognize and manage the opportunities, since the drivers are intangible resources it is not alway easy to identify what resources or skills constitute valuable tools to leverage on in operations. Hence, it is crucial to analyze the transformation process of intellect into value offerings, to enable development of an operational approach. Intellectual property rights are crucial tools that enable management

of the transformation process as they can be utilized to obtain desirable control positions and competitive advantage over other actors on the market.

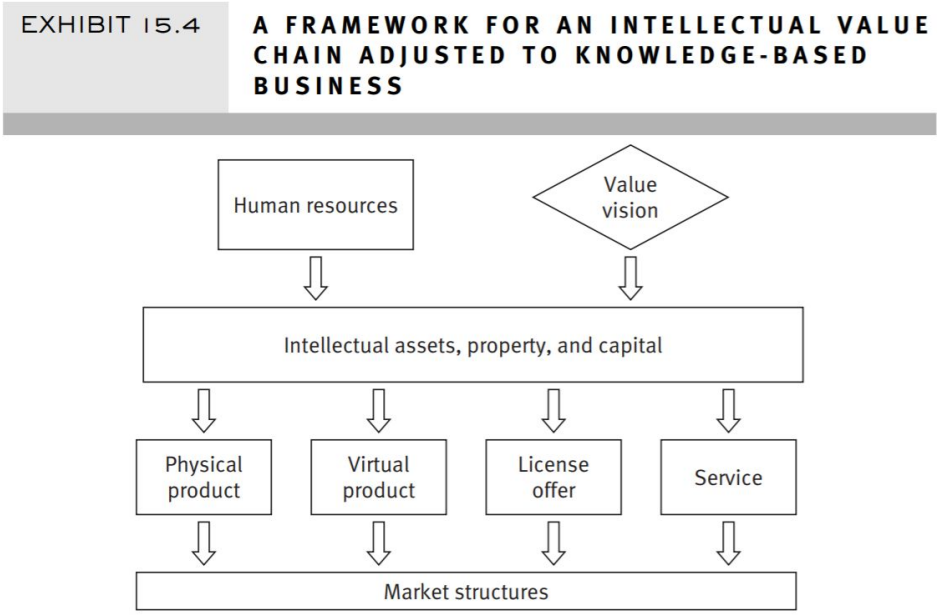

Figure 3. A Framework for an Intellectual Value Chain Adjusted to Knowledge-Based Business (Berman, 2009, p. 282). The intellectual value chain focus on leveraging on intellectual assets and property rather than the production and distribution of physical goods. The intellectual value chain is built on the human intellect and is dependent on knowledge rather than physical things.

2.6 Value Proposition

Value proposition is a crucial parameter when creating strategies around business and constructing business models. Value creation in a setting where customers are highly affecting the market requires the value creator to take their pains and gains into account to deliver a valuable offer. In order to position the products or service around the customer values, certain tools could be used to ensure the fit between offering and market. Dr Alexander Osterwalder created a framework that is built on the relation between the customer profile and value proposition of refined or new offerings (Osterwalder et Al, 2014). The purpose is to map the pains, gains and problem or task the customer needs to perform, in relation to the product or service, the gain creators and pain relievers of those. The gains are benefits expected or needed by the customer; the gain creator is the added value from the product or service. The pains are negative experiences in relation to the problem or task the customer needs to perform; the pain relievers are the value that alleviate the pains.

The aim is to achieve a fit between the customer profile and the value proposition of products and services that alleviate the most significant pains and enable the greatest gains. The identified value proposition in theory needs to be tested and receive feedback from customer to bring new insights and enable iteration of value proposition. The competitive advantage

the value proposition brings could be evaluated by identifying improvement areas and marketing core messages (Osterwalder et Al, 2014).

2.7 Intellectual Property Rights

The World Intellectual Property Organization, WIPO, refers to Intellectual Property as creations of the mind. The IP system is a theoretical concept and social construction which the society has agreed upon. The intellectual property are protected by law to give recognition and monetary benefits for the creator. It was at the Paris Convention for the Protection of Industrial Property in 1883 and the Berne Convention for the Protection of Literary and Artistic Works in 1886 as the importance of intellectual property first was recognised. According to WIPO, the IP system aims to foster an environment in which creativity and innovation can flourish by balancing the innovators and the societal interests. An intellectual property right, IPR, gives the rights holder the right to exclude others from making copies, producing or using their property for commercial purposes for a certain period of time (WIPO, 2019). IPR can be divided into four categories; patent rights, copyright, trademark rights and design rights.

2.7.1 Patents

A patent provide an exclusive granted right for an for a novel technical solution to a problem. It can refer to a product or process which provide a new way of achieving something. The patent protection is limited to a maximum of 20 years from the patent filing date, called the priority date (PRV, 2019). The patent right are enforced by court, which can stop patent infringement and also deem a patent invalid if it does not uphold the conditions of patentability and are challenged by a third party (WIPO, 2019).

Conditions of patentability

Novelty: The invention has to be unknown and undisclosed prior to the patent application. Prior art refers to the existing body of knowledge and novelty means the including of characteristics to the invention that does not exist in the prior art of that particular technical field. The invention is seen as known if it has been made public, this includes the use and publications made by the inventors themselves (PRV, 2019).

Inventive step: The invention must differ significantly from previous inventions to that point that the invention wouldn't be obvious to a person skilled in the art or technical area (PRV, 2019).

Industrial applicability: The invention must have industrial applicability which means if should be able to be produced or utilized in any kind of industry (PRV, 2019).

In relation to the mentioning conditions the invention must have patentable subject matter acceptable under law. This can differ somewhat between jurisdiction as it depends on national law, however the following are generally not allowed as patent subject matter in

most countries; scientific theories, mathematical methods, discoveries of natural substances, plant or animal varieties, commercial methods or methods of medical treatment (not medical product) (WIPO, 2019).

2.7.2 Copyright

Copyright is an exclusive right for creative works as e.g. music, films, literature, source code architecture and applied art as product designs. Copyright does not require registration and applies for at least 50 up to 70 years after the death of the copyright holder (PRV, 2019). Copyright grants an exclusive right to the right holder to use the creative work or authorize or prohibit the any form of reproduction, translation, or adaptation of the work. There might be new upcoming standards for copyright protection as the widespread distribution of copyrighted works on the internet have started an international debate regarding this question. WIPO Copyright Treaty (WCT) and the WIPO performance and Phonograms Treaty (WPPT) have stated that they aim to clarify international norms to prevent unauthorised access and use of creative works on the internet (WIPO, 2019).

2.7.3 Trademark Protection

A trademark protection covers symbols that can be used to identify an individual or a company, or certain goods or services associated with that company. The symbols can be words, figures, letters or digits, personal names or slogans or packaging of a product. The sign that must be deemed unique and distinctive from other products or services in order to not be confusable to the customer. The trademark protection applies for a period of ten years at the time, but can be extended by ten year period at the time indefinitely. Trademarks protection is used to enable international trade through the hindering of unfair competition of counterfeiters, the unauthorized use of a trademark. If there is an trademark infringement made, the trademark owner can enforce the trademark legally in court. To obtain a trademark protection an application of registration have to be filed with the national or regional trademark of the jurisdiction of interest. An international registration can be made through WIPO; the Madrid Agreement Concerning the International Registration of Marks and the Madrid Protocol (WIPO, 2019).

2.7.4 Industrial Design Protection

Industrial designs protect the appearance and shape of a product or material, but not the actual technical function. To achieve registration as an industrial design right, the design has to be new and original. Design protection gives the owner the right to exclude others from unauthorized copying or imitations. The protection time period differ between jurisdictions but applies for a maximum of 25 years with a five year grant and the possibility for further renewal. If the design covers a spare part or a component of a product the protection validity is never longer than 15 years (PRV, 2019). The protection is limited to the granted jurisdictions, WIPO however offers an international filing through a treaty, *Hague Agreement Concerning the International Registration of Industrial Designs,* where an applicant can file

for an international design registration and designate the jurisdiction of interest (WIPO, 2019).

2.8 Intellectual Property (Rights) Strategy

A company can have several intellectual property rights, as only one product can be subjected to different intellectual property rights. All from trademark of the company name or products, patents, copyright etc. The collection of a company's intellectual property rights is referred to their intellectual property rights portfolio. An Intellectual Property Rights Strategy, often referred to as a IP Strategy, is a strategy covering the management of a company's intellectual property rights portfolio. The IP strategy should be aligned with the business strategy in order to maximise the commercial benefits of the intangible assets, therefore in the construction of an IP strategy the external market perspective including analysis of competitors, commercial risks and the company's long-term commercial aim be taken into consideration The IP strategy covers the acquiring, maintaining and defending of the companies Intellectual property. The acquiring of intellectual property rights has several strategy parameters where strategic decisions needs to be made in correlation with the commercial objective e.g type of intellectual property, jurisdiction, technical scope and planned commercial use (PRV, 2019). The acquiring processes differ from intellectual property type, however they have some similarities. The applications requirements for each intellectual property can be found in the section *Intellectual Property Rights.*

2.8.1 Patent Application Process

To secure a patent, a patent application including the title of the invention, indication of its technical field and a disclosure of the invention needs to be filed. The language in the patent must be clear and comprehensive for an individual with an average understanding of the field to the point of detailed level for her to be able to use or reproduce the invention. The content must include background, description of the invention and claims for determination of the extent of protection scope to be granted by the patent. The patent offices, which have the authority to grant the patent applications, can be either national offices, e.g. United States Patent and Trademark Organisation (USPTO), or regional offices for a group of countries, e.g. European Patent Office (EPO). The applicant of the patent application can therefore chose in which jurisdictions they seek patent protection, either through a direct national filing or in a regional office where an applicant can request protection in one single or several countries (WIPO, 2019).

2.8.2 PCT Patent Application

In a Patent Cooperation Treaty (PCT) administered by WIPO, an applicant can designate their countries of interest through a single patent filing as the PCT filing has the same effect as a national filing (WIPO, 2019). Within 30 months from the priority date of the PCT patent filing, the applicant must proceed with their PCT application in an individual country.

However, according to the USPTO, the applicant should file a demand before the expiration of 19 months from the priority date if one wish to take advantage of a national phase entry time limit of at least 30 months from the priority date. (USPTO, 2019)

2.8.3 Provisional Patent Application

A provisional patent application is a patent application approved in the United stated by the USPTO. The provisional patent application is not made public nor examined for a year from the application date. Within one year from the filing date a non-provisional application can be filed and claim the priority date of the provisional patent application. The provisional patent application does not publicly disclose the invention which provide the applicant with the choice to within one year proceed with an non-provisional patent application or chose to keep the invention undisclosed without any associated cost during the first year from application date (USPTO, 2019).

2.8.4 Continuation Patent Application

A continuation, divisional or continuation in part patent application are approved in the United Stated by the USPTO, to be used to claim benefit of earlier filing date, cross-reference to other applications or add claims not disclosed in a prior patent application (USPTO, 2019). The continuation-in-part patent should not be confused with a non-provisional patent application claiming priority from a provisional patent. A continuation in part patent should repeat a substantial portion of the prior patent application and should name an inventor or inventors that are named in the prior application for it to constitute as a continuation-in-part of the prior application (MPEP, 2018).

2.8.5 Open-Source Software

Proprietary software are based on source code that are protected under proprietary licenses and enable therefore only the authors to legally copy or alter the software source code. Open source software are on the contrary made open by the authors for everyone to use, copy, alter, share or further develop the underlying source code (Lerner, J., & Tirole, J, 2002). Open source software are in general covered by open source licenses which grants the user permission to use the source code for any given purpose of choice (Choose a License, 2019). Depending on the open source license the open source software are subjected to the alterations or further development made to the source code are controlled. Copyleft licenses as, Apache Licence or GNU General Public License, state that alterations made to the source code needs to be shared without charge of a license fee (Apache.org, 2019).

2.9 Summary of Applicable Theories

The IAM framework is applied as the methodology for this study and the other theories are applied as theoretical views and in the conduction of analyses of findings. Below are the theories and their purpose of application are presented.

IAM framework
Application in Study:The foundation for the methodology

Phase of Study: Throughout the study

Resource-Based Theory
Application in Study: Alternative view to the IAM framework for Claiming Intellectual Assets

Phase of Study: Phase I

Value Chain
Application in Study: Basis for strategic business tool that could create competitive advantage, provide basis for value chain of smart dressing

Phase of Study: Phase III

Intellectual Value Chain
Application in Study: Providing significance of what value knowledge brings from a business perspective

Phase of Study: Phase III

Value Proposition
Application in Study: Constitutes a foundation for value creation based on knowledge about customers

Phase of Study: Phase III

Intellectual Property Rights
Application of Study: The foundation of legal control positions that are leveraged upon when creating value from intellectual assets

Phase of Study: Throughout study

Intellectual Property Strategies
Application of Study: Tools for enforcing and leveraging on intellectual property rights in a business setting

Phase of Study: Throughout study

3. Methodology

In this chapter, the method is presented and will provide the reader with the research design and strategy that are utilized for this study. The method of the study is divided into three phases Claiming Intellectual Assets, Control Positioning and Utilization Opportunities, which follow the structure presented in the IAM framework.

The research method was constructed according to the framework presented in Bryman and Bell's *Business Research Method* (Bryman & Bell, 2015). The research method was divided into three phases, which correspond to the three research questions, but only the first two phases include deductive and inductive elements as the third phase is rather exploratory and no revised theory is created. The research methodology is presented in *Figure 4*. The investigation of the intellectual assets and possible market entry for the Medtech company in question was based on the Intellectual Asset Management framework, IAM framework (Petrusson, 2015), presented in the theory section. The research study in question relates to intellectual property strategies for a Medtech company which is interested in entering a new technical field. Since the research area of Digital Healthcare is research heavy similar to academic environments, where management of intellectual assets and the utilization of those are of greatest concern in order to govern a market entry, the IAM framework is suitable to use as a base for the theoretical framework.

The phases, each one dependent on the one prior to it, required different design and strategy for completion. Each phase started with an assumed theory related to the research questions, which was investigated through a study with an appropriate design and strategy. Inductively, collected data were analyzed to produce a revised theory, hence providing a starting point for the next phase. However, iteration in the process and revision of the methods were necessary during the process. A representation of the research methodology can be seen in *Figure 4*.

The research designs were based on the assumptions that the key variables were epistemologically objective, hence, the analysis of data was considered objective as well. In order to validate the objectivity in the data collection, certain quality criteria needed to be met. The quality criteria for each phase is to be found in the sections of method for each phase.

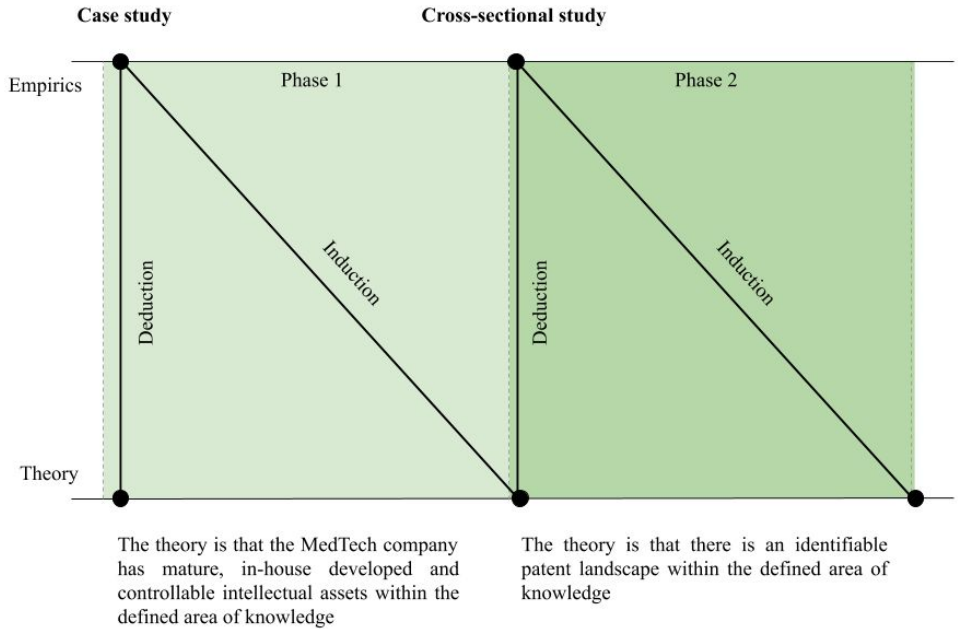

Figure 4. A visualization of the research methodology. The two phases and their iterative deductive and inductive methods, with research designs and theories for respective phase, are depicted.

3.1 Research Design & Strategy

Phase I in the research method covered the internal analysis of the MedTech company where the intellectual assets were identified and categorized through interviews and internal documentation. The focus in the internal analysis was identification and objectification of internal resources to establish the technical foundation, from which products and services could be developed. Semi-structured interviews with key personnel were conducted and provided information on the latest development and intellectual assets within the MedTech company. Phase II in the research method investigated the external landscape with a focus on mapping the patent landscape to provide for the position of competing actors and maps of technical scopes. This was conducted through an iterative analysis of patent searches. Phase III in the research method covered an investigation of value creation and enablers in relation to the area of knowledge. This last phase was rather exploratory and provided for an exploratory discussion. The research design and strategy for each phase are presented in *Table 3* below.

As the study relates to the investigation of strategic positioning of intellectual property for a MedTech company entering in to a new field of technology, based on internal assets, such as materials and know-how, in combinations of external digital solutions, knowledge-based view of the competitive advantage will be applied to IAM framework in phase III, utilization decisions, to challenge and assist in the assessment of the future competitive advantage in the final strategic intellectual property recommendation.

Table 3. Presentation of the research design and strategy for each phase of the research. Here, the purpose and process for each research question are presented, as well as what tool that were applied for the analysis of the data. Presented is also the communication of the findings.

Phase	Research Question	Investigation perspectives	Purpose	Process	Research design	Research strategy	Applicable tool	Communication
I	What mature, in-house developed and controllable intellectual assets can be claimed in a traditional MedTech company in the defined area of knowledge?	What internal intellectual assets can be identified within the defined area of knowledge?	Identify internal IAs	Claiming IAs	Case study - semi-structured interviews with key employees - internal documentary data	Qualitative data	Identification	Asset list
		How can the identified intellectual assets be categorized?	Categorize IAs				Tags and categories	Asset list with tags
		How can the identified intellectual assets be compared to each other based on specific evaluation points?	Evaluation of IAs				IA evaluation	Asset plot
II	What are the technical gaps in the patent landscape in the defined area of knowledge?	How does the IP landscape look for the defined area of knowledge?	Map IP landscape	Positioning an external environment	Cross-sectional study - searches in databases - searches in public sources	Quantitative data	Control position evaluation (technology tree, control map)	Spreadsheets and visual figures
III	What control positions are relevant to build to enable value creation in the defined area of knowledge?	How does the market and competition look within the defined area of knowledge?	Market maturity	Utilization decisions	Exploratory study - semi-structured interviews with key personnel - searches in public sources	Qualitative data	Market analysis	Summary
		What value can be created from the utilization opportunities in the defined area of knowledge?	Identify value creation				Utilization decision (value chain, value proposition)	Value chain
		What capabilities and control mechanisms enable the value creation?	Identify value creation enablers				Utilization decision (value chain)	Value chain enablers

The theoretical framework is built upon key concepts, applicable tools and key variables. A summarization of respective elements can be found in *Table 4*.

Table 4. The theoretical frameworks, key concepts, applicable tools and key variables for the research.

Theoretical framework	Key Concepts	Applicable tools	Key Variables
IAM framework: Claiming intellectual assets	Identification of Intellectual asset	Identification	Background, Objective, Application.
	Categorization of Intellectual asset	Tags and categories	Data, Database, Observation, Theoretical framework, Technical solution, Visualization, Instruction, Software, Narrative, Creation
	Evaluation of Intellectual asset	IA evaluation	Technology Progression, Technology Control, Technology Dependency
IAM framework: Positioning	Intellectual Property Landscaping	Control position evaluation (Technology tree, Control Map)	Jurisdiction, legal status, Technology coverage, Technology maturity
IAM framework: Utilization Opportunities	Market maturity	Market analysis	Product launches

IAM framework, Resource-based Theory, Value chain	Value creation	Value chain, intellectual value chain, value proposition	Intellectual property rights, capabilities, value proposition

3.1.1 Epistemological and Ontological Considerations

When conducting a research study, the key concepts need to be defined in order to plan a suitable research methodology, which will be able to answer the research questions at hand. In this section the key concepts are plotted in *Figure 5*, after considerations made of their subjective versus objectiveness in an Ontological and Epistemological perspective.

1. *Identification of Intellectual Assets:* The definition of Intellectual assets is used collectively within the field of knowledge. Identification of intellectual assets is a support system within the acknowledged IAM framework. The support system can be conceived as epistemologically objective and ontologically subjective as it has been decided upon and collectively agreed to exist in the specified format. As the process will be followed in the depicted manner, no subjective opinion of the authors will be of issue.

2. *Categorization of Intellectual Assets:* Categorization of intellectual assets are a support system within the acknowledged IAM framework. The support system uses tagging of intellectual assets into certain categories which have been collectively perceived as accepted terms. Thus, the collective has a harmonized view of how intellectual assets should and could be categorized through the IAM framework and can therefore be conceived as epistemologically objective and ontologically subjective. As the process will be followed in the depicted manner no subjective opinion of the authors will be of issue.

3. *Evaluation of Intellectual Assets*: Evaluation of intellectual assets is a support system within the acknowledged IAM framework with specified value parameters. The process can be conceived as epistemologically objective and ontologically subjective as it has been decided upon and collectively agreed to exist in the specified format. As the process will be followed in the depicted manner, no subjective opinion of the authors will be of issue.

4. *Intellectual Property Landscaping*: Intellectual property landscaping per definition have been collectively agreed upon in the knowledge area as an acknowledged process within the IAM framework for determining the intellectual property environment. The process can be conceived as epistemologically objective and ontologically subjective as it has been decided upon and collectively agreed to exist in the specified format. As the process will be followed in the depicted manner, no subjective opinion of the authors will be of issue.

5. *Market Maturity:* The concept can be conceived as epistemologically objective and ontologically subjective as it has been decided upon and collectively agreed to exist in the specified format. As the process will be followed in the depicted manner, no subjective opinion of the authors will be of issue.

6. *Value Creation:* The concept can be conceived as epistemologically objective and ontologically subjective as it has been decided upon and collectively agreed to exist in the specified format. As the process will be followed in the depicted manner, no subjective opinion of the authors will be of issue.

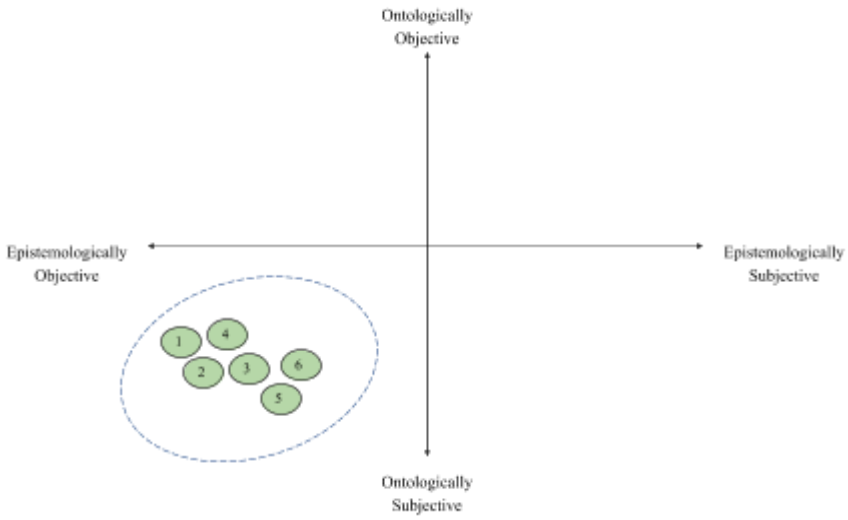

Figure 5. Visualization of the scale of epistemological and ontological, objective vs subjective perspectives. Plotted in the graph are the key concepts, 1-6.

3.2 Phase I – Claiming Intellectual Assets

Phase I intended to claim intellectual assets, IAs, of a single organization, the MedTech company. Hence, identification, categorization and evaluation of intellectual assets were the key steps in accordance with the applicable IAM framework. This phase therefore consisted of a case study of the MedTech company. The design was an intensive, detailed study of a single system through a combination of qualitative methods to gain in-depth insights of internal intellectual assets. Collection of data were achieved through semi-structured interviews with key employees and documentary data collection from internal documentation. The data was validated through certain quality criteria for confirmability, credibility, transferability and dependability which are presented in *Table 5*. Documentation

of internal assets, such as knowledge assets and product requirement specifications that enable product development, were of highest interest.

Table 5. Quality criteria for qualitative data in phase I.

Tests	Tactic	Actions	Mitigation of issues
Confirmability	Used the credible source of the IAM framework, as well as the credible source of the interviewees, whom possess knowledge of the internal intellectual assets.	Preparation of semi-structured interviews. Created a template with questions based on the IAM framework and the key variables. The interview template can be seen in Appendix I.	In order to collect the data from the interviews, a structure that supported the purpose of the interviews (identify IAs) was needed; this to avoid biased questions and collection of unnecessary data.
Credibility	Explicit documentation of interviews and internal documentation. Use of templates with the same questions for ensuring the same variables and measurement of the compiled data.	Data collection through interview conduction of ten (10) semi-structured interviews with key personnel. The Internal documentation was provided by Global IP director and Global IP managers or retrieved at the IP portfolio management system. Further details of the active patent portfolio of the MedTech company were retrieved at the patent databases, Orbit Intelligence and Derwent Innovation.	To ensure that the data is credible and truthful, but also to ensure that the data is collected in the same manner for future comparison.
Transferability	A replicable logic in evaluation of the collected data enabled by following the IAM framework and the applicable structure.	Interview data analysis through structuring the data collection. Creation of an asset list with tags in accordance with the IAM framework, which constituted the basis for the evaluation plots with the suggested parameters from the IAM framework; Technology progression, Technology Independency, Technology control.	This was done to avoid biases in the objectification and evaluation, in order to be objective and comprehensible for anyone who wants to understand the research study.
Dependability	Spreadsheet template with source management and structured compilation of the data. The data collection from the interviews and internal documentation follow the IAM framework and are therefore replicable. IAM framework is followed according to the literature and presented in the different parts (I, II, III) in the phases.	Follow the templates and spreadsheet for all data.	To avoid misunderstanding of where the sources of information are derived and in order to make the study replicable for anyone to conduct the study.

3.2.1 Preparation

The interview questionnaire template used in the interviews was constructed based on the presented questions from *Claiming Intellectual Assets* in the IAM framework. The questions presented in the IAM framework are directed towards researchers in an academic setting; therefore, the interview questionnaire was adapted to be applicable for the key employees at the MedTech company, the interview template can be found in *Appendix I*.

3.2.2 Semi-structured Interviews

The use of semi-structured interviews enabled flexibility during the interviews. The questions in the interviews were aimed at capturing what assets the interviewees believed are the most valuable for the company in retrospect, right now and for the future, as well as for the development within their scope of work. The interviews were in total ten (10) and all had a duration of one (1) hour each, and are presented in *Table 6*. In addition to the interview's conformation of provided information, comments on the patented or patentable aspects of the provided information from the interviews and the internal documentation were given continuously throughout the process from the Global IP Director and the Global IP Managers at the MedTech company.

Table 6. This table presents the titles and technical areas of the interviewees.

Semi-structured interviews		
Interview	**Title**	**Technical Area**
01	R&D Manager Adhesive and Fluid Handling Research	Adhesive materials
02	Director R&D Technology Platforms Wound Care	Wound Care
03	Technical Integration Manager R&D	Preventive care
04	Global Marketing Director Digital Health	Wound Care & Marketing
05	Product Development Manager	Chronic wounds
06	Material Concept Development Manager R&D	Materials
07	IT Director - Business Relationship Management	Connectivity
08	Director R&D Chronic Wounds	Chronic wounds
09	R&D Manager Bioactive Research	Biomarkers
10	R&D Material Development Manager	Materials

3.2.3 Internal Documentation

The internal documentation (see *Table 7*) was provided by the global IP director and the global IP manager, and was used when the intellectual assets were identified. The documentation was complemented with the use of the two patent databases, Orbit Intelligence and Derwent Innovation.

Table 7. Internal documentation is presented along with a description and source.

Internal Documentation			
Type of documentation	**Description**	**Investigated Amount**	**Provided by**

Patent and design portfolio	>100 patent families	54 patent families	Derwent Innovation, Orbit Intelligence, Global IP Manager.
Preparatory patents	1 unpublished patent application	1 unpublished patent application	Global IP Director
Internal communication	Digital healthcare	1 PowerPoint presentation	Global Marketing Director
	Treatment IP portfolio	2 PowerPoint presentation	Global IP Manager

3.2.4 Data Analysis

The data collection of the provided information from the interviews and internal documentation were documented and structured in excel sheets. In accordance to the IAM framework, the intellectual assets were identified from the interview material and confirmed from the internal documentation. The intellectual assets identified are limited to the ones that were emphasized by key personnel in the interviews and hence considered relevant for this case study, however, these are far from all intellectual assets that build the MedTech company. Intangible resources identified from the interviews which were not applicable in the IAM framework, as they were not transferable, were gathered and described without further evaluation.

The active patent portfolio was investigated to support and complement the information of the intellectual assets identified and extracted from the interviews.

The IAs were all given an ID to facilitate tracking further on in the analysis. The different categories describe how the intellectual assets can be claimed based on their nature and the value they bring to a setting (see descriptions below in *Table 8*). Objectification describes what the IA entails, while scientific result communicates the output or function from a technical perspective. Social benefit or value creation communicates what value the IA brings to the user or society. The control column refers to what mean that is used in order to legally control the IA, in other words what intellectual property right.

The intellectual assets were objectified and categorized and structured in an Intellectual Asset List with categorization tags in accordance with the IAM framework and sub-category tags to create an overview of the internal intellectual assets. Sub-category tags were used when several IAs fall under the same main category, to easier separate them and ease comprehension sub-categories were added. The use of sub-categories was recommended by the IAM framework together with inspirational keywords which contributed to the basis for the sub-categories. The sub-categories presented in *Table 8* and used in the Intellectual asset list, *Table 9*, are furthermore creatively constructed by the authors. An additional tag was added to the Intellectual Asset List, called technology platform, with the purpose to separate assets that are considered digital from others.

Table 8. The categorization, sub-categorization and technology platform tags, which were used for the Intellectual Asset list.

Main Category	Description
Solution	Technically based solution to a scientific problem

Software	Organized set of data that perform certain tasks
Instruction	Practical guidance of how to carry out specific activities
Narrative	Undocumented knowledge, confirmed by interviewees
Database	Structured data collection available in a systematic way
Sub-category	**Description**
Technology	A material or system which enables a technical function.
Creation Process	Method or process which enables creation of a material or product.
Product	Complete product, launched or ready to be launched, or advanced prototype which solves a problem.
Testing	A solution which enables control of quality or behavior of another technology, product, composition etc.
Digital Service	A digital solution which provides a technical function or other output to a user.
Design	The structure or creative appearance of a material or product providing a solution to a problem.
Algorithm	Instruction within a data system which provide guiding information or an action output depending on a specific input.
Composition	Recipe including ingredients or components within a system or material.
Know-how	Valuable knowledge regarding technology with commercial prospects, i.e. the construction, application or use of a technical invention.
Electronic database	Structured and organized data which have been made real both physically and virtually.
Technology platform	**Description**
Dressing	Related to a material that will be in contact with the skin for caregiving purpose
Digital	Related to technology that collect, structure or manage data, or connectivity

3.2.5 Evaluation

The created Intellectual Assets List with provided categories constituted the basis for the evaluation plots. The identified intellectual assets were evaluated on three technology parameters suggested in the IAM framework; their technology progression or maturity, possibility for legal control of the technology and technology dependency on external actors or other technologies. The evaluation was based on a scale of 1-3 on each technology parameter according to the evaluation scale presented in *Figure 6.*

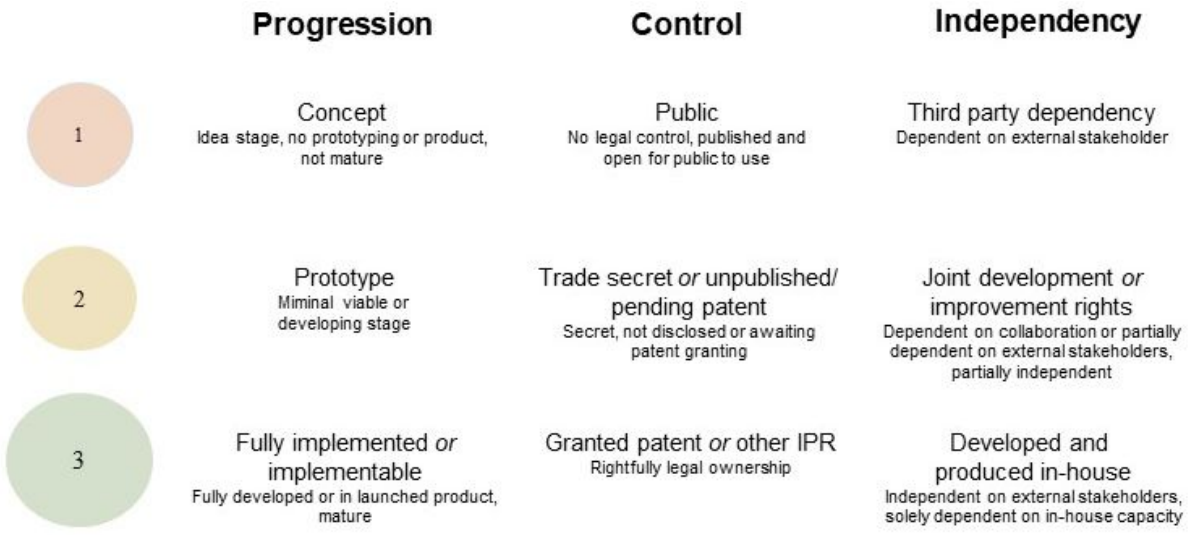

Figure 7. The technology parameters for the IA evaluation are illustrated in the figure above. The score levels of each parameter are explained and implemented in the evaluation table, Table 10.

Technology progression is divided into concept (score 1), prototype (score 2) and fully implemented or implementable (score 3). Technology control is divided into public (score 1), trade secret or unpublished/pending patent (score 2) and granted or other IPR (score 3). Technology independency is divided into third party dependency (score 1), joint development or improvement rights (score 2) and developed and produced in-house (score 3).

3.3 Phase II - Control Positioning

Phase II intended to create an overview of the intellectual property rights as well as the intellectual property strategies in the area of knowledge. A control map was created in order to investigate what technologies cover the patent landscape, what control other actors' practice over the technologies and if there are positioning opportunities within this field. Due to the immature nature of the area of knowledge, patents were considered the main source of intellectual property rights information, as patents provide the technical scopes and other IPRs related to data managing are not published, disclosed or easily revealed.

In accordance with the steps in the IAM framework, knowledge fields were identified by iterating patent searches, control was mapped through patent landscape analysis and compiled technology trees were constructed to lay the basis for a road map that will be utilized in phase III. This phase was a cross-sectional (quantitative) designed method to investigate and map out the patent data. Data was collected in a systemized manner based on specific patent variables (technical scope, classifications, legal status, assignee) in several cases, in order to create a quantitative data collection to detect patterns and benchmark the patent landscape. Data were collected from the patent databases Derwent Innovation and Orbit Intelligence, and the data were searched and retrieved based on constructed search strings and recommendations from key persons at the MedTech company. The quality criteria for this phase is presented in the *Table 11* below.

Table 11. Quality criteria and how the quality is assured for the quantitative data in phase II.

Tests	Tactic	Actions	Mitigation of issues
Objectivity	Use of patent databases that are credible, objective and neutral sources, as well as running searches in more than one database.	Patent searches in Derwent Innovation and Orbit Intelligence; mostly Derwent Innovation, but complementary searches were run in Orbit Intelligence.	As one patent database could lag behind on patent publications, change in status, etc., it was considered necessary to use at least two well established databases.
Internal Validity	Explicit documentation of search string constructions in spreadsheets and same patterns in data collection, as well as use of same variables in collection.	Data collection in above mentioned databases with constructed search strings with use of keywords and classifications within the technical area for a smart dressing. Limited after chosen time frames. Set up and retrieved patent information from patent alerts set up by search strings above mentioned.	In order to avoid that any relevant data would be missed, the search strings were constructed and saved in a structural manner; this was a way of ensuring no information would pass by.
External Validity	A replicable logic in evaluation of the collected data through the explicit documentation and	Compiled data and search strings in excel files and sorted uniformly; download from patent databases to obtain uniform variables. Analyzed	The patent data needed to be compared in a certain manner to ensure that all data was evaluated on the same parameters, otherwise

	structured data management.	the data through comparison of key variables (foremost technical scope).	validity of the comparison would not be sufficient.
Reliability	Spreadsheet template with source management and structured compilation of the data (patent list and search string constructions). The data collection from the databases follow the spreadsheet structure and the same variables are collected from each sample and are therefore replicable.	Follow the spreadsheet for all data.	Just like when comparing the data in the same manner throughout the study, the patent data needed to be compiled in the same manner for all data, otherwise there would be unreliable gaps.

3.3.1 Patent Landscape

Patents were searched for via constructed search strings in patent databases, data was collected and organized in spreadsheets and finally, the collected patents were analyzed. After every search and analysis, the search was optimized and iterated in order to refine the relevant scope for the area of knowledge. The search became more specific for each iteration and the patents were mapped out in a landscape in order to display the control positions in the area of knowledge. The patent landscape covers from broad technical scopes close to the relevant area of knowledge, to narrow technical scopes constructed to cover the definition of a smart dressing. The method of collecting and analyzing the patent landscape can be summarized in four steps:

1. *Identifying knowledge field*
2. *Search string construction*
3. *Collection of data*
4. *Analysis of patents*

3.3.1.1 Identifying Knowledge Field

To be able to construct relevant search strings and define the patent landscape for the area of knowledge, it was crucial to gather knowledge about wound care dressings, connectivity in dressings and monitoring of wounds. This was partially done in the pre-study (*see Background and Theory*), but additional knowledge was gathered through the interviews in phase I and through patent documentation that key persons at the MedTech company considered significant for this study, which stemmed from patent alerts generated from confidential patent search strings. The knowledge consisted of how wound dressings is designed and constructed, what sort of technology that is used for monitoring wounds and what components could comprise a smart dressing. The knowledge was compiled, and unconstructed searches were initiated in the patent databases to create an awareness of what technical scopes that is relevant and what wording that is used within the field of knowledge. IPC classification was noted in order to apply suitable classifications to the construction of

search strings. None of the findings from the unconstructed searches were officially documented in spreadsheets, but were saved for internal usage.

3.3.1.2 Search String Construction

The compilation from the identified knowledge fields was used as a starting point in constructing search strings (see *Appendix II*). The search strings were constructed in an iterative manner, which means that a search string was applied in one patent database, the findings were screened, followed by adding more specificity to the next search. The specificity was determined through screening of the findings by

- Detecting technical scopes and claims that did not fit the area of knowledge – wording was added to the search string in the aftercoming search to exclude these.
- Finding alternative wording that was used for components or functions that fit the area of knowledge – wording was added to the search string in the aftercoming search to include these.

Hence, the scope of the search strings became more specific, but complementary to the search string constructions, filters were added to filter out irrelevant data as well as delimit the searches further.

3.3.1.3 Collection of Data

The search strings were limited to be applied in the patent databases Derwent Innovation and Orbit Intelligence. The unconstructed searches were not documented, but all of the search string constructions that were constructed with the reasoning described in section *Search string construction*, were documented in the spreadsheet (see *Appendix II*). Findings that were screened manually, search strings 10 and 11, were all exported into separate spreadsheets and documented by number of patents, date of search, construction, applied filters and reasoning. The findings from search string 10 were used for the benchmarking and the findings from search string 11 were more in-depth analyzed for the use in a patent landscape.

Delimitations: use of patent databases Derwent Innovation and Orbit Intelligence.

3.3.1.4 Analysis of Patents

The analysis of patents was both quantitative and qualitative. The quantitative analysis comprised sorting the variables of the patents; assignees, jurisdictions, legal status, which cannot be interpreted qualitatively by the reader. The qualitative analysis comprised screening the relevancy of the technical scope, meaning analyzing the patent claims. The term relevance refers to whether the patents' technical scope corresponds to the predetermined and delimited scope of what a smart dressing comprises, which must be aligned with the area of knowledge. For each search string an additional aspect of relevancy was added by specifying

the construction further, each search string becoming more delimited than the prior. This, in order to exclude technical claims that did not correspond to what a smart dressing comprises.

Search strings 2-6: Random patent samples were screened for technical scope. The screening comprised brief reading of title and claims to discover terms or wording that were not relevant for the area of knowledge, upon which the search string was adjusted to exclude terms and wording.

Delimitations for these searches: a smart dressing that does not include negative pressure wound therapy, surgery or implants, beds or is incontinence related.

Search strings 7-9: Random patent samples were screened for technical scope here as well, but the screening comprised in-depth reading of claims to discover terms or wording that were not relevant for the area of knowledge. Search strings were adjusted after analysis.

Delimitations for these searches: a smart dressing that include a dressing with a use for wounds and that does not include alternative wording for negative pressure, diapers or wipes, is hair related or include biometric measurements, such as ECG and EEG.

Search string 10: See benchmarking.

Search string 11: All patents were screened for technical scope. The screening comprised in-depth reading of claims to determine whether the patents claimed a technical scope that was relevant for the area of knowledge. Patents were collapsed into families in Derwent Innovation and sorted based on relevancy level (see *Table 12*); medium relevance and high relevance, while the not relevant patents were filtered out. The highly relevant patent families were analyzed in Orbit Intelligence by constructing automated charts of assignees, geographical coverage, technical domains and legal status.

Table 12. The relevancy levels that describe how the patents were screened based on relevancy, are presented here.

Relevance determination	
Not relevant	Not claiming a wound dressing as such, monitoring of wound, measurement of wound characteristics nor electronics coupled to a dressing; could be claiming negative pressure wound therapy and is therefore not relevant.
Medium	Claiming wound dressing and monitoring of wounds, but could relate to other application areas than measuring the wound characteristics, such as prevention of wounds rather than existing wound treatment.
High	Claiming wound dressing, monitoring of wounds, application in relation to treatment of existing wounds, communication of wound characteristics and processing of data to determine status or scores of a wound or wound progression, electronics integrated in or adjacent to a

	dressing; could be relevant even if no dressing is claimed, but required is analysis of wound characteristics by processing data received from wound monitoring system.

3.3.2 Top Assignee Analysis

Top assignees are assignees with several patent families with high relevance; these were further investigated in an analysis comprising detailed mapping of technical scope, legal status, intellectual property strategy (priority claims, designation of states and patent applications) and entity form. The technical scopes of the patents were compiled and mapped out for the top assignees. The technical scope mapping is presented in technology trees, that present technical components and functions, for each top assignee. The technology trees were compiled into one extensive technology tree that theoretically would represent the technical requirement specifics and the current technical scope of a smart dressing. These technical requirement specifics of a smart dressing will represent the iterated definition of a smart dressing, as it is different from the initial definition and considered more correct after the analysis of the external environment.

3.3.3 Benchmarking

The area of knowledge is immature, which can be seen in the uprising patent landscape with a majority of pending patents. To understand and investigate possible trends in the prosecution prior to patent granting, a benchmark of the granted patents within a relevant scope were executed. The patents were retrieved from search string 7, but the search was narrowed by filtering out the alive, granted and published after 2015. The filters were complemented with manual screening of granted patents from 2011-2015, of which the patents deemed with high relevance, i.e. including sensor and dressing, were added to the benchmarking data.

The retrieved patents were compiled in an excel file (see *Appendix III*), with data on patent number, jurisdiction, assignee, application date and granted publication date. Each granted patent was investigated on the prosecution from the US patent office using File Wrapper, USPTO.

Information of amended, cancelled and added claims were qualitative retrieved from Non-final and Final rejections and compiled in the excel file. For each patent prosecution, comments on the reasoning of the patent examiner and the relevance of technical scope in relation to smart dressings, were noted by the reader.

The time to grant was calculated from application date and publication date for each patent and was compiled and divided by amounts of investigated patents to get an indication of the average time to grant in the area of knowledge.

3.4. Phase III - Utilization Opportunities

Phase III intended to further investigate what utilization opportunities that exist based on the findings in phase I and phase II. The road map was the starting point when investigating considerations that concern utilization, where the road map in this study comprised the compiled technology tree together with the analysis of product launches. Opportunities (gaps and value offerings) were identified by mapping of the intellectual assets in relation to the compiled technology tree, as well as mapping of the value creation value chain (see Value Creation). Value offerings that could match the customer profile were considered in the value creation mapping. Preconditions, resources and restrictions for acting on the opportunities were investigated by identifying what capabilities and control mechanisms that enable value creation from a smart dressing (see Value Creation Enablers). Utilization decisions are discussed and presented in the final conclusions.

This phase was both exploratory and qualitative, as the study explored utilization opportunities for smart dressings in relation to the internal intellectual assets and the external environment. Phase III explored what value that could be created from a smart dressing and what enabled the value, such as what control positions that are possible and what capabilities that are required. This was followed by an exploratory discussion of recommendations and control position strategies.

The IAM framework was applied just like in the other phases, but in this phase the framework had a business approach rather than an academic. The utilization opportunities in a business setting differ from the opportunities in an academic setting, since the value creation, that is the basis for the opportunities, is based on what value that can be proposed to the customers. Thus, this phase took business or market focused theories (e.g. value chain analysis) into consideration and put emphasis on value creation for customers. Hence, the leverage on the internal and external analyses can be exploited rather through business than through research.

The data in phase III that refers to interviews or meetings from key persons, are qualitative, which is the case for the provided material from key persons and public sources also. The quality criteria for this phase is presented in *Table 13* below.

Table 13. Quality criteria for qualitative data in phase III.

Tests	Tactic	Actions	Mitigation of issues
Confirmability	Used the credible source of key persons, whom possess knowledge of the market, but also material from the interviews. Used public sources that are credible, objective and neutral to support analysis.	Preparation of semi-structured interviews in phase I (see interview template in *Appendix I*). Meetings with key persons have been held with continuous intervals during the study to gather market related information.	Interviewing key persons that obtain great knowledge and experience in the knowledge field provided credible sources over the reality and the industrial standard practice within the field. However, several people were interviewed, hence decreasing the personal bias in the data.
Credibility	Explicit documentation of meetings, provision of material related to market and value creating activities. Explicit referencing.	Material was provided by key persons at the MedTech company at meetings. Market research analysis was provided by the Customer Insight & Market Research Manager, as well as access to a market research account at Frost & Sullivan. Additional material related to value creating activities within the field was provided by the IT Director and the Global Marketing Director Digital Health.	External information was gathered in addition to the internal information to provide another view of the topic; this is order to bring a nuance and credibility to the data..
Transferability	There is a replicable logic in evaluation of the collected data of product launches enabled by explicit documentation of variables. However, due to the exploratory nature of other parts in this phase, transferability could be difficult to achieve, but due to that this phase compile data from both phase I and phase II, transferability has been achieved through prior phases.	Product launch data analysis through structuring the data collection. Creation of compilation from the asset list (in accordance with the IAM framework) and patent landscape (quantitative data from databases Derwent Innovation and Orbit Intelligence).	To avoid readers from misunderstanding or not understanding the data, as well as ensuring that the data will be transferable in other cases, this tactic was used.
Dependability	Spreadsheet template with source management and documentation of compilation of the data. The data collection from the key persons are provided through the provided material sources, which make them replicable.	Follow the templates and spreadsheet for all data.	This tactic was used to ensure the replicability as well as avoiding providing a biased view of how the data is presented.

3.4.1 Launched Products

Launched products were searched for in public search engines and public sources. The search engines that were used are Chalmers Library Database, PubMed, Google, Google Scholar and Science Direct. The search words used were *smart or intelligent with dressing or bandage.* The findings were structured in a spreadsheet and analyzed by commercial stage or maturity. The analysis of commercial stage provided a foundation for market indications.

3.4.2 Internal Environment in relation to External Environment

The internal intellectual assets identified in phase I were mapped out on the technology tree from phase II, in order to match the intellectual assets with the technical requirement specifics to establish whether the MedTech company could claim possession of any required technologies. The basis was the technology tree, in which each box and branch was analyzed to determine whether any intellectual asset matched the technical scope. The boxes and branches in the technology tree that comprised a technical scope/technology that could be claimed possession over by intellectual assets were marked by red lines.

3.4.3 Smart Dressing Value Chain

When the value chain was constructed, the material value chain theory was in mind when presenting what components are involved in the value chain. The intellectual value chain was used as approach when presenting what value propositions that can be leveraged on and what knowledge and capabilities that are considered important for the components of the value chain.

In order to determine what opportunities there are to create value and what could constitute value propositions, the technical scope of a smart dressing needed to be complemented with additional value creating aspects that are not necessarily connected to the physical components of the smart dressing. A smart dressing does consist of both hardware and software, but as software could be challengeable to control via patents, the patent landscape does not reveal whether software is included or how it is implemented in the hardware. However, there are indications that software is integrated in most of the relevant patents since i.e. computing devices and executable instructions are claimed. Software, instructions, data, data collections, etc. could be managed by other intellectual property rights than patents, hence the software aspects need to be added to the construction of the value chain in order to obtain a fair picture of how the entire chain of a smart dressing could look and what value it could create.

The value chain was constructed solely based on the product of a smart dressing and the generated data from the user of the smart dressing, showing the interaction between patient, dressing and data management in the form of value that is created by every interaction. Hence, showing interactions with parties that will be benefited from the value created by the smart dressing. The value chain does not comprise a traditional material value chain with

suppliers but rather an intellectual value chain with a focus on value proposition from each component in the chain. The value proposition, or value offerings, presented in the value chain were considered to represent gain creators and pain relievers that match pains and gains that are expressed by the customer profile. The customer profile was provided by the MedTech company and was derived from the intangible resource of customer knowledge.

The components in the value chain were partially determined based on the technology tree, but were complemented by a market research which provided what sort of components regarding data management that should be included in a smart dressing. Based on that market research material provided by the IT Director and the Global Marketing Director, software aspects could complement the technical requirement specifics and provided the foundation for a smart dressing value chain. The market research was generated by Frost & Sullivan (Frost & Sullivan, 2019), and summarized material was provided to support the construction of the smart dressing value chain.

Value creation opportunities, the value proposition, from the value chain were elaborated on in the analysis. The analysis of what value that could be created was exploratory and the reasoning was based on material from interviews in phase I, meetings with key persons, market research and basically all material, orally as written, that has been provided during the study. The logic in the reasoning was controlled by key persons at the MedTech company who possess knowledge. However, the sources of information were complemented by articles and publications of data management.

3.4.4 Value Creation Enablers and Control Mechanisms

When value creation opportunities had been elaborated upon, the parameters that enable value creation were investigated. The value creation was enabled by certain capabilities and control mechanisms with intellectual property rights, which were investigated by searching information from public sources. The value creation enablers are presented in a visualization of the smart dressing value chain, but without the value offerings as the interactions with parties that will be benefited from the value offerings are excluded. Included is instead the components needed to build each part of the value chain; e.g. what components that are needed to build the smart dressing (electronic and dressing components). The components and parameters are presented in *Figure 21* with the value creation enablers. Given the aspect of control mechanisms, relevant data regulations needed to be studied as well.

4. Findings & Analysis

Here, the findings and analysis of this research study are presented under the same chapter, as some of the findings are inseparable from the analysis. The three phases are separately presented to distinguish the analyses from each other and make each analysis easy to track back to the methods and research questions.

4.1 Phase I - Claiming Intellectual Assets

The findings and analysis presented in this section refers to the result from phase I, which referred to claiming the intellectual assets according to the IAM framework.

4.1.1 Identification & Categorization of Intellectual assets

All identified intellectual assets are presented in the table below, *Table 9*. Worth mentioning again is that these IAs are far from all intellectual assets that build the Medtech company, but only the ones that were emphasized by key personnel and hence considered relevant for this study.

Table 9. The IAs are presented with their anonymized ID in the list. The IAs are tagged by category, sub-category and technology platform. The scientific result and the social benefit/value creation are shown, as well as what legal control that is currently applied.

IAID	Category	Sub-category	Objectification	Scientific result	Social benefit/ value creation	Technology platform	Control
IA01	Solution	Technology	An improved material design.	Transfer of liquids within the dressing	Better micro environment in wound due to moisture control	Dressing	Patent
IA02	Solution	Creation Process	Improved process of creating a material.	Softer materials which enables faster and more efficient method of creating foam.	Less environmental impact. Reduce the damages on machines in production (knifes, scissors) and prolong the lifetime of machines.	Dressing	Patent
IA03	Solution	Creation Process	New method of applying a compound to materials.	Improved use of silver coating in healthcare products. Instant and slow release of silver.	Reduce total amount of silver in a dressing. More effective use of antibacterial compounds in products for patients	Dressing	Patent
IA04	Solution	Product	Product of a material with certain functions.	One layer with functions to absorb exudate, blood and other liquids with little retention	Fill out wound cavities, removable after healing due to non-dissolving/non-tearing of the material	Dressing	Patent license
IA05	Solution	Product	Improved product of a material with certain functions.	Softer and more flexible material, higher wet tensile strength	Premium feel to the material, more user friendly. Higher wet strength which enables	Dressing	Patent

					more application areas where it does not break when it is removed.		
IA06	Solution	Product	Product of a material with certain functions and compounds.	One layer with function to absorb exudate, blood and other liquids with little retention and be antimicrobial due to silver ions.	Antimicrobial effect in wound treatment	Dressing	Patent
IA07	Solution	Technology	New functions of a material.	Anisotropic material for several applications	Reducing skin damage	Dressing	Patent
IA08	Solution	Digital Service	New software-implemented support system for caregivers.	Software based support system with image recognition	Clinical decision support for caregivers, reduce errors in diagnostics and treatment	Digital	Patent
IA09	Solution	Digital Service	Computer implemented method for customized products.	Software based portal	Digital portal for caregivers to design surgical tray as desired	Digital	Patent on technical function, not the software as such.
IA10	Solution	Design	An improved product design.	Higher flexibility in the dressing through structural design change in the non-woven fibers.	Better fit for use in difficult areas on the body, knees, elbows etc.	Dressing	Patent and design protection
IA11	Solution	Creation Process	A new functionality of a method in a material process.	Pathways which enables gravity resistance.	Hinders exudate from leaking	Dressing	Possibly patented
IA12	Solution	Testing	New solution for simulated clinical testing.	Complex solution for simulated wound fluid, close to real wound fluid, to give more realistic response in testing	Pushing the norms to make this a standard test fluid	Dressing	Published
IA13	Solution	Creation Process	Method of producing improved material.	Improved silicon adhesive	Improved application use on previously unused areas due to the increase in adhesive power.	Dressing	Trade secret and patent
IA14	Software	Digital Service	Mobile application with a purpose to support treatment.	Platform application for analyzing wounds	Analytical tool to support caregiver and patient	Digital	JDA
IA15	Instruction	Composition	Instructions of certain requirements for a material.	Documentation of required demands for the non-woven material	Better performance and market standard of the non-woven functions	Dressing	Trade secret
IA16	Instruction	Algorithm	Algorithm for the software-implemented support system.	Evaluates and ranks different products after the exact necessary need.	Recommend products appropriate for the treatment need.	Digital	Copyright
IA17	Instruction	Composition	Instructions for certain compositions for a material.	Improved adhesive	Improved application on previously unused areas due to the increase in adhesive power.	Dressing	Trade secret
IA18	Narrative	Know-How	Undocumented knowledge narrated by persons skilled in the art, interpreted as know-how.	Adhesive features are based on know-how about the patients and their experience with adhesives	Better adhesives for the patients, great recognition of adhesive among users	Dressing	Trade secret
IA19	Database	Electronic database	Collection of data used for the software-implemented support system.	Structured collection of wound data that provide statistically reliable basis for clinical decisions	More reliable clinical decision support for caregivers	Digital	Copyright
IA20	Solution	Digital Service	Product and method of electronically read identifiable information	Using readable tags in medical dressings as a control function for prevention of pressure ulcers.	Ensure and conform compliance in preventive wound care.	Digital	Patent

The intellectual asset list shows similarities and differences between the identified intellectual asset regarding dressings and digital technologies. Within dressings the IAs are related to improved functions or methods of earlier launched products or materials. The intellectual assets are mainly related to improved functions in materials, methods or design, processes of creating materials or solution for improved or new desired functions.

Within digital technologies the intellectual assets are new and unmatured, and include structured collection of data, programmed digital products and algorithms instructing recommendations.

Most of the internal intellectual assets are identified as solutions and are to a large extent covered in patent applications or granted patents. Technical solutions in an early development stage, concepts, are generally quickly filed for patent protection, but since the technical field of premium dressings is mature, the concepts are often patented in combinations to achieve novelty and technological height in the patent application. One indication that seem to highlight the maturity of the technical field of premium dressings, is that most of the patent scopes claim an improved design, material, process, method or product of an existing product, or new methods of applying materials in a dressing construction. There are new functions and features of materials and products claimed as well, however only a few.

Most of the intellectual assets are related to dressings, which is the main focus in production, however, there is also a few intellectual assets that are identified as digital assets. These are categorized to be solutions, software, database and instructions (algorithms). It is assumed that these intellectual assets were considered significant to mention by the interviewees, because of the purpose of this study. Thus, the digital assets are not directly linked to dressings, but rather wound care. However, it was crucial to analyze these in order to establish the technical level of the MedTech company and determine whether the digital assets could be centric for a development of a smart dressing. The digital assets are not improvements of earlier intellectual assets, but newly created and reveal a scarcity of digital assets. There is an indication that there is some effort put into creation of digital assets which are of varied sort.

4.1.2 Intangible Resources

In addition to the intellectual assets, it is revealed through the interviews that additional resources, which cannot be objectified as intellectual assets, exist within the Medtech company. These intangible resources are claimed to be centric resources for the Medtech company according to the interviewees, since they are crucial for enabling the current business activities. These intangible resources did not fit into the categorization based on the IAM framework, hence they could not be evaluated accordingly. Instead, these additional resources could be evaluated by the use of an alternative framework, such as the resource-based theory where the resources can be evaluated on whether they are valuable,

rare, inimitable and non-substitutive. However, there is a need to understand the external environment in order to evaluate these parameters, which is not examined in this phase. Below is a selection of the identified intangible resources:

- Knowledge about customer (both patients and caregivers) pains and needs in relation to wound treatments, adhesives, dressing constructions and material
- Know-how in production processes and material logics and reasoning, i.e. undocumented knowledge of why a specific process or material is constructed in a certain way to perform as desired
- Experience and insights, so called business intelligence, of the traditional and premium dressing industry and field

These are difficult to transfer due to their nature and the inconvenient to measure, monitor, evaluate and value. However, the intangible resources are considered significant to the MedTech company, since they constitute a valuable foundation for the current business activities of producing dressings. The difficulties to objectify and make the intangible resources transferable could constitute lack of control over them, since they are not eligible for any protection with intellectual property rights other than trade secrets.

The risks related to the intangible resources are lack of applicable control mechanisms, which can make the resources sensitive for leakage. However, the nature of the resources also makes them difficult to transfer, and thus, difficult to leak. One aspect to consider in order to obtain more control is implementing and structuring knowledge management, which could make the intangible resources more transferable and hence easier to control.

4.1.3 Evaluation of Intellectual Assets

The identified intellectual assets are evaluated on three technology parameters; their technology progression or maturity, possibility for legal control of the technology and technology dependency on external actors or other technologies. The evaluation is based on a scale of 1-3 on each technology parameter according to the evaluation scale presented in *Figure 6*, and the digital assets are presented in *Figure 8*. The evaluation score and reasoning of each technology parameter for the respective Intellectual asset (IAID) is shown in *Table 10*.

Table 10. The technology parameters, and the scores of those, for each IA are presented in the table below.

IAID	Category	Subcategory	Progression	Control	Independency
IA01	Solution	Composition	1	2	3
			Conceptual level	Pending patent	Developed and produced in-house
IA02	Solution	Creation Process	1	2	3
			Conceptual level	Pending Patent	Developed and produced in-house
IA03	Solution	Creation Process	2	2	3
			Prototype	Pending patent	Developed and produced in-house
IA04	Solution	Product	3	3	1
			Fully implemented	Patent cross-license	3rd party developed
IA05	Solution	Product	3	2	2
			Fully implemented	Pending patent	Improvement rights
IA06	Solution	Product	3	2	2
			Fully implemented	Pending patent	Improvement rights
IA07	Solution	Technology	3	2	3
			Fully implemented	Pending patent	Developed and produced in-house
IA08	Solution	Digital Service	2	2	3
			Prototype	Unpublished patent application	Developed and produced in-house
IA09	Solution	Digital Service	3	2	3
			Fully implemented	Pending patent	Developed and produced in-house
IA10	Solution	Design	3	2	3
			Fully implemented	Pending patent	Developed and produced in-house
IA11	Solution	Creation Process	1	2	3
			Conceptual Level	Partly patented	Developed and produced in-house
IA12	Solution	Testing	3	1	2
			Fully implemented	Published	Developed in-house,

					produced by external party
IA13	Solution	Creation Process	3	2	3
			Fully developed	Trade secret	Developed and produced in-house
IA14	Software	Digital Service	2	1	2
			Prototype	Open-source	Joint development
IA15	Instruction	Composition	3	2	3
			Fully implemented	Trade secret (Cannot obtain higher control)	Developed and produced in-house
IA16	Instruction	Algorithm	2	3	3
			Prototype	Copyright	Developed and produced in-house
IA17	Instruction	Composition	3	2	3
			Fully developed	Trade secret	Developed and produced in-house
IA18	Narrative	Know-how	3	2	3
			Fully implemented	Trade secret	Developed and produced in-house
IA19	Database	Electronic	2	3	2
			Prototype	Copyright	Joint development
IA20	Solution	Digital Service	2	2	3
			Prototype	Unpublished patent application	Developed and produced in-house

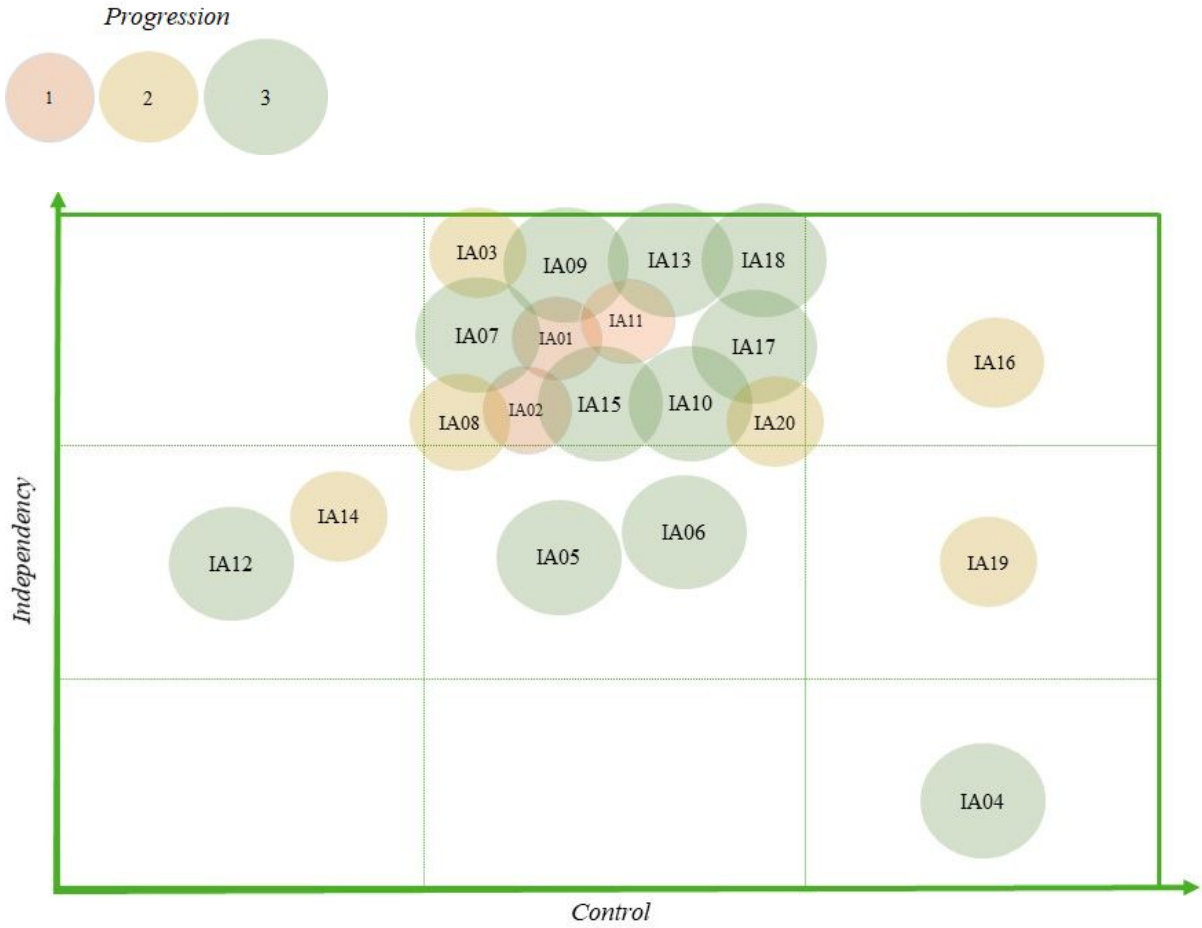

Figure 6. The IAs, presented as bubbles with their IDs in the middle, are plotted based on their evaluation scores. The X-axis presents the control parameter, scores 1-3 from left to right. The Y-axis presents the independency parameter, scores 1-3 from bottom to top. The sizes and colors of the bubbles present the progression parameter, where the smallest red bubble is score 1, the middle yellow bubble is score 2 and the largest green bubble is score 3. There is no scale or difference in scores within one score box in the plot, but one box on each axis represents the same score along the axis until the axis pass on to the box adjacent.

Figure 8. The intellectual assets related to digital are singled out from the evaluation plot. The IAs with a blue border are connected to the same invention with the database, software, algorithm and application user interface.

Progression: Eleven (11) out of twenty (20) of the intellectual assets are mature technologies or implemented in launched products. This indicates rather mature technologies related to dressings, but also that there are few new creations on the uprising. This could depend on the requirements to comply to the new EU regulations regarding medical devices (*MDR*), which requires strict documentation, new rules on clinical evidence and new risk classification (European Commission, 2019). The new regulations demand time consuming documentation and adjustment of R&D routines to be compliant, which have slowed down the innovation processes for 2019. Regarding the digital assets, only one of six constitutes a fully implemented technology while the rest are on a prototype stage, which leads to the conclusion that most of the digital assets are immature and recently created.

Control: Fifteen (15) out of twenty (20) of the intellectual assets are either covered in patent applications, both published and unpublished, or by trade secrets. As much as ten (10) patents are pending and not yet published because they have been filed within the last couple of years. The intellectual assets that are on the lowest control level are either published for the purpose of creating new testing standards or based on open source. Hence, there has been a conscious strategy behind the control position. The three assets that score the highest in control parameters are protected by copyright (2 out of 3) and a granted patent (1 out of 3). It could be argued that copyright as an intellectual property right is not as strong or enforceable as a granted patent, but it does not protect a technology as such but rather algorithms and

structures of data collections, which could comprise a centric IP protection in data-driven settings.

The evaluation parameter control could be discussed whether the evaluation scores are reasonable, since the valuation of technology control depend on situation. In some cases, trade secret could be considered more valuable than patent protection, e.g. a process could potentially be preferable to protect with trade secret, since it could be difficult to prove patent infringement on a manufacturing process. The strength of a control position is related to the enforceability and value the business impact that enforceability could provide. The risk of losing control of the intellectual asset in relation to the possible value a strong control position will provide is important to consider when scoring a control position from low to high value and choosing how to protect the asset, through patent, trade secret or publication. Hence, the scoring of control position depends on the situation. It is crucial to ask the right questions in relation to the situation, for instance how difficult it is to reverse engineer, how easy it is to prove third party infringement.

Independency: Fourteen (14) out of twenty (20) of the intellectual assets are independent on external stakeholders in order to be developed and produced, which indicates that a lot of the competence and knowledge that build the intellectual assets exist in-house. The digital assets are mainly independent on external stakeholders, as all solutions are invented in-house and all the algorithms are created in-house. The software and the database, which are related to each other, are jointly developed together with a partner.

4.1.4 Summary of Phase I

It can be concluded that most of the intellectual assets identified are related to wound dressings and are categorized as technical solutions; these are rather mature in technology progression, developed in-house and have pending patents to claim control. Based on interviews, it is assumed that the Medtech company is strong in their core business activities in wound care and especially wound care dressings but have a scarcity of digital assets and knowledge.

4.2 Phase II – Control Positioning

The findings and analysis presented in this section refers to the result from phase II, which referred to investigate the intellectual property landscape and control positions.

4.2.1 Search String Construction and Collection of Data

Terminology and wording specified for the field of knowledge were retrieved from the pre-study and phase I, which based the initial definition of smart dressing and was used to create the initial patent searches. The constructions of the search strings and the date of search are found in *Appendix II*.

4.2.2 Patent Landscape High Relevance

Findings from search number 11 were after an in-depth analysis of technical scope divided into high relevance, medium relevance and non-relevance (for the area of knowledge) sub-groups (see *Appendix IV* for the patents on a high and medium relevancy level). The 28 patent families in the high relevance group are visualized in a patent landscape analysis, including technical and geographical coverage, assignees and legal status. The automated charts in *Figure 9-12* presented below are constructed by using Orbit Intelligence.

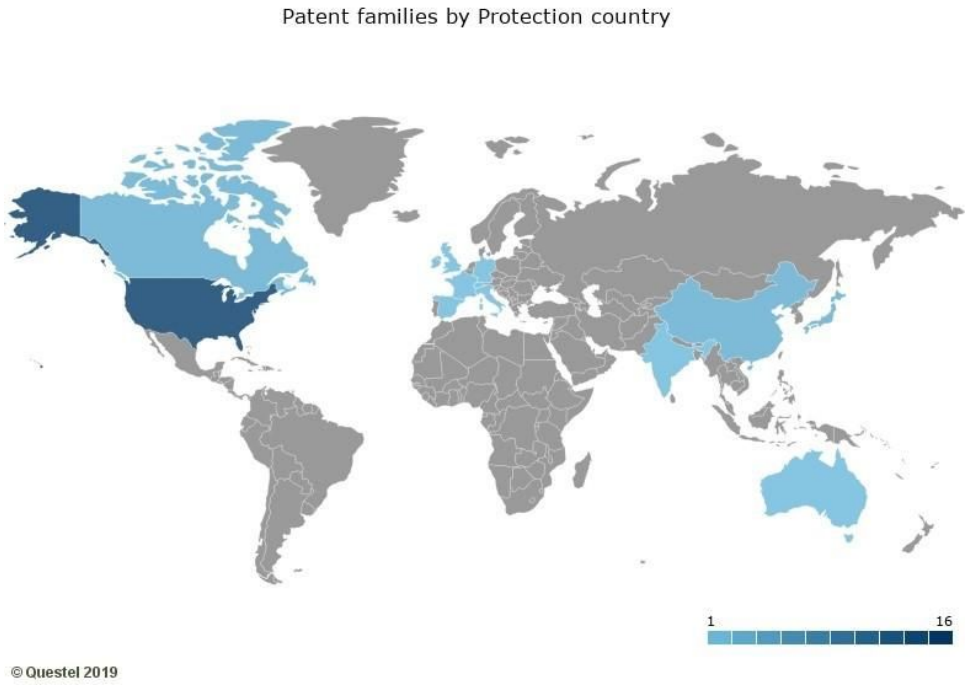

Figure 9. This chart is extracted from Orbit Intelligence and shows the geographical coverage of the patents with high relevance (Orbit Intelligence, 2019).

The patent filings are highest in the United States, US, with 16 patent families. The European Union, EP, are closely following with 12 patent families and third comes WO applications with 8 PCT applications.

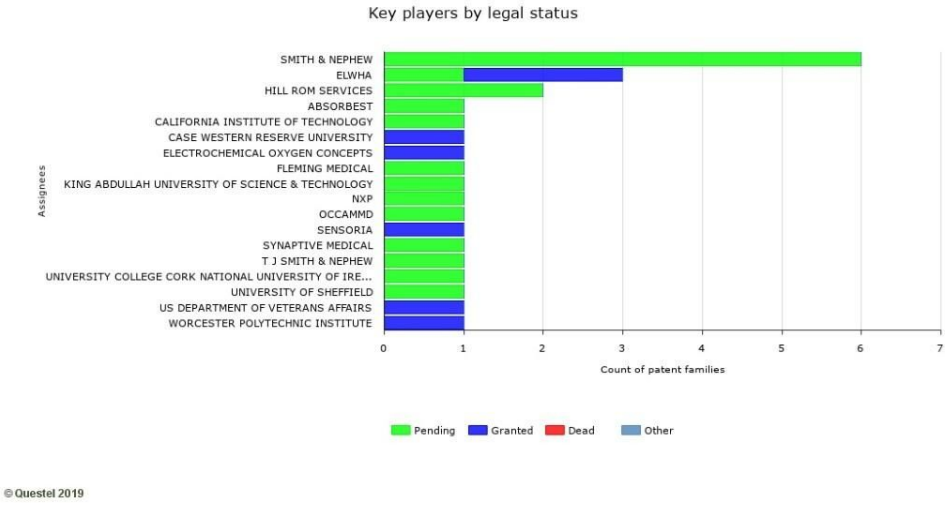

Figure 10. This chart is extracted from Orbit Intelligence and shows the assignees of the patents with high relevance (Orbit Intelligence, 2019).

The key players filing patents in this area are shown in *Figure 10*. In the top with highest amount of patent families are Smith & Nephew with 7 patent families, 6 patent families under the entity Smith & Nephew and 1 patent family under the entity, TJ Smith & Nephew. Indicated by the legal status coloring the patent families are all pending which also can be said about the majority of the applications. The second key player from the top is Elwha, with 2 granted patent families and 1 pending patent family. Hill Rom Services have 2 patent families pending meanwhile the rest of the assignees have only one patent family, either pending or granted.

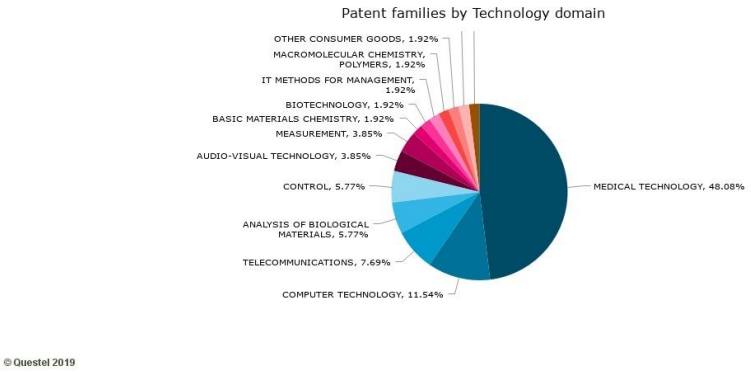

Figure 11. This chart is extracted from Orbit Intelligence and shows the technical domain of the patent with high relevance (Orbit Intelligence, 2019).

The Technology domains in *Figure 11* of the patent families are in majority within Medical technology, which is to be expected due to the area of wound care and wound dressings. The other 50 percent are distributed over several technology domains with the highest percentage on Computer technologies, Telecommunications, Analysis of Biological Materials and Control technologies. For a wound dressing to be classified as smart, connectivity is

necessary. Electronic technologies are therefore also expected to be in the top technical domains.

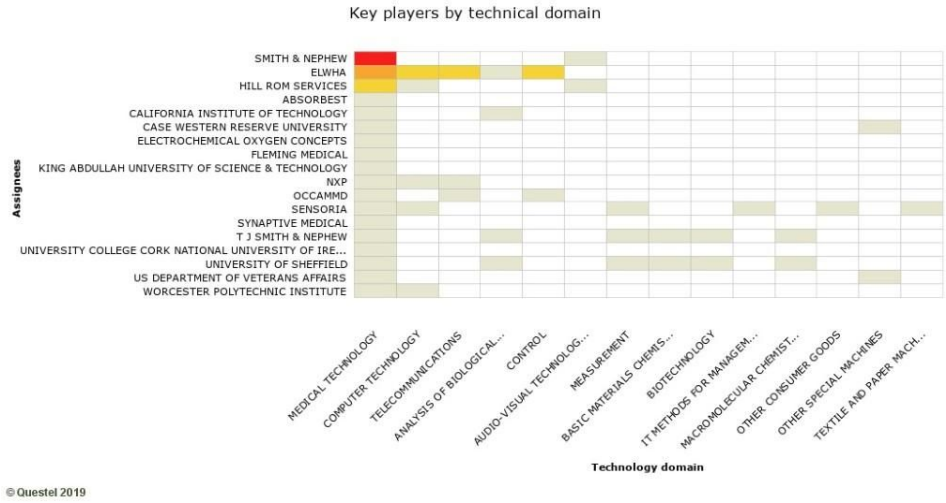

Figure 12. This chart is extracted from Orbit Intelligence and shows the key players by technical domains of the patents with high relevance (Orbit Intelligence, 2019).

Looking at the Technical Domains in *Figure 12* of the key players it can be established that they are all positioned in the Medical Technology domain. Six of the eighteen assignees; Absorbest, Electrochemical Oxygen Concepts, Fleming Medical, King Abdullah University of Science and Technology, Synaptive Medical and the University College Cork National University of Ireland, have their patent families solely within the Medical Technology domain. The other twelve assignees have combinations of the Medical Technology domain and at least one other technical domain, where Computer technologies, Analysis of Biological Materials, Measurement and Telecommunication are in the top. Smith & Nephew has all their patent families within Medical technology and only one of them in combination with Audio-visual technology. Hill Rom Services position themselves in the same technology domains as Smith & Nephew with one addition in Computer Technologies. Elwha however has their patent families distributed over Medical technology, Computer Technology, Telecommunications, Control and Analysis of Biological materials.

4.2.3 Top Assignees

A detailed analysis of the top assignees; Smith & Nephew, Elwha and Hill Rom Services, comprising detailed mapping of technical scope, jurisdictions, legal status, filing strategy (priority claims, designation of states and patent applications), company structure and collaborations with other stakeholders. This is presented in *Table 14.*

Table 14. Presented are the assignees, the company structure and the patent strategy.

Assignee	Company Structure	Patent strategy
Smith & Nephew	MedTech company	Divide inventive parts into several patents
Elwha	Holding company, LLC	Continuation in part
Hill Rom Services	MedTech company	Jurisdiction; US and EU.

4.2.3.1 Smith & Nephew

The six similar patents are all filed within a period of two months through PCT applications. Five of them claim priority to US provisional patent applications, while the sixth claim priority to several unpublished US applications. This is presented in *Appendix V*.

The patent filings all relate to a wound monitoring and therapy apparatus and system, but the filings have slightly different aspects and contributions to the technical scope of a final product (see *Figure 13)*. The concept or product that the filings seemingly intend to protect is a wound monitoring system comprising a dressing with integrated sensors in the skin contact layer, configured to measure wound data. The sensors, connected to flexible printed circuits which are coupled to an electrical ground, will send signals to a controller located in a remote computing device. The transmitted signals include the wound data which will be encrypted according to a security protocol and a value indicative of a physiological parameter will be determined. The circuits, sensors and substrates are coated to protect the electronic components. Sensors are positioned in an array and are restricted by masking layers to sense towards the direction of the wound.

The patent strategy includes claiming both product and method of operations for all patent filings, however, for the filings claiming electrical components integrated into the apparatus, the process of constructing the components together is also included. The patent claims in the patent applications have a broad technical scope and some are even repetitive with the same claims but with small adjustments towards a narrower scope.

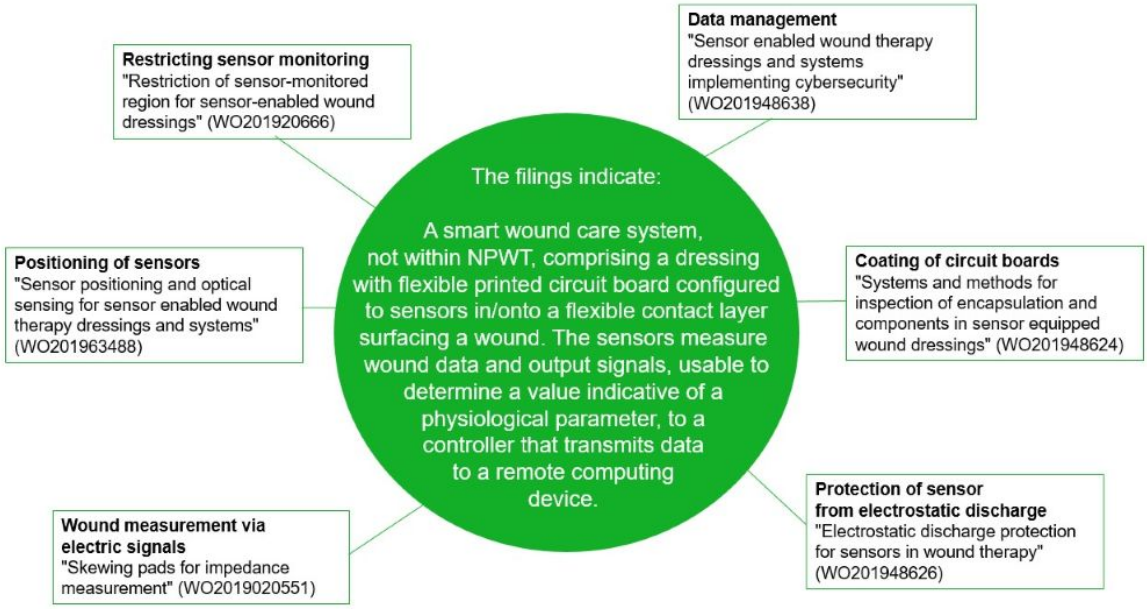

Figure 13. A visual summary of the patent filings from Smith & Nephew and the smart wound care system which the patent filings cover.

4.2.3.2 Elwha

The patents from Elwha in this study can be seen to be a part of the same patent family since they all claim priority to 2012US-13445220. The patent family consists of continuation in part patents and claims closely related inventions. The patent family can be structured as three sub-families, due to the continuation in part applications. The three sub-families all refer to the same invention but emphasize on different aspects of the invention. On this present day, 2019-04-17, there are seven granted patents and four pending patents. Due to the use of continuation in part patents the difference in scope is difficult to distinguish.

Sub-patent family 1

Sub-family 1 (see *Appendix VI*), is focused on the invention of an appurtenance for reporting information regarding a wound dressing. The appurtenance has a substrate that is attached to a wound dressing and attached to the surface of the substrate is a transmission unit that is provided with a circuitry and antenna. The claims are focused on the components of the appurtenance and the technology of measuring a wound characteristic. However, the claims are not indicating what that wound characteristics should be and rather focusing on the sensor as such, the transmission and a processor with NFC.

Sub - patent family 2

Sub-patent family 2 (see *Appendix VI*), has more elaborated claims than sub-family 1. This in relation to the higher amount of patent applications and the different focus of each patent applications claims. The application use is specified for a patient, i.e. an appurtenance for wound dressing to cover a patient's wound. A sensor unit and an electronic identifier are added to the claims of the invention as well as extended projections from the substrate. The projections extend into an interior region of the wound dressing to sample a fluid associated with a wound and depending on the moisture level infection can be indicated. The moisture level activates an antenna to transmit a signal and a memory saving recording enables comparison of the transmission's signals. Data gathering is achieved by continuously saving transmission signals in a memory, which can be used to obtain a monitoring trajectory. The claims do not mention any healing output, only the use of monitoring the wound dressing through moisture levels.

Sub - patent family 3

Sub-patent family 3 (see *Appendix VI*), includes EP patent applications. The patent applications are designated EP applications from two similar PCT applications. The scope of the invention of each patent application is however slightly different, where one application focus on the system for monitoring wound dressings and the other focus on the method of monitoring the appurtenance, which monitor the wound dressing.

4.2.3.3 Hill-Rom Services

Hill Rom Services has two patent families within the High Relevance Patent Landscape. The inventions claimed are related to systems for monitoring wounds.

Patent family 1

Patent family 1 (see *Appendix VII*), from Hill Rom Services, is considered to have a technical scope of a smart dressing, as it covers a wound dressing system that monitors a wound and includes a sensing device that determines whether an infection is likely to occur based on comparing wound data to predetermined values that are indicative for infection. The indicative values are predetermined and are reference values, such that an alert is outputted if the measured wound data indicate infection. The predetermined values are stored in a memory module, however there is no claim of communication to any database. Thus, it is indicated that no machine learning is applied. Even though the smart dressing comprises an integrated sensing device responsive to the measured data by outputting alert and activating heating elements it is categorized as basic smart dressing due to lack of machine learning or claim of external communication.

Patent family 2

Patent family 2 (see *Appendix VII*), from Hill Rom does not comprise a dressing, but a portable device for the use of monitoring wound characteristics through an imaging component. The technical scope of this patent family does not include a smart dressing as such but include remote wound monitoring. The purpose is to monitor wound characteristics and indicate a wound score to determine the status of the wound, which is similar to the other patents relating to smart dressings, only that this invention is not applied on the skin.

4.2.3.4 Top Assignee Analysis

The top assignees all have applied for the United States for jurisdiction of the patent filings. Either through a directly filed patent in the US, a provisional patent application or through designation of US in a PCT application. The legal statuses of the patent families are all pending for Smith & Nephew and Hill Rom Services. Elwha have both pending and granted patents in the US, in the EU however, they have only two pending EP patents designated from two lapsed PCT applications.

Smith & Nephew patent filings were initially difficult to distinguish from each other as they have high number of broad and partially overlapping claims and are closely related to each other in technical scope. The claims structure and receptiveness indicate a strategy from Smith & Nephew to cover a broader technical scope and preparing for the case of claims being objected or rejected in prosecution.

Hill Rom Services have similar strategies for both their patent families, with a US provisional patent as first filing, the scope is limited to product and system claims and further applications have jurisdiction in US and EP. The US patent applications are more specific with more definite wording and details added in the claim in comparison from the EP patent

applications. The added specificity of the US patent applications indicates a priority of the US market and the difficulty to patent software related inventions in the US.

Hill Rom Services and Smith & Nephew are both Medtech companies that have their core business in non-connected wound care. Their patent applications with the added technical domains of Computer Technology and Audio-Visual Technology shows a strive to obtain a control position within smart wound care.

Elwha is branching their patent portfolio within this field using continuation in part patenting where claims are continuously adding or amending to obtain broader technical scope. Elwha has a diverse and extensive patent portfolio and their core technology are difficult to establish due to lack of launched products. Elwha is a part of Intellectual Ventures, which is one of the world largest patent holding companies, this in addition to the lack of commercialization through any launched products and high number of patent litigations, indicate that they are ensuring their return on investments through litigating patents. The strategy of increasing the number of patents filings through continuation in part patenting in the United states, indicate that Elwha are investing in their patent portfolio within this field.

4.2.4 Technology Trees

The technical scopes claimed in the patents from the top assignees are presented in separate technology trees for each assignee.

4.2.4.1 Smith & Nephew Technology Tree

The technology tree comprising the technical scope from Smith & Nephew's patents, includes both electronic components and dressing components on a relatively detailed level, as they specify the dressing construction as well as the electronic components (see *Figure 14*). However, they do not specify in detail what wound characteristics to measure as they claim a lot of different sensors that could measure different characteristics. The technical scope includes data management and connectivity, as the measured data will be transferred, encrypted and provide a value indicative of a physiological parameter. Time reference is claimed in order to enable healing progression trajectories, hence providing prediction of the progression.

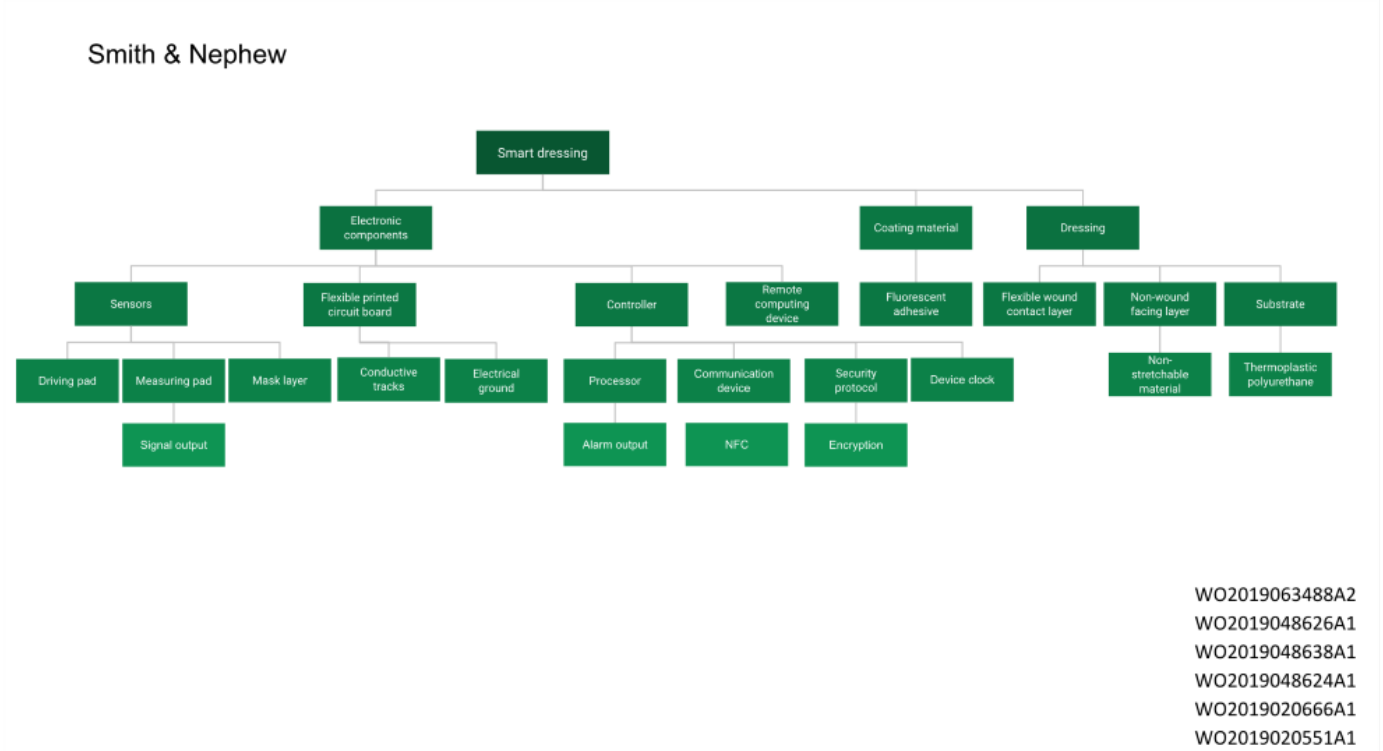

Figure 14. Electronics, dressing and computing are included technologies in the technology tree based on Smith & Nephew's patents. See Appendix VIII for better resolution.

4.2.4.2 Elwha Technology Tree

The technology tree comprising the technical scope from Elwha's patents, does not include a dressing as such, but rather electronic components applicable for use on a dressing (see *Figure 15*). The technology could perhaps be integrated in a dressing since it is supposedly applied adjacent to a dressing and penetrates the layers. This could indicate that Elwha does not possess the competence or knowledge needed to integrate the electronic technologies into a dressing. The technical scope includes data management and connectivity between local and remote devices. Time reference is claimed in order to enable healing progression trajectories, just like Smith & Nephew.

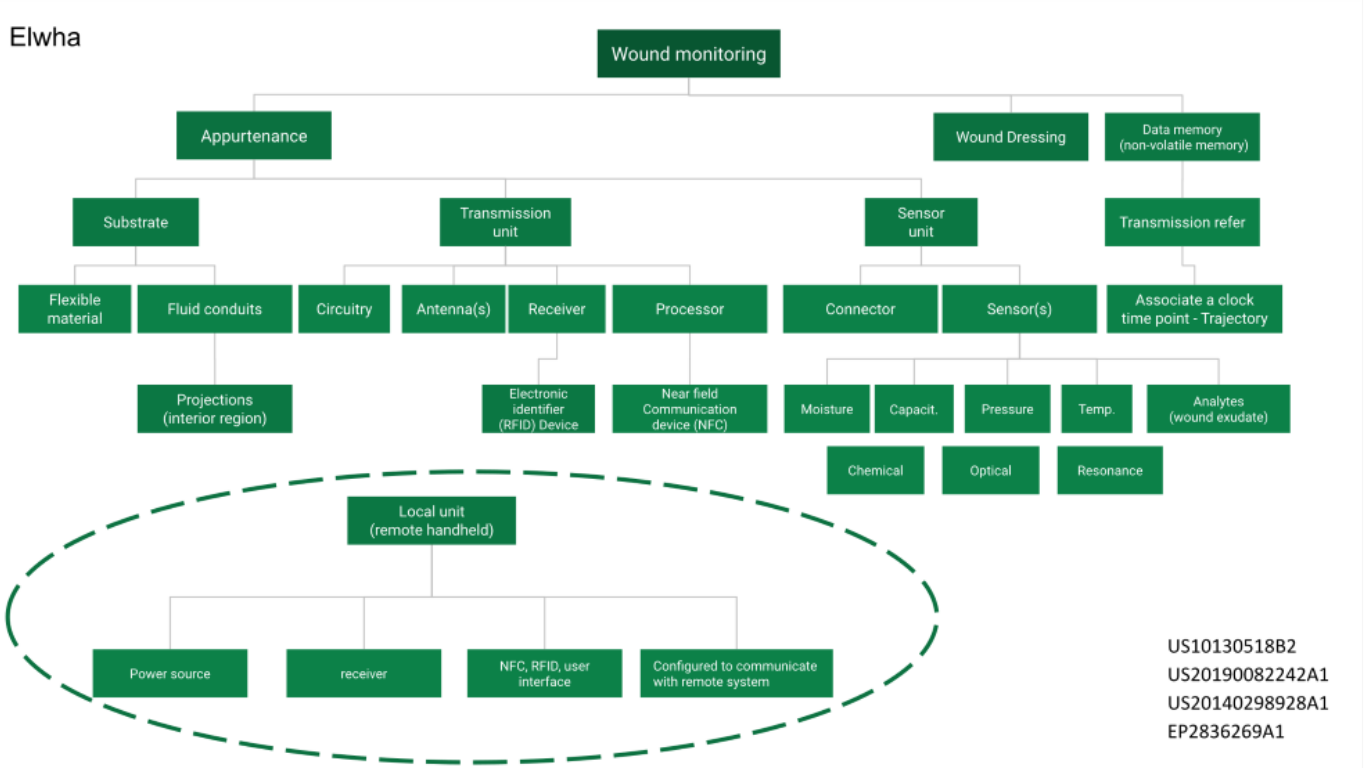

Figure 15. Electronics and data management are included technologies in the technology tree for Elwha. No dressing as such is claimed, but the application is on or adjacent to a dressing. See Appendix VIII for better resolution.

4.2.4.3 Hill Rom Services Technology Tree

The technology tree comprising the technical scope from Hill Rom's patents, includes both electronic components and dressing components, but the dressing components are not claimed in detail and is assumed to be very basic (see *Figure 16*). The technical scope includes data management where the memory module executes instructions on input data that will output an alert. The input data will be compared to predetermined data and seemingly not collected to improve the output through machine learning.

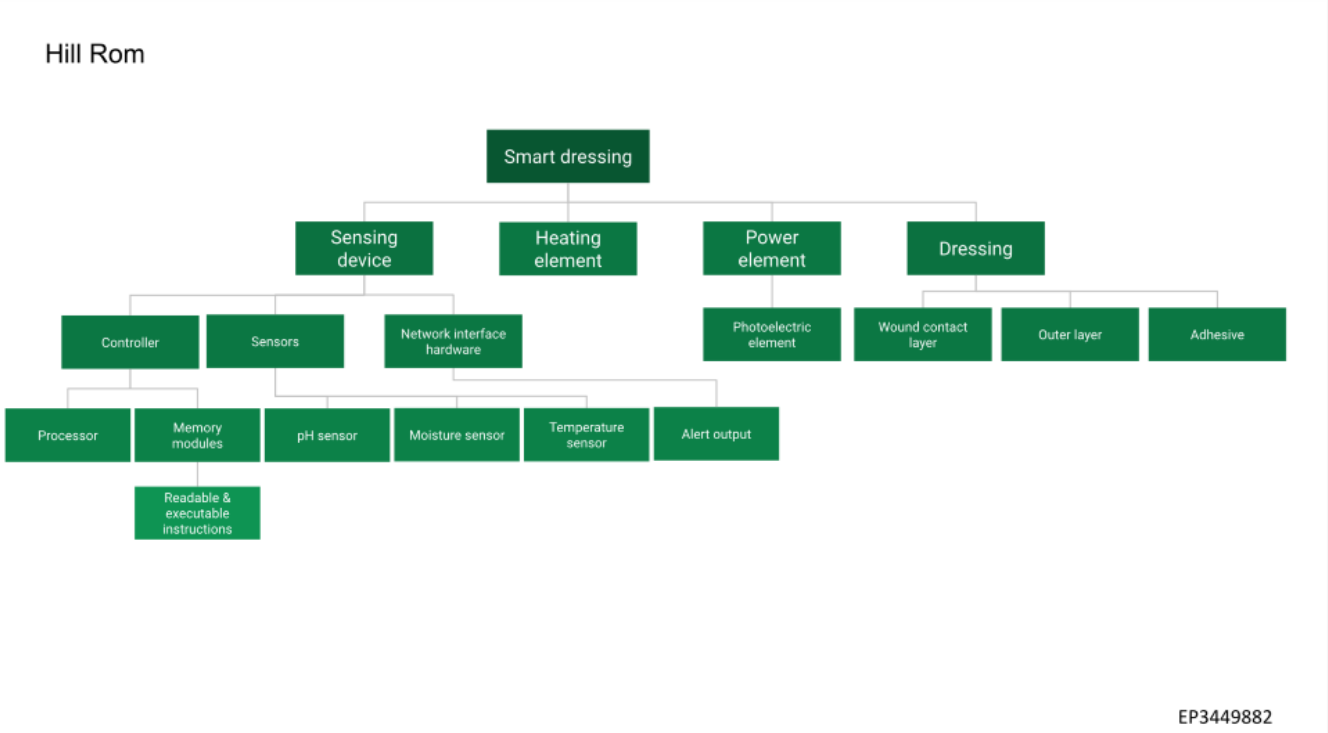

Figure 16. Electronics and dressing technologies are included technologies, as well as rather basic data management, in the technology tree for Hill Rom. See Appendix VIII for better resolution.

4.2.4.4 Current Technical Scope of Smart Dressing

A compiled technology tree was constructed based on the top assignees' technology trees, which is considered to comprise relevant technical requirement specifics for a smart dressing in theory, demonstrated in *Figure 17*. It was established that a smart dressing would comprise of components divided into two large component groups: dressing and electronics, whereas electronics include sensors and components enabling connectivity and computing. It is assumed that this division occurs naturally since none of the technologies within the two component groups are novel within their group, but the combination of components from both groups is. This is confirmed in the patent landscape as there are only a few relevant patents that relate to dressings that include these specific electronic components for the use of monitoring wound characteristics. Above the two component groups, it was discovered that data also played a big part in the technical scopes. However, data, computing and data processing are not physical components but rather functions, since they rather relate to software than hardware. Therefore, it was considered to be more explicit to extract the technical scope that covered data processing to an additional tree that is function-oriented instead of component-oriented. These functions could potentially be claimed by other IPRs than patents, which should be taken into consideration when leveraging on utilization opportunities.

Concluded is that two of three assignees (Elwha and Hill Rom) are more focused and detailed on electronic components but choose to designate the application of the technologies in or onto dressings, without much specificity around the dressing. However, one assignee (Smith

& Nephew) claimed specific technologies in the dressing components, and these are the technical requirement specifics that build the dressing components in the compiled technology tree. This technology tree is considered to cover the technical scopes that are relevant in the patent landscape and the technical aspects of a smart dressing, but as of today none can claim control over the complete theoretical product. Different actors try to claim control over parts of the technology tree. Data, computing and data processing are claimed on a conceptual level, as it seems to be difficult to determine exactly what sort of data to measure (wound characteristics) and how the output responsive to indicative values should perform. This could indicate lack of knowledge in relation to wound characteristics. There could be an indication that there is a larger gap in the scattered patent landscape regarding the specific wound characteristics to measure. If there would be an opportunity to claim a specific wound characteristic with certainty, it would affect what sensor to claim and perhaps how the measured data would be handled.

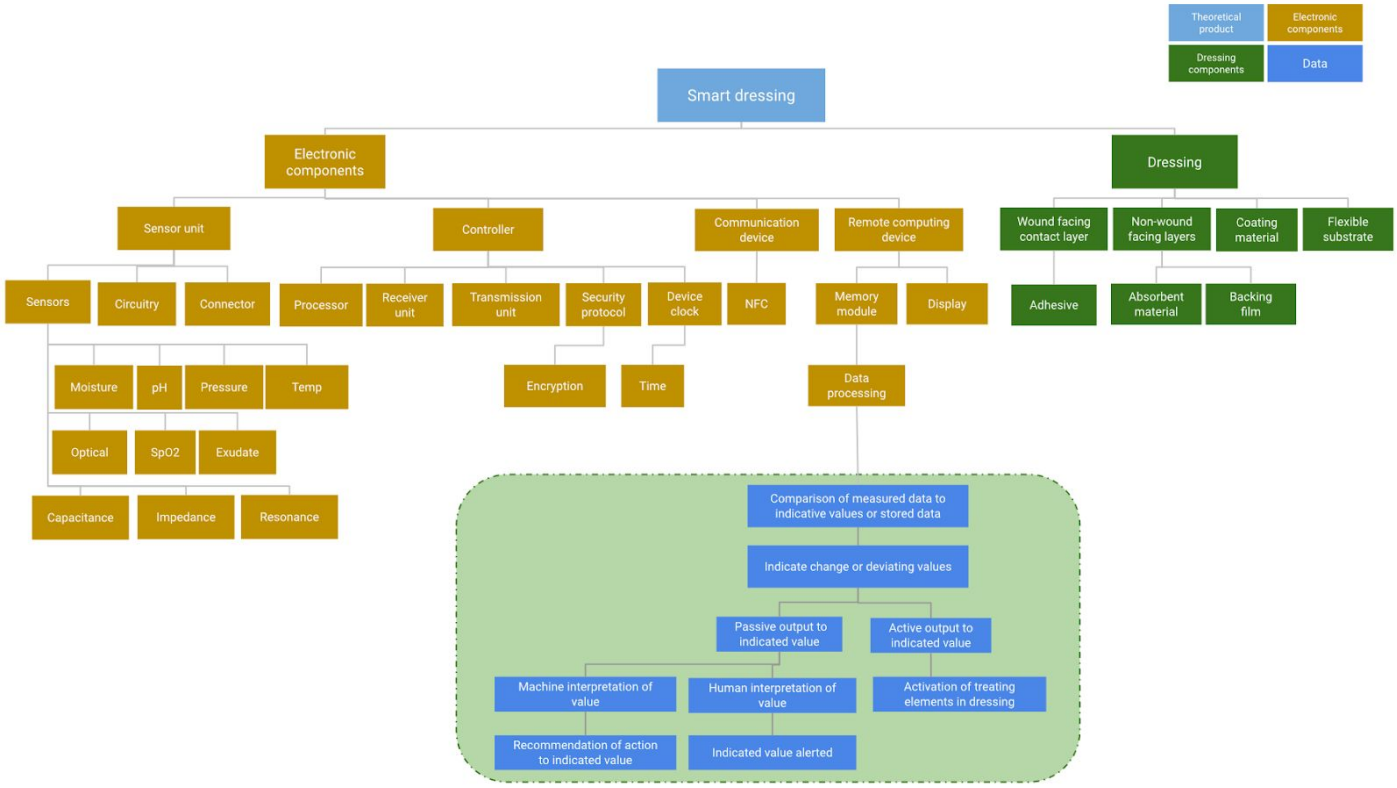

Figure 17. Technology tree presenting the theoretical technical requirement specifics for a smart dressing, which is the iterated definition of smart dressing. The yellow and dark green boxes present the components of a smart dressing, while the dark blue boxes present functional steps of data processing from data input to output. See Appendix VIII for better resolution.

4.2.5 Benchmark Result

Findings from search number 10 were used for the benchmarking. The eleven granted patents were investigated on prosecution from patent application to patent granting. The total amount of claims in respective patent applications and the amendment, cancellation and addition of claims during respective prosecution and their time to granting can be found in *Appendix III*.

A summary of the patent examiners reasoning during prosecution for rejection or objection of claims, can be found in the comment column in *Appendix III*.

4.2.5.1 Benchmarking Analysis

The benchmarking indicates that high number of claims in the patent applications are rejected due to lack of specificity, use of indefinite and not distinct wording or subject matter. Another common source for rejection is existing prior art for the claimed invention. The approximate time to grant was established to be 36 months, the benchmarking showed continuous amendments, addition and cancellations of claims which result in an extensive prosecution and in extension a long time to grant.

The procedure is faster when no cancellations or additions are made which could be found in a single patent prosecution in the benchmarking, the patent, US9788583B1, had only twenty (20) claims, three (3) independent claims and seventeen (17) dependent claims, which were all approved within five (5) months. Unlike this patent, most applications went through several amendments, cancellations and additions, hence the time to grant average is as much as three years (36 months). The prosecution indicates through the rejection due to lack of specificity, use of indefinite and not distinct wording or subject matter and prior art difficulty, that since the field of knowledge combines two mature technical fields with generic technologies, the claims need to clearly show the novelty. Use and application area of the claimed invention therefore needs to be specified.

Old or generic technology in other fields, electronics and wireless technologies, in combination with wound dressings makes it difficult to obtain coverage or technical height if not specified application use to achieve the criteria of non-obviousness. Showing that the wound dressing has a new technical function or improved quality can therefore be necessary.

4.2.6 Summary of Phase II

US is identified to be the focused market, however immature market with a majority of pending patents. The patent claims are generally broad and unspecific of what wound characteristic to measure. There are only a few actors in the patent landscape with patents of high relevance, whom only cover parts of the technology tree. Due to a pending landscape, there is low control from other actors over the technologies combined in the technology tree. The compiled technology tree shows the technical requirement specifics for the theoretical product of a smart dressing. The technology tree is divided into two component groups, electronic components and dressing components, and the functions of data processing. The component groups do not include technology that is novel by itself, but the potential novelty rather lies in the combination of technologies from the two component groups. Data, computing, data processing and connectivity are covered in the technology tree, but might be protected by other control mechanisms than patents.

4.3 Phase III – Utilization Opportunities

In the third phase, the study explores what utilization opportunities there are for smart dressings for the MedTech company regarding the internal intellectual assets and resources in relation to the external environment with the patent landscape.

Further, phase III explores what value smart dressings and the generated data create, as well as what enablers that should be required for the value creation. This will build the foundation for what opportunities there are as well as what control positions that are relevant and possible to obtain for the opportunities.

4.3.1 Publications and Product Launches

The field of smart dressings is futuristic and even if the application use is wide there is still no product launched on the market. However, there is a product launch planned in the late of 2019 by Spinali Design on a Smart Bandage for detection of infection, however the use will only relate to preventive care as a starting point as additional medical testing needs to be conducted in order to launch it as a treatment and medical product. Preventive care is also the first step for Berkeley University with their Smart Bandage that can detect bed sores before they are visible to a medical professional. The Smart Bandage project are funded by The Flexible Resorbable Organic and Nanomaterial Therapeutic Systems (FRONTS) program and are entering clinical trials shortly. The categorization of preventive care instead of medical treatment lowers the requirements for approval as the product does not fall under medical appliances, which will most likely reduce the time to market (Yang, 2019).

There are a few publications from universities in the United States and United Kingdom which cover the field of Smart Dressings. Swansea University Institute of Life Science have created a Smart Bandage, which in addition to sensing the state of the wound using nanotechnology also provides information of the user to a smartphone, e.g. location and movement activities. The project however has not reached commercialization and are still in development stage (Spinoff, 2019). Engineers from several institutions including MIT, Harvard and Tufts University have created a New Smart Bandage that monitor and dispense drugs to the wound as required depending on the health state of the wound (Tufts Now, 2019). The Smart dressing systems comprise a hydrogel layer facing the wound surface, the hydrogel layer comprise thermally-activated drug releasing beads . On the opposite facing surface the hydrogel layer is covered with a disposable 3D-printed flexible substrate comprising a thermometer and pH sensor array (Medgadget, 2019). The smart dressing communicates with a reusable electronics module which receives sensor readings and transmit electronic control signals for drug release. The electronics module communicates through Bluetooth communication to a mobile device, e.g. smart phone. The project is also in an early phase of verification as it has not reached human testing (Mostafalu, P. et al, 2018).

4.3.2 Internal Environment in relation to External Environment

The summary from phase II comprises the technology tree, which represents the technical requirement specifics of a smart dressing as well as the technical scope that is claimed in the

external patent landscape. The summary of phase I comprises a list of intellectual assets that can be claimed by the MedTech company. What can be concluded is that the majority of intellectual assets are categorized as *dressing* in the technology platform category and thus, comprising dressing related materials, processes and constructions, and moreover it can be concluded that all the branches under the *Dressing* box in the technology tree can be claimed by several intellectual assets belonging to the MedTech company. In other words, the MedTech company possesses knowledge about and intellectual assets in the technologies required to create and control the *Dressing components*. However, there are no intellectual assets that cover any branches under *Electronic components*, but a few under *Data processing* as there is one digital patentable intellectual asset (IA08) that relates to a support system for clinical decisions. The MedTech company possesses intellectual assets that cover the components and functions marked with red lines in the technology (see *Figure 18*). Thus, the MedTech company does lack intellectual assets within electronic components and need to complement that in order to develop a smart dressing.

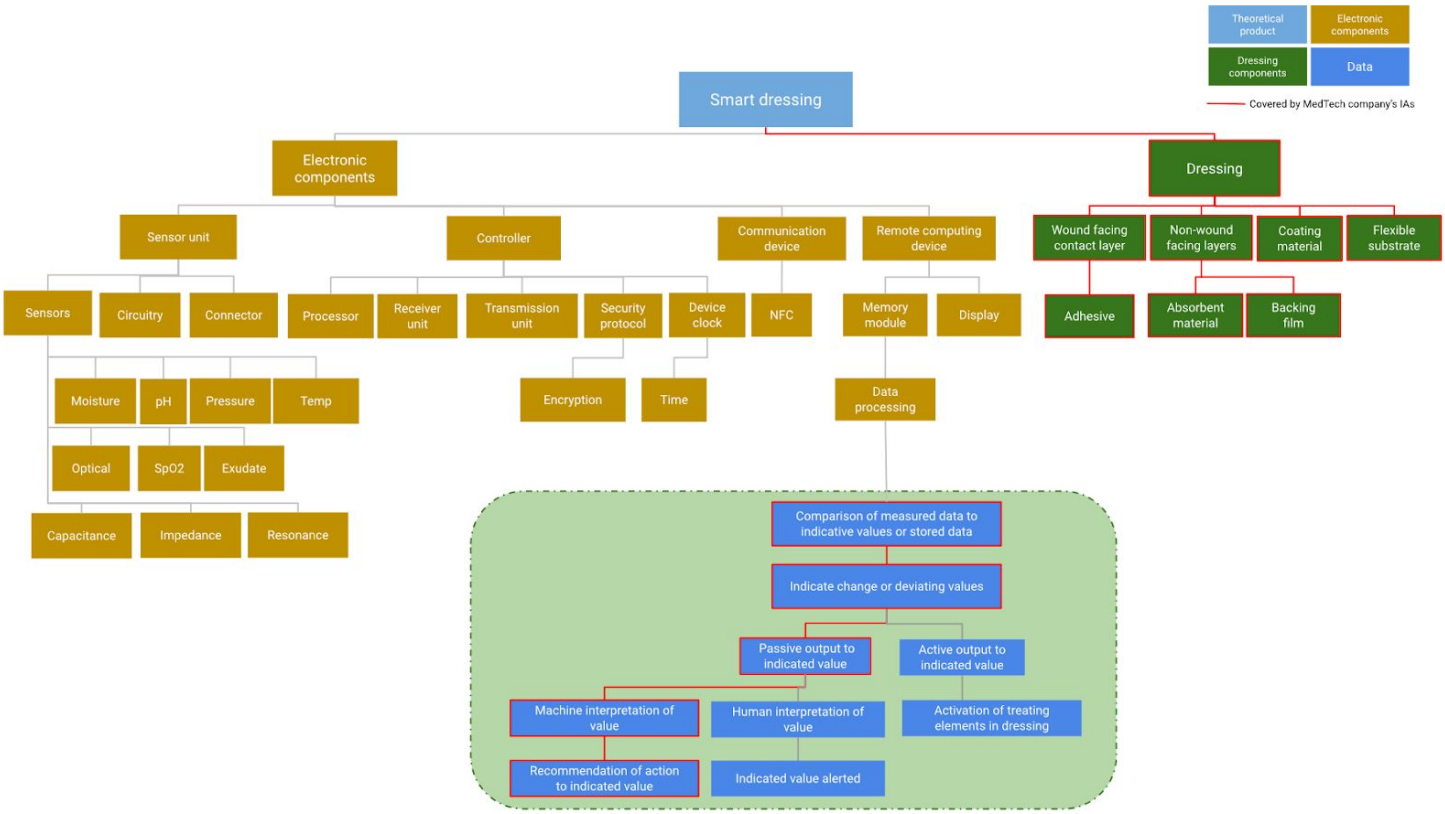

Fig 18. The technology tree has the same construction as the compiled technology presented in Figure 17, but here the MedTech company's IAs are included to cover the boxes where they possess knowledge. These are marked in red lines. See Appendix VIII for better resolution.

4.3.3 Smart Dressing Value Chain

The value chain for the smart dressing value chain presents what potential value a smart dressing and the generated data could create, which is relevant when considering utilization opportunities since it will provide for value propositions. The value creation could be dual – one aspect is the value it brings to the individual patient that uses the smart dressing and the

other is the societal value creation of utilizing the large amount of generated data. The value propositions could therefore look different depending on whether the purpose is to provide treatment for a patient or develop new products to increase wound care efficiency. Important to mention is that the value offerings explored were matched with the customer profile. The customer profile was based on the knowledge and insights that the MedTech company possesses from patients and caregivers (see Findings & Analysis, Intangible resources).

In order to elaborate on the potential value that can be created from a smart dressing, the value creation from a premium dressing should be discussed to bring nuance to the elaboration. The smart dressing will most likely provide for all of the value propositions from a premium dressing, but will create additional value in several aspects as a smart dressing comprises of more features.

4.3.3.1 Current Value Creation from Premium Wound Dressings

The premium dressing provides passive treatment for the individual patient by contributing to a beneficial wound healing environment that manages i.e. exudate and moist, but also providing skin protection and an easiness of removing the dressing due to gentle adhesive that will not harm the wound or skin further. The premium dressing provides value for the individual patient (see *Figure 19*). These value offerings are enabled by the internal intellectual assets categorized under the technology platform *Dressing* in phase I.

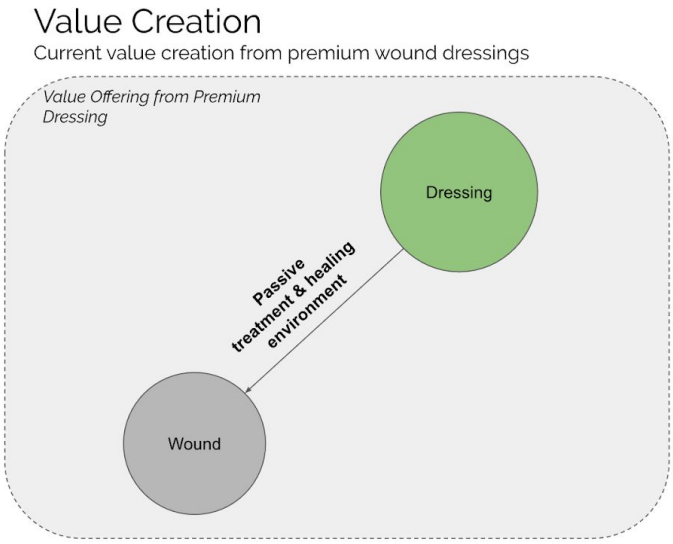

Figure 19. The value offering from a premium dressing is presented in the figure. It does provide for passive treatment and healing environment.

4.3.3.2 Value Creation - Value Offerings from Smart Dressing

The value a smart dressing and the generated data could create is presented in the *Figure 20* below. The schematic figure shows the physical and virtual product of a smart dressing and the associated interactions with parties that will be benefited from it. The value offerings

from each interaction are matched with the customer profile, that was generated by the MedTech company.

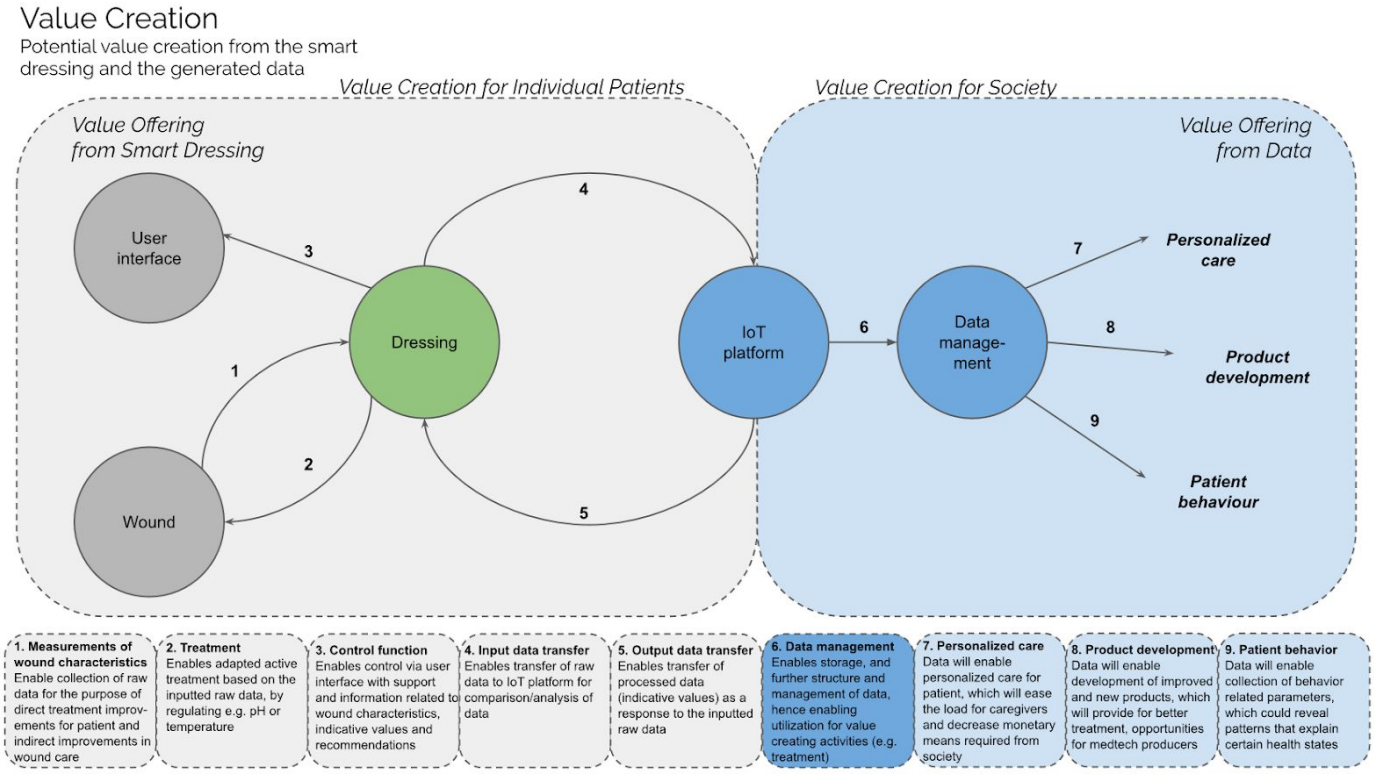

Figure 20. The value chain for the smart dressing with interactions with patients and society that propose value offerings. The potential value creation is both from the smart dressing and generated data. See Appendix VIII for better resolution.

1. Measurements of wound characteristics

The measurements of wound characteristics enable collection of raw data that could be used for the purpose of directly improving the treatment for the individual with the wound characteristics, as the output will be responsive to the data input. It will also enable indirect contribution of improving treatments in wound care for the large mass of patients (see *7. Personalized care* further down).

2. Treatment

The dressing enables adapted active treatment based on the inputted raw data e.g. by releasing drugs or by regulating pH or temperature to respond to the needs of a beneficial wound environment. Just like a traditional premium dressing the dressing construction comprises a passive treatment as such as well.

3. Control function

The control function is enabled via a user interface that will provide the patient, but also caregiver, with support and first-hand information related to the measured wound characteristics, healing progression and predictions. Passive output could be provided by alerting indicative values or as recommendations of treatment. An important output could

consist of alerting when the dressing needs to be disposed when it gets saturated, hence increasing the efficiency in usage by decreasing unnecessary waste of unsaturated dressings.

4. Input data transfer

Connectivity enables that the raw data is transferred to an IoT platform for procession and comparison/analysis of data.

5. Output data transfer

Connectivity enables that the processed data is transferred to the dressing and smart device for either active or passive output (indicative values responsive to the inputted raw data).

6. Data storage

The IoT platform enables communication between the smart dressing and data storage, providing processed data to the smart dressing and wound characteristics to the data storage. Inputted raw data will be processed and analyzed; processed data will be packaged to comprehensible instructions based for a dressing to conduct treatment (instructions comprising algorithms) or for the patient and caregiver (instructions comprising recommendations). The data gathering enables storage and structuring of data in a database, which can be utilized for several purposes such as customizing personalized care, product development or comprise foundation for mapping out patient behaviors. The value enabled by data does indirectly depend on the storage, as the data must be stored in order to be utilized and create value. The larger the data collection becomes, the more evidence could be provided for data-driven treatment, as well as the contribution to other purposes becomes more significant. Value can be created either by directly utilizing the data for a certain output (treatment or product development) or by providing it to other value creators (selling data). However, selling the data requires control – both ownership control and compliance to established data regulations. Ownership of data and compliance to established data regulations are discussed in Data Regulations (further down).

7. Personalized care

Data will enable personalization of care for patients, which will ease the load for caregivers and decrease monetary means required from society. As the data collection of wound characteristics, continuous monitoring of those and response to output data will grow, the foundation for output will be more solid and evidence-based. It could enable distinction of patient groups and profiles, and thus constitute more statistically correct predictions of what and how a patient with certain wound characteristics will progress and react on different treatments. The more data from different patients that are collected, the more alternative outputs are possible to construct and adaptable for different patient profiles, hence making the treatment customized for individual patients.

This data-driven development of care is evidence-based, validated by data and is continuously improved by new inputted data. Personalized care will provide better and more efficient care to patients, but also ease the work of caregivers. The data-driven care will provide caregivers with validated clinical recommendations and support rather than requiring caregivers to make clinical decisions by themselves, hence making it easier to comply to the routines/standards. It will also be easier for caregivers to prove compliance in case of incidents/accidents, which could constitute an incentive as it could decrease costs related to insurances. In the US, where private healthcare is dominating the sector, health insurance is crucial for patients to obtain treatment as well as caregivers are held liable for ensuring the right treatment. With personalized care it is easier to prove compliance for caregivers and avoid maltreatment, thus leading to reduced risk of being sued as the treatments are validated by data. Beyond reduced insurance costs, the increased efficiency could optimize staffing, operations, purchases and increase the sense of control for the patients. Overall, it will generate a general good in society.

8. Product development

Data will enable development of new or improved products, which will provide better care for patients, more efficiency in treatments and create growth opportunities for medtech producers. A data-driven product development is closely aligned with personalized care, as the greatest value offering is providing improved treatments for patients. However, developing goods or services also create revenue streams for producers and distributors, hence creating an opportunity for them to grow as well.

9. Patient behavior

Data will enable collection of parameters related to behavior and not necessarily related to wounds, which could reveal patterns in life style that cause certain health states. This data could therefore be utilized for other purposes than wound care and provide foundation for other research or product development areas. Patterns of patient behavior could also provide caregivers with necessary information to understand the patients and what parameters that could affect treatment.

4.3.4 Value Creation Enablers and Control Mechanisms

In order for value creation of a Smart Dressing system to be enabled, capabilities and control mechanism are required. These are presented in *Figure 21*, and described in detail in the section below.

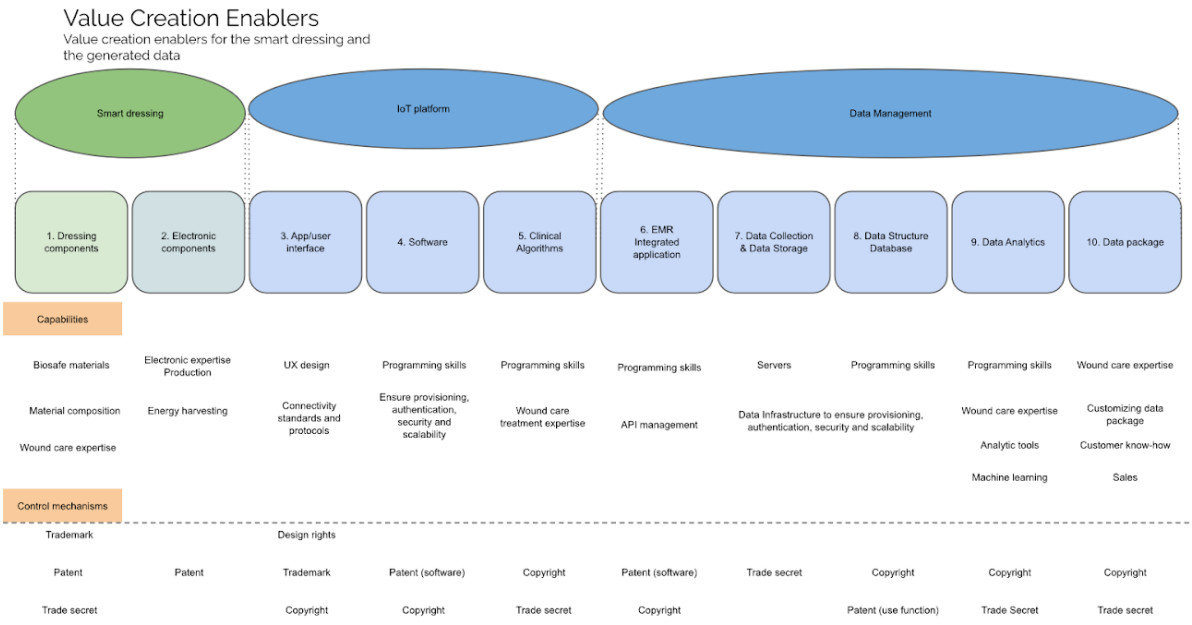

Figure 21. The value chain with enablers, capabilities and control mechanisms, for value creation is presented in the figure. See Appendix VIII for better resolution.

Smart Dressing

1. Dressing components: The control mechanism is generally patent protection for technical methods and construction of the materials in the dressings. Compositions materials, e.g. adhesive ingredients, are kept as trade secrets as it is difficult or even impossible to reverse engineer chemical reactions which are not reversible. Capabilities in material composition, biosafety and wound expertise are central for the creation of dressing components.

2. Electronic components: The control mechanism is patent protection for the electronic components, as it is often easy to reverse engineer. Some components are off the shelf as the previous patent protections have expired, therefore the present and future patent protection covers the combinations of components which provide a certain technical function. Electronic components are easier to reverse engineer as the components are able to be separated from each other, therefore patent is necessary. Capabilities to create electronic components which are meant to be used in smart dressings, are in addition to expertise in electronic production, expertise energy power solutions which are implementable in wound dressings, e.g. energy harvesting (King et al., 2017).

IoT Platform:

3. Application: The application (the App) requires competencies within UX design and connectivity standards and protocols, e.g. Bluetooth and wifi (de Arriba-Pérez, Caeiro-Rodríguez and Santos-Gago, 2016). If the user interface is established to have creative height, it can be subjected to copyright. As the App often are based on or include parts of Open source, see next section *Software*, the source code as such cannot be protected with copyright therefore it is common to build a strong brand for the application and especially the user interface. Trademark can be filed for the coloring, font, product name and slogans included in the user interface and thereby protect and control the application.

4. Software: Software is protected mostly with copyright as the source code can be subjected to copyright. Software can also be protected by software patents, I.e. patenting the technical function or solution that the software provides. Source-code can be protected with copyright if it is constructed from scratch. Open-source software are common to use as it enables the use of existing source code, if this is the case copyright is not applicable, instead a open source license is needed to have in place (Lerner, J., & Tirole, J, 2002). Copyright is a weak intellectual property right for source code, as you need to see the source code in order to prove that an actor is infringing on the intellectual property right. This in relation to the uprising use of open-source code, the trademark has become more and more important as an intellectual property right for data-driven solutions. In order to create a software which is meant to be used in digital healthcare solutions, capabilities within programming, provisioning, authentication, data security and data management are especially important.

5. Clinical Algorithms: Algorithms are subjected to copyright protection. The creation of clinical algorithms requires wound care expertise as the output will depend on provided input e.g. measurement data from the wound. The programmer who create the algorithm therefore need to know what the algorithm should recommend or have as an output for each certain input.

Data Management:

6. EMR integrated application: API management is crucial for data-driven applications (de Arriba-Pérez, Caeiro-Rodríguez and Santos-Gago, 2016). The application which will manage, and transfer patient data needs to have top security management and be integrable to EMR. The creation an EMR integrated application therefore requires capabilities within API management for the implementation of a robust API system (Lerner, J., & Tirole, J, 2002).

7. Data Collection & Storage: The data will primarily be stored unstructured in its original format after collection from different smart dressing systems. No investment or effort is put into structuring the data, therefore is copyright not applicable and trade secret protection should instead be applied. Required capabilities to store the data is foremost servers and competencies to operate the servers, as the data collection expands, as the data points gathered increases, the capacity requirements of the servers' increase, i.e. the need of increased efficiency or number of servers (de Arriba-Pérez, Caeiro-Rodríguez and

Santos-Gago, 2016). As the servers will store sensitive medical and patient data, high security data management is required to ensure compliance with patient data regulations.

8. Data Structuring: Database(s) are created through the structuring and organizing of data into catalogues in a data warehouse (de Arriba-Pérez, Caeiro-Rodríguez and Santos-Gago, 2016). The catalogues can be based on value relationships, functions or operations. The structuring and storage of the database requires effort, i.e. investment. Ownership of the database can therefore be claimed as an investment has been made.

9. Analytics tools: Analyzing the data is essential to extract potential value offerings. Analytics tools are based on software and can be claimed by the same intellectual property protection discussed in section Software. It can also be protected by trade secrets if the company have all the data analyzing in-house. Analyzing the data will beside from analytics tools require wound expertise to interpret the measurement data, without wound expertise the data analysis will not be complete as the measurement data will not be put in to the right context. The analytic tools can also include machine learning software, the data included in the storage are key components for enabling machine learning as the data will improve the machine learning software (King et al., 2017).

10. Data package: The packaging of data is the last step to ensure value creation. The data package will be transferred either within the company to different departments, e.g. R&D department to product development, or to a customer, e.g. hospitals, government, insurance companies etc. There is an importance of wound care expertise in data management as data will become diverse as it will be collected from several smart dressing systems; treating different individuals with different complex difficulties of disease combinations and used on different geographical locations during different time intervals. Collecting and storing data might seem as a challenge, but the main challenge lies within finding and extracting the value from the data. According to Sean Martin, CTO of Cambridge Semantics, the main challenge is to take advantage of the opportunities of the data collection not the actual gathering of data (Martin, 2019). Knowledge of the market is required to create and package value offerings for respective actor on the market. This is an essential capability to ensure value extraction from the analyzed and packaged data. The packaging and transcription of the data make it subjected to copyright protection and in extension it can be protected by a contract or a license agreement between the company and the customer.

4.3.5 Data Regulations

Data regulations in the jurisdictions of interest, EU and US are presented and shortly compared in the section below.

4.3.5.1 The General Data Protection Regulation

The General Data Protection Regulation (GDPR) came into force in the EU on May 25, 2018. The data security regulation covers all personal data, not exclusively health information. The regulation is setting a standard for how to manage sensitive personal data and data concerning

health. GDPR regulation applies to all entities processing personal data regarding an EU citizen. The location of the company or the processors as such are therefore not relevant if the data processing include personal data from an individual which resides in EU, the GDPR regulation are applicable. The penalties for a breach of GDPR result in a fine between 20 Million Euros, as the lowest amount, or up to 4 percent of the annual turnover, if it exceeds 20 Million Euros. To be complaint to the GDPR regulation a consent which clearly state the purpose of the data processing in a clear and comprehensible manner, is needed from the data subjects. A provided consent should always be able to be retracted as easily by the data subject as it should be to provide the consent. In addition to the consent the entity must have taken necessary technical and organizational security measures when processing the data to be compliant with GDPR. The more sensitive data, the higher should the security measures be (Eugdpr, 2019).

In medical treatment, the processing of sensitive personal information is permitted if the purpose is either preventive or occupational medicine, medical diagnosis or treatment, provision of health care or social systems on the basis of EU or a member state law or contract with a health professional (Sivilli, F. 2019).

4.3.5.2 The US Health Insurance Portability and Accountability Act

The US Health Insurance Portability and Accountability Act of 1996 (HIPAA), governs data categorized as Protected Health Information (PHI). The scope is narrower than the data governed by GDPR, PHI is limited to any type of created information which can be used to identify an individual from their medical record, e.g. created, used or disposed information during a medical diagnosis or treatment or diagnosis. The PHI covers all identifiers for an individual which are used in medical treatments or in the billing process of the treatments, e.g. name, address, date of birth or death, age, date of admission or discharge, telephone numbers, social security number, biometric identifiers etc. The HIPAA ensure the data subject to obtain access to the data which are related to them and the entities safety measurements taken of the data. The two most important rules of the regulation, which demands extensive organizational involvement through management and structure of the PHI through high documentation, reporting and tracking, is the HIPAA Security Rule and HIPAA Privacy Rule (Group, C. 2019).

There are specific guidelines under the HIPAA Security Rule for how to manage PHI electronically. Electronic PHI (ePHI) is any protected health information that is created, stored or transferred electronically. It covers all media used to store data, e.g. computers, portable hard drives, smart phones or portable storage devices as USB or SD cards. The guidelines also govern the transmitting means of data, as email or file transfers using e.g. Wi-Fi, Ethernet, modem, DSL or cable network connections. The HIPAA Privacy Rule aim to ensure security and maintain the integrity of the stored or processed data and thereby require that all technical, administrative and physical safeguards have been taken by the company to ensure the confidentiality of the data (Group, C. 2019).

All companies working with storage are treated as Business Associated in the HIPAA regulation, this means that all entities need to have a Business Associate Agreement when dealing with data or data storage services, e.g. a cloud storage. The agreement should include which entity that is liable in the case of a data breach, and clearly state what administrative, physical and technical safeguards of the data, that will be maintained by each entity (HHS.gov, 2019).

In medical treatment, both the use and disclosure of protected health information is permitted for treatment purposes including provision, coordination or management of healthcare or health care services. The services can either be between health care providers, including consultations regarding a patient or referral of a patient to another health care provider, or between a healthcare care provider and a third party (Sivilli, F. 2019).

4.3.5.3 Comparison of Regulations

Both GDPR and HIPAA have a tight regulation around data related to personal health. HIPAA however only regulates the relationship between the covered entity of the data and their business associates which will be in contact with data in any form, e.g. law firms, billing companies and data storage companies, meanwhile GDPR applies to any organization which will process any EU residents personal data, e.g. an international company which offer a service to an individual in the EU will need to comply with the GDPR regulations. The permit needed from the data subject also differs between the regulations, the GDPR regulation demands explicit consent from the data subject including full transparency of the purpose and planned use of the data meanwhile the HIPAA regulation only regulates the use and dispose of the data not the requirement of explicit consent from the data subjects. If the requirements of security and privacy within the HIPAA regulation are met by the covered entity, the use and dispose of the PHI are allowed (Sivilli, F. 2019).

4.3.6 Summary of Phase III

Data creates new and more value offerings to patient, caregiver, insurance companies and hospitals, than what dressing as such would do. US is the focused market and they have other regulations than what applies in EU; which could imply easier to commercialize and faster time to market. The smart dressing and the IoT system can obtain patent protection as a system, even if some of the included components only can be subjected to copyright and trademark protection. This is seen in the Patent Landscape Analysis, were assignees have claimed product and system patents, the new combination of dressing materials and electronic components can through the achievement of new technical solutions be patented. The patented system can also in this case include the IoT platform, I.e. the technical solution the IoT platform provides to the smart dressing. There is a lack of product launches on the market and it can therefore not be established if the actors are planning to use other intellectual property protection than patents for their products.

4.4 Summary of Findings & Analysis

The majority of the internal intellectual assets that were considered of value for a smart dressing, were related to dressings: constructions, processes, materials, functions, compositions, etc.. It was concluded that there was a scarcity yet a few digital intellectual assets, but these were not as mature as the ones related to dressings. Most of the intellectual assets were conceived in-house and were protected by pending or granted patents, as they were patentable solutions.

The external environment presented a scarce patent landscape with only 28 patent families that were considered relevant. The technical scopes of the top assignees' patents were compiled into a technology tree that could be consider to represent the technical requirement specifics of a smart dressing. The technology tree covered dressing components, electronic components and data processing functions. What was unspecified in the technical scope is the wound characteristic to measure. The benchmark analysis showed that there is a challenge to obtain granted patents in the field of smart dressings, since the patent field is an intersection of two other dense patent fields, which lowers the threshold for being generic in claims and hence increase the risk of claim rejection.

In order to create value from a smart dressing, certain interactions between patients and society should be considered in order to build value propositions. The value creation from the smart dressing is what brings the leverage in a business setting and generated data is a large contributor to value creation. However, data requires certain capabilities and control mechanisms other than patents in order to be leveraged upon.

5. Discussion

Below follows a discussion on the findings and analysis from this research study. The discussion will concern the two sub research questions and the main research question. This will be followed by a discussion about accuracy of the method as well as surprising result and expected result.

5.1 Research Questions

The discussion will concern the two sub research questions, before the main question is discussed.

5.1.1 Sub Research Question 1

What mature, in-house developed and controllable intellectual assets can be claimed in a traditional MedTech company in the defined area of knowledge?

The IAM Framework & Resource-based theory

The IAM framework is adjusted for the identification of intellectual assets which can be turned into intellectual property and leveraged on to create intellectual capital by the entity. Intangible resources which cannot be documented and categorized in accordance with the IAM framework and fitted into an intellectual asset list, fall out of the scope of the study even if they can be essential for the value creation and success of the company. Therefore, it was necessary to consider resource-based theory as a complement to the IAM framework when investigating the opportunities of value creation, as there can be intangible resources which are key in the value creation process. The intangible resources identified in the study came to be essential as value creation enablers for smart dressings.

Dressing related IAs

The Medtech company possess mature and in-house developed intellectual assets within applied material science, which is applied in their core business activities. When the control parameter is considered, they are all controllable, but the level of control differ even though the majority of dressing related IAs are either categorized as trade secrets or pending patents. These IAs comprise creation processes, composition of material, technical features for a dressing, combinations of materials and constructions and dressing design. They cover extensive knowledge of dressing features, production and usage. The claiming process identified mature intellectual assets within combinations of dressing layers, to achieve different qualities and functions from the dressing. The identified IAs could provide for prerequisites for integrating new material or components into the dressing, since the profound knowledge could lower the threshold for such an integration, remove uncertainties of how the dressing features and material would be affected as well as mitigating risks of failure. This

could make the MedTech company more susceptible for new knowledge, which would be necessary if they choose to enter the field of smart dressings.

Digital related IAs

Mature intellectual assets have been identified of a database for a supportive systems to caregivers and digital service with digital identification tags within dressings. It can be stated that the Medtech company does not possess as much intellectual assets within digital technologies as within applied material science. The Medtech company are lacking in infrastructure and internal resources within digital wound care solutions, however it can be established that there is a desire to improve and complement their value proposition towards caregivers and patients, to keep up with the market trends of digital healthcare.

Technology Control

The aspect of *the Intellectual Asset List Evaluation,* the intellectual assets, the mature intellectual assets have received a high score in maturity (Technology Progression) and a high score in in-house development (Technology Independency), however have they received a medium score on controllability (Technology Control). This due to that they are treated as trade secret, pending patent or patent application and are therefore not a granted patent which would provide the highest score. The evaluation parameter Technology Control in phase I could be discussed whether the evaluation scores are reasonable, since the valuation of technology control depend on situation and business aim. In some cases, trade secret could be considered more valuable than patent protection; a process could potentially be preferable to protect with trade secrets, since it could be difficult to prove patent infringement on a manufacturing process. On the other hand, trade secrets do not provide any protection at all if it would be disclosed, hence, there is a need to have a managerial structure around trade secrets that prevent disclosure or leakage. The strength of a control position is related to the enforceability and value the business impact that enforceability could provide. The risk of losing control of the intellectual asset in relation to the possible value a strong control position will provide is important to consider when scoring a control position from low to high value and choosing how to protect the asset, through patent, trade secret or publication.

The Intellectual assets mentioned above are considered to be mature, in-house developed and controllable, as they are currently undisclosed or in a pending patent applications. Established is that the MedTech company possess IAs related to dressings that are both mature and the knowledge resides in-house. The digital related IAs are scarce, yet they seem to imply a willingness to extend into a digital field.

5.1.2 Sub Research Question 2

What are the technical gaps in the patent landscape in the defined area of knowledge?

Immature Market

Due to the lack of launched products and a non-existing market, as well as uncertainty of other actors' undisclosed pipeline and development, the most certain source of the maturity or progression of smart dressings should be patents. This, because of the publication of patent applications. Therefore, the patent landscape and indications of patenting trends in this study should be emphasized as the most certain forecast of the future outlook for smart dressings.

Two Integrated Fields of Knowledge

Established through the patent landscape analysis is that the field of smart dressing is an intersection of two mature patent fields that are dense, electronics and wound dressings. Therefore, a technical scope relating to only one of those fields is quite generic by itself, but in combination with the other one it could be considered patentable. The analysis of the prosecutions in the benchmark revealed that one common ground for rejecting patent claims was that the technology was too generic when a claim only referred to one of the patent fields. However, the patents that combined the two mature fields and provided definite wording were accepted in prosecution. To reach the conditions of patentability the claims need to show that the wound dressing has a new technical function or improved quality through the combinations of technical fields, to achieve the criteria of novelty and non-obviousness.

Knowledge Gap

There are indications of a knowledge gap in the patent landscape on which wound characteristics that have the highest relevance in wound healing. Wound progression and indicators that are essential for the best wound treatment performance have not been established. Patent applications within the area of knowledge show the difficulty in determining which wound characteristics that is of highest interest to measure in a smart dressing. The patent applications have broad claims which aims to include as many indicators, wound characteristics, as possible.

There will probably be a first generation of smart dressings, which are shown in Section *Product Launches and Publications and the Patent Landscape*, that will measure wound characteristics e.g. pH and temperature. The data gathered from these smart dressing systems could provide new and more information of wound progression and new parameters of wound healing, which today might be unknown. The first generation of smart dressings would in this manner help in filling the knowledge gap on wound treatments. The actor(s) who are able to establish the most crucial indicator(s) for wound healing will gain a first mover advantage in smart dressings and future connected wound care, in addition to store

valuable data for product development of other non-connected premium wound care dressings.

Uncertainty of Sensors
Another aspect to consider that is dependent on what wound characteristics to measure, is the construction and technical features of sensors, as the sensors would differ depending on wound characteristic. The sensor construction as such will affect the dressing components, hence there is a need to regard what type of sensor when integrating it into the dressing.

How the sensing components implicate the dressing functionality are uncertain. Sensor or electronic components which are positioned in the outer layer e.g. backing film of the dressing can affect the evaporation of exudate, in addition to the fluid transportation within wound dressing.

Contribution to Research
The initial definition of a smart dressing, that is presented in 1.2.6 the *Background*, included sensing devices integrated into a dressing, controlling devices connected to the dressing that receive signals or measurements, which are processed and analyzed to provide outputs (Tufts Now, 2019; Kassal et al., 2015; Pal et al., 2018; Brocklesby et al., 2013; Schrage, 2017).
What is known about dressings are that they are able to manage wound fluid, provide beneficial healing environments and possess other suitable features (Molnlycke, 2019). Connectivity will enable collection, communication and generation of data, which will be key within the healthcare sector in the future (Jabri, 2019). These statements are known and some even obvious, but what this study has shown is that there are parameters that are still unknown to the wound care industry; technical gaps in e.g. wound characteristics that indicate difficulties in obtaining granted patents. What this study contributes with and wants to emphasize is the gaps and the significance of uncertainties that creates. Furthermore, the importance of obtaining data regarding wound healing to fill in these knowledge gaps.

5.1.3 Main Research Question

What control positions are relevant to build to enable value creation in the defined area of knowledge?

To enable value creation in the defined area of knowledge there are several control positions relevant to build as different components and aspects of the technology are eligible for different intellectual property rights. In addition to the use of patents there could be an opportunity in the functions enabling management of the generated data since they are eligible for other intellectual property rights, such as copyright, trademark, design and trade secrets. The summary of the IPRs that should be taken into consideration are presented in *Table 15.*

Table 15. The IPRs and associated strategies that should be created in relation to the smart dressing are presented in this summarized table.

Smart dressing system components	**Description**	**Intellectual property right**	**IPR strategies**
Product (dressing + electronics)	*Product and system patent*	*Patents*	*Patent on conceptual level with definite wording to obtain a patent within the field and US provisional patent with a broader technical scope covering the system. From the provisional patent file a PCT application designating US and EP (and/or other jurisdictions of interest). As the US is the main market for the field of knowledge, the use of continuation in part patents is recommended for improvements and specification of designating wound characteristics and specifying other aspects of the product system e.g. functionalities enabled by implemented software. Take into consideration that data related claims need more specificity in the US.*
Readable and executable instructions for data processing	*Algorithms*	*Copyright*	*Excluding right upon creation of the works, therefore there is no need for registration.*
Unstructured data gathering	*All gathered but unstructured data retrieved from the smart dressing*	*Trade secret*	*Documentation of data to objectify the subject data, contractual control with secrecy and non-disclosure clauses with stakeholders*
Structured data collection	*Database*	*Copyright*	*Set structure, keep in mind the data regulation requirements of security and privacy measures.*
User interface	*Graphics*	*Design*	*Apply for US design patent to cover the US jurisdiction.*

Product	*Material patterns and product perception*	*Design*	*Apply for US design patent to cover the US jurisdiction for material patterns and product perception. Apply for design protection within EP for the product perception.*
Application	*Coloring and fonts, product and service name, slogans.*	*Trademark*	*Align with marketing strategy and match the value proposition.*

Patent Control

The use of patent protection is required for the commercial protection of the smart dressing as it contains part that are possible for a competitor to reverse engineer, therefore is a product and system patent including dressing components, electronic components and the software implemented functions recommended. In order to achieve a patentable subject matter the claims requires specific and definite wording of the application use.

Copyright Control

Established in the value chain is that data is a crucial part of extracting value from a smart dressing. The data will be processed and computed according to executable instructions (algorithms) to achieve an output. Copyright should be applied to manage the databases with the generated data, as the databases are valuable tools to store and manage the data. Since the value offerings to the society (personalized care, product development, etc) are dependent on how the data is understood and managed, it is crucial to structure it. The packaging and transcription of the data is therefore subjected to copyright protection.

Trademark Control

Within healthcare and medical technologies, it is important that the brand resonates quality and safety. The consumer, i.e. the caregiver or the patient, must trust the brand in order to choose to use it. If consumers are ensured through procurements with hospitals, the brand of the products need to resonate with the hospital's values (and budget). For data management trademarks will be more important than before to protect user interface of applications. Building a strong brand, investing time and effort in customer interaction will therefore be essential in reaching and keeping customers within the healthcare sector as well as enhancing the brand.

Design

The graphics of the user interface can be protected with design protection. Design protection can also be applied for the entire products or aspects, materials or components, of the product. In the United States one can acquire protection of material design which e.g. if the sensors are positioned in a certain pattern in which can visually be seen on the dressing it can be subjected to design protection.

Trade Secret & Data Regulation Compliance

For the data collection and storage trade secret should be applied. It could be discussed whether the generated data will be the largest value creator as shown in the value chain. As the servers will store sensitive medical and patient data, high security data management is required to ensure compliance with patient data regulations. The need for managing data with other control mechanisms will require that other aspects are taken into consideration, such as compliance to GDPR within EU, HIPAA in the US and cybersecurity requirements.

Data Drives Intellectual Capital

Referring back to *Contribution to Research* in 5.1.2, where it is stated that the technical gaps should be heavily emphasized, the technical gaps are further elaborated on here in relation to intellectual property strategies. The technical gaps should be the most crucial aspect to take into consideration when building the intellectual property strategy, as the gaps provide for an opportunity for any actor to leverage on. The technical gaps are related to data and generation of data, since wound characteristics to measure are pure data, the knowledge gap of what characteristic to measure requires data collection and in turn determines what sensor to integrate into dressings. Thus, digitizing wound dressings would enable collection of such data, and that data will eventually drive the development of either smart dressings that measure specific wound characteristics or other improved products that can leverage on the data collection indirectly. In other words, data drives the development and determines what intellectual assets that are crucial to conceive or acquire in order to create smart dressings, as well as how the intellectual assets should be protected through intellectual property rights in order to be leveraged upon and create intellectual capital.

5.2 Method Discussion

Patent Databases

In this study, two patent databases were used for searching for patent data and the accuracy of findings could of course be questioned. In most searches the two databases had very similar hits, yet it differed to some extent. It could be considered that Orbit Intelligence provided data that had been disclosed later in time, while there was a delay in Derwent Innovation with a few weeks. It could also be discussed whether all relevant patents within the area of knowledge and associated variables are to be found in the databases. This could constitute a source of error in the patent landscape.

IAM Framework

The theoretical framework that comprised the foundation for the methodology is, as mentioned earlier, adapted for an academic environment. However, this study is conducted in a business environment where the medical technology industry is in focus, it could therefore be discussed whether the IAM framework was suitable or not to apply. The authors believe

that the framework was suitable throughout the study, yet it had to be adjusted to fit the last phase. Since phase I and phase II analyzed the internal and external environment, there was not much of focus on the market or business. However, in phase III the business approach was added to the study, which required an adaptation of the framework. This was addressed by applying the tools related to value creation (*value chains, value proposition*) to leverage on the intellectual assets in relation to a smart dressing. The biggest obstacle with applying the framework has not to adjust it to a business setting, but rather how to communicate the framework to the MedTech company in a comprehensible manner. This was however mitigated by continuous updates on the progression of the thesis work and was considered valuable by them as well.

5.3 Findings Discussion

The findings that were considered expected as well as unexpected are presented in the sections below.

5.3.1 Expected Result

During the pre-study, the authors obtained a very brief perception of what a smart dressing could comprise and what components that would be essential. Based on that perception, it was expected that the relevant IPRs along with the subject of right would be similar to those that were considered relevant in the research and established in the Discussion. It was expected that data would be of significant value for patients, caregivers and the society. Also, the maturity in the patent landscape related to premium dressings (not smart) was expected. The maturity and claims of the IAs related to dressings within the MedTech company was also quite expected, since the MedTech company is considered as a big player in the industry.

5.3.2 Surprising Result

The complexity of wounds and wound care was not expected; the difficulties of determining what wound characteristics to measure (the knowledge gap) was surprising, since it was expected that the science of wounds was well known and fully understood by the stakeholders in the industry. The complexity of especially chronic wounds was a major surprise and to the authors' knowledge, there is no published research or literature that can explain the complexity. The reason depends on the large amount of parameters that affect the wound healing and the difficulty to determine what parameter that has the largest impact, hence making it difficult to determine what wound characteristic that would be a suitable measurement or marker. There is a lot of research going on within the industry, but right now the most valuable wound characteristic to measure is considered the "*holy grail*".

It was also surprising that the patent landscape was scarce and did not contain more than 28 highly relevant patent families, as it was assumed that the patent field would be more mature than what the analysis showed.

6. Conclusion

In this chapter, the study is summarized and the discussion about the research questions is concluded to provide concise answers, recommendations and key takeaways. An intellectual property strategy is provided along with reasoning on what the strategy is based on.

The study confirmed that traditional medical technology companies stand before a challenge to ensure continued value creation in new emerging markets of connected devices, due to several reasons such as the current market, patent landscape and technical gaps. Based on the findings and analysis throughout the study, intellectual property strategies were presented to provide recommendations on how to address the challenges.

The current situation of the market with no launched products and the patent landscape, with a scarcity of relevant patents as well as the majority with a pending legal status, could indicate commercial opportunities for a actor with wound care knowledge to fill in the technical gaps and obtain a market position. As of now, there are only a few patent grantings that potentially could block freedom to operate, however the true difficulties within the patent landscape are to combine claims of electronics and dressings in a patentable manner to avoid generic claims, the knowledge gap of wound characteristics and the uncertainty of sensors as a result of the knowledge gap. This difficulty could potentially be resolved by identifying the knowledge gap of what wound characteristics to measure in a wound dressing.

Due to the complexity in wounds, what parameter that affects wound healing the most is uncertain and hence what wound characteristic to measure is uncertain as well. Lacking knowledge of wound characteristics leads to an ignorance of what intellectual assets that would be crucial to have, thus, aggravating the development of a smart dressing. However, through digitizing dressings and enable data collection through monitoring, one can address the challenge by starting in the other end. Generating data, even if it is uncertain what data that is crucial, will eventually generate greater knowledge of wounds and characteristics, which can be applied to improve and develop the technology. Improvements and developments in the technology will generate even more, and hopefully more specific, data. Digitization of dressings is a key step to enable data generation and could be seen as a knowledge ecosystem, in which generation of data will generate more knowledge which will generate specific data. The data could be utilized to create smart dressings, but it is also valuable when developing or improving original products as well. Data could potentially provide for more radical than incremental improvements, but should be considered valuable for both radical and incremental purposes. This knowledge ecosystem could therefore be considered necessary to be a part of for future developments and for a possible entry on the market of smart dressing.

In additional to what value data generation brings to the development of wound care, the value to the customer is extracted from how the data is interpreted and requires wound and

wound care expertise in order to communicate the data. Knowing the customer needs and which data that has value for the product development is key when structuring the data. Expertise in wounds and wound care will also play a grand role in achieving algorithms for clinical decisions. Structuring the data is perhaps the most crucial part in the data management, which will require both an infrastructure around data, such as databases and tools for packaging data, and compliance to data regulations.

An intellectual property strategy could and should consider the value that is created from a smart dressing, both the dressing as such with physical components and software implemented functions, and the generated data. The balance in achieving novelty and claiming a broad technical scope for a smart dressing could be approached by filing patents with a focus on improvements and specifications of what wound characteristic to measure. Established is that when entering into data management of medical appliances, such as smart dressings, other IPRs are needed to be grasped. There are opportunities to create a control position for the functions that enable management of the generated data, since they are eligible for other intellectual property rights, such as copyright, trademark, design and trade secrets. However, to leverage on the opportunities there is a need for an intellectual property strategy where these are included. Concluded is also that the technical gaps are sought to be be solved in order to determine what intellectual assets that are crucial to conceive or acquire. These could potentially create new control positions which will require intellectual property strategies to be leveraged upon in order to create intellectual capital.

7. Continuation of Study

In this chapter, the authors' thoughts on the conducted study as well as considerations for future studies are presented. Delimitations are criticized and suggestions on how to proceed with the study are discussed.

The value chain was created on a high level and generalized from the result of the technical requirements of a smart dressing system. Due to the lack of products on the market the created value chain was created with a futuristic perspective. The accuracy and interchangeability of components in the value chain are therefore uncertain due to the futuristic parameter of the smart dressing system. The focus of the study has been on the technical requirements of the smart dressing, e.g. dressing and electronic components. The patent landscape of the area of knowledge laid the ground for the technical requirements of smart dressing in the value chain. The required data components were established through patented claims and articles on data management. Due to time constraints and the data management has not reached as detailed view as the technical components in the smart dressing, shown in the tech tree. The value chain could therefore lack in information of data components necessary to meet the technical requirements to ensure compliance with data regulation standards of security and privacy parameters. The capabilities listed are probably not the extensive list of capabilities needed, therefore the recommendation is to investigate the data management further. The control mechanisms listed should also be taken into further consideration as the knowledge of data management increases, as new capabilities or new functions gets listed, which currently are not added, the control mechanisms should be iterated. However, the control mechanism for other data management functions are likely to fall under the same categories currently listed, i.e copyright, software patent, trade secret and/or trademarks.

The continuation of this study should naturally be focused on the technical gaps, and just like mentioned in *Knowledge Gaps* (5.1.2) and *Data Drives Intellectual Capital* (5.1.3) there should be an aim for wound care industry actors to digitize to enable initiation of data gathering. An actor should enter into the knowledge ecosystem and investigate what intellectual assets that are needed as well as what control positions that could be created.

The generated data could provide for either development of smart dressings or improvements of non-connected products, the question is only how an actor acquires that data. The data can be acquired through generation of data from early smart dressings, or it can be bought from other actors. The availability of that data will depend on ownership of the data and how willing the data owners are to sell or license out their data. In addition to the data that is directly related to wound characteristics, other data will most likely be gathered as well. Patient health data that is not necessary but secondary will be collected, since no actor know what data that is crucial to collect yet. For instance, data related to behavior, such as eating

and sanitary habits, but also gender, age and other lifestyle factors, could be collected. Markers that are indicators for diseases will most likely be collected as well, which can contribute to research in other areas than wound care. What can be stated is that a lot of knowledge will be generated through the data. Even if an actor choose not to digitize, there is a need to investigate how to enter into the knowledge ecosystem and take part of what value that can be extracted from the generated data.

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9. Appendices

I. Interview templates
II. Search string constructions
III. Benchmark findings & analysis
IV. High & medium relevant patents
V. Top assignee analysis - Smith & Nephew
VI. Top assignee analysis - Elwha
VII. Top assignee analysis - Hill Rom Services

APPENDIX I

Interview templates

IDENTIFY RESEARCH RESULTS

1. What is the scope of your area of research/employment?
2. What are you (your research group) trying to achieve through your research area? What underlying needs and demands are you trying to meet?
3. How far have you progressed in your research process? What have you created? Have you created a concept, a prototype or launched a product/material?
4. What application should or can your research have?
5. What concrete research is now being conducted and will be conducted in the future within the area (prevention, chronic, acute, digital)?
6. How do we describe our research in project reports and in financing applications (objectification of the area)?
7. How do we describe our research results in documentation? For who or when are they presented?

<u>KNOW-HOW</u>

8. What are your teams' competencies in this field that are unique? Are there single individuals who carry this knowledge or is it clearly documented in instructions?
9. Are there processes that are kept secret within the company in development of the product/material?
10. Are there valuable technics that you believe are of importance?

<u>TECHNICAL ASPECTS</u>

11. How adaptable is the technology? Adjusted for specific product, e.g. functionalities, qualities, pressure/weight etc.
12. Are further developments of the technology currently made or is it only production of the material as such?

CLAIM RESEARCH VALUE

13. If we plot the internal research work on a timeline, how has our research evolved and how important is each knowledge asset?
14. How is the research area developing, what can we expect in terms of future significant results and how important are our knowledge assets in this process?

CLAIM UTILITY

15. What are the applications, what are the benefits and what does each knowledge asset contribute?
16. What alternative solutions, processes, etc., exists to your knowledge assets?
17. Are the assets unique and important in relation to competitive technologies?

18. What risks and negative consequences are associated with the utilization of our knowledge assets? Side-effects of the technology/material?
19. How extensive is the need for development before the knowledge asset can be utilized?
20. What preconditions/obstacles exist to be able to commercialize the knowledge assets
    a. Competencies, clinical trials etc.

CLAIM CONTROL POSITION

21. Regarding the knowledge assets, is it important and possible to argue that they include secrets and are subject to confidentiality?
22. Does utilizing knowledge assets require receiving permission from others?

APPENDIX II

Search String Constructions

Table 16a. The conducted patent searches with search string parameter, search string construction and patent findings, number of patents.

Search no.	Search string parameter	Search string construction
1	Abstract/Title/Claims	(dressing or bandage or patch or pad) and (wound or medical) and (measur* or monitor* or detect*)
	IPC-Any	A61
2	Abstract/Title/Claims	wound and (measur* or monitor* or detect*) and (sensor or sensing device or appurtenance or unit or circuit*) and (communicat* or transmit* or receiv* or remot* or portable or wireless)
	Claims	(dressing or bandage or patch or pad) and (wound or medical) not (electrocardiogram or heartbeat or pulse)
	IPC-Any	A61
3	Abstract/Title/Claims	wound and (measur* or monitor* or detect*) and (sensor or sensing device or appurtenance or unit or circuit*) and (communicat* or transmit* or receiv* or remot* or portable or wireless)
	Claims	(dressing or bandage or patch or pad) and (wound or medical) not (electrocardiogram or heartbeat or pulse) not negative pressure
	IPC-Any	A61
4	Abstract/Title/Claims	wound and (measur* or monitor* or detect*) and (sensor or sensing device or appurtenance or unit or circuit*) and (communicat* or transmit* or receiv* or remot* or portable or wireless)
	Claims	(dressing or bandage or patch or pad) and (wound or medical) not (electrocardiogram or heartbeat or pulse) not (negative pressure) not (bed* or incontinen*)
	IPC-Any	A61
5	Abstract/Title/Claims	wound and (measur* or monitor* or detect*) and (sensor or sensing device or appurtenance or unit or circuit*) and (communicat* or transmit* or receiv* or remot* or portable or wireless)
	Claims	(dressing or bandage or patch or pad) and (wound or medical) not (electrocardiogram or heartbeat or pulse) not (negative pressure) not (bed* or incontinen*) not surg*
	IPC-Any	A61
6	Abstract/Title/Claims	wound and (measur* or monitor* or detect*) and (sensor or sensing device or appurtenance or unit or circuit*) and (communicat* or transmit* or receiv* or remot* or portable or wireless)
	Claims	(dressing or bandage or patch or pad) and (wound or medical) not (electrocardiogram or heartbeat or pulse) not (negative pressure) not (bed* or incontinen*) not surg* not implant
	IPC-Any	A61
7	Abstract/Title/Claims	wound and (measur* or monitor* or detect*) and (sensor or sensing device or appurtenance or unit or circuit*) and (communicat* or transmit* or receiv* or remot* or portable or wireless)
	Claims	(dressing or bandage or patch or pad) and (wound or medical) not (electrocardio* or EEG or ECG or heartbeat or pulse) not negative pressure not (bed* or incontinen*) not surg* not implant*
	IPC-Any	A61
8	Abstract/Title/Claims	wound and (measur* or monitor* or detect* or diagno* or heal* or treat*) and (sensor or sensing device or appurtenance or unit or circuit*) and (communicat* or transmit* or receiv* or remot* or portable or wireless)
	Claims	(dressing or bandage or (patch near3 wound) or (pad near3 wound)) and (wound or medical) not electrocardio* not EEG not ECG not heartbeat not pulse not (negative pressure) not bed* not incontinen* not surg* not implant*
	IPC-Any	A61
9	Abstract/Title/Claims	wound and (measur* or monitor* or detect* or diagno* or heal* or treat*) and (sensor or sensing device or appurtenance or appartus or unit or circuit*) and (communicat* or transmit* or receiv* or remot* or portable or wireless)
	Claims	(dressing or bandage or (patch near5 wound) or (pad near5 wound)) and (wound or medical) not electrocardio* not EEG not ECG not heartbeat not pulse not cardi* not (negative pressure) not npwt not vacuum not suction not bed* not incontinen* not surg* not implant* not hair not diaper* not wipe*
	IPC-Any	A61
	Title	not (npwt or negative pressure)
	Application date	(2001-01-01) - (2019-04-08)
Search no.	Based on	Filter added
10	Search string 7	Granted
		Alive
		After 2015
		Manual screening of relevant patents between 2011-2015
11	Search string 9	Priority date from 2010
		Alive
		Manual screening of patents with relevant claims

Table 16b. The aim and reasoning of the construction of each search string, with included number of patent findings.

Search no.	Search name	Aim	Reasoning	No. of findings
1	Initial string	Test whether search scope is broad and get indication of the technical domain and technology	Dressing (or the like), wound (or the like) and measuring/monitoring/detecting are required basic words according to the initial definition of smart dressing, since the smart dressing is supposedly a dressing that can measure wound characteristics	15 586
2		Iterative search on the prior one, aims to narrow the search further and deepen the focus of the electronic components in a smart dressing	The prior search was too broad and unspecific, therefore it was considered necessary to add requirements to the search strings that were related to the definition of smart dressing, such as sensors or sensing device and communication; also, claiming a dressing and wound in the claims would help to sort out the medical technology appliances that do not relate to wound dressings (e.g. measurement of biometric data such as heartbeats)	1000
3		Iterative search on the prior one, aims to narrow the search further by adding "not negative pressure" in claims	Many patents include negative pressure technology, which is not within the scope of study but closely related to this study's definition of a smart dressing	680
4		Iterative search on the prior one, aims to narrow the search further by adding "not (bed* or incontinen*)" in claims	Many patents relate to incontinence and sensors in beds, which is not within the scope of study	558
5		Iterative search on the prior one, aims to narrow the search further by adding "not surg*" in claims	Many patents relate to surgical instruments, which is not within the scope of study	516
6		Iterative search on the prior one, aims to narrow the search further by adding "not implant" in claims	Many patents relate to implants, which is not within the scope of study	487
7	Base for bench-mark	Iterative search on the prior one, aims to narrow the search further by adding "not (...EEG or ECG)" in claims	There are still patents that include electrocardiogram and electroencephalography, but in abbreviated versions, which are not within the scope of study	464
8		Iterative search on the prior one, aims to narrow the search further by adding more specific wording to Abstract/title/claims and "near3 wound" in claims	Several patents relate to irrelevant fields, such as automotive, due to the wide meaning of pad and patch, hence the word wound is required to be claimed within three words from pad and patch	359
9	Smart Dressing	Iterative search on the prior one, aims to narrow the search further by adding more specific wording for both Abstract/title/claims and Claims, as well as adding a timeframe	There are still patents that relates to negative pressure, therefore the term is excluded in the title and more specific wording is needed; as well as some old patents show, therefore the time frame was added to exclude patents that were obsolete (since this area is young)	299
10	Bench-marking	Benchmarking the granted patents within a rather close patent landscape in order to obtain data of time to granted patent and data of rejection/approval of claims and claim specificity within the technology field	Due to the scarcity of granted patents within the field of technology, benchmarking the time to grant as well as the claim scope would be helpful in order to obtain a perception of requirements for a granted patent within the patent landscape	11 families
11	Smart Dressing - High Relevance	Sorting the highly relevant patents and organizing them according to their level of relevancy	The findings in search 9, "Smart Dressing", include the patents considered most relevant within the field of technology for a smart dressing, but some of them still cover technical scopes that are not relevant for the definition of smart dressing and those need to be filtered out manually	100 46 INPADOC families 53 DWPI families

APPENDIX III

Benchmark Findings & Analysis

Table 17. The benchmark findings and analysis are presented here. Publication numbers, the outcome of the prosecution of claims and time to grant are among others presented.

Title	Publication number	Total claims in application	Amended	Cancelled	Added	Application Date	Granted	Time to grant (Months)	Jurisdiction	Comment
Medical Tube Safety Device	US9788583 B1	20	0	0	0	5/26/2017	10/17/2017	5.0	US	All 20 claims approved, 3 independent claims. Alarm assembly, method and kit.
Intelligent humidity control burn and scald treatment system	CN105999 440B	10	5	2	0	7/4/2016	2/27/2018	22.0	CN	EP designated through PCT pending. The two cancelled claims were merged into the first claim, which is the only independent claim (hence a broader independent claim)
Wearable thermometer patch comprising a temperature sensor array	US1008052 4	20	4	0	0	12/20/2017	9/25/2018	9.00	US	Rejection due to indefinite wording in claims, unpatentable over prior art. The wording in the independent claims was amended to be more specified, which further approved the dependent claims to the independent claim in question.
Sensors, interfaces and sensor systems for data collection and integrated remote monitoring of conditions at or near body surfaces	US8925392 B2	23	12	13	12	1/30/2012	1/6/2015	36.00	US	Indefinite wording (and/or), prior art and obvious.
Integrated surface stimulation device for wound therapy and	US1020170 3B2	12	6	5	5	3/31/2015	2/12/2019	48.99	US	7 withdrawn claims. Rejection due to too abstract and

infection control										generic ideas, ideas are convention al for the industry; governmen al patent (easier to obtain granting?)
Energy-deli very system and method for controlling blood loss from wounds	US9168178 B2	22	6	6	1	5/22/2012	10/27/2015	41.00	US	Obvious, rejected claims due to not allowed wording - objected - needs to be rewritten in an independen t form.
Dressings and methods for treating a tissue site on a patient	US9492325 B2	41	1	41	24	4/14/20122	11/15/2016	67.00	US	Independen t claims are amended to be more specific. Rejected and objected claims due to prior art.
Dressing for wound treatment	US1010526 5 B2	93	8	56	0	2/11/2014	10/23/2018 EP granted 16/05/2018)	56.00	US, CH, EP, DE, GB, HK, IE, JP, AU	Indistinct subject matter described, unclear claims, rejected due to prior art as well - resulting in rejecting in a large amount of claims
Systems and methods for wound healing	US1002227 4B1	33	0	33	20	6/2/2015	7/17/2018	37.00	US	All claims were cancelled since they related to a method of improving wound healing, but the amended claims relate to a system.
Wearable therapeutic device	US9008801 B1	31	All claims	5	6	11/24/2011	4/14/2015	41.00	US	Claims rejected due to non-statutor y subject matter - an abstract idea therefore rejected as ineligible subject matter. Other claims rejected due to prior art. first original independen t claim, 28-31 which relate to the method of providing a therapeutic device. Providing was not ok

										subject matter.
Device for monitoring blood leakage from wounds	US9854980 B2	11	6	5	5	4/2/2015	1/2/2018 (EP pending)	33.00	SE, US, AU, CA, JP, CN	The claims where rejected due to indefinite and not distinct wording, but also due to invention directed to human organism
Time to grant medium (months):								36.00		

APPENDIX IV

High & medium relevant patents

Table 18. The patents that are either highly or medium relevant (search string 11) are presented in the table. The patents that are considered highly relevant are marked with "High" in the column of Relevance, while the medium relevant patents are marked with "Medium".

Publication Number	Title (English)	Assignee - Original	Priority Date	INPADOC Family Members	Comments	Relevance	Legal status
WO2019063488A2	SENSOR POSITIONING AND OPTICAL SENSING FOR SENSOR ENABLED WOUND THERAPY DRESSINGS AND SYSTEMS	SMITH & NEPHEW PLC	2017-09-26 | 2017-11-15		Very relevant! Relates to positioning of sensors in a dressing	High	PENDING
US20190083025A1	DEVICES, SYSTEMS, AND METHODS FOR MONITORING WOUNDS	Hill-Rom Services Inc.	2017-09-12	US20190083025A1 | EP3454340A1	Does not output a recommendation, but only alerts an indicative value.	High	PENDING
WO2019048626A1	ELECTROSTATIC DISCHARGE PROTECTION FOR SENSORS IN WOUND THERAPY	SMITH & NEPHEW PLC	2017-09-10 | 2018-03-28	WO2019048626A1 | GB201804971D0	Very relevant! Relates to protecting sensors in a dressing from electrostatic discharge	High	PENDING
WO2019048638A1	SENSOR ENABLED WOUND THERAPY DRESSINGS AND SYSTEMS IMPLEMENTING CYBERSECURITY	SMITH & NEPHEW PLC	2017-09-10 | 2017-09-11 | 2017-11-15 | 2017-11-15	WO2019048638A1 | GB201718870D0	Very relevant! Relates to management and processing of wound data transmitted from sensor	High	PENDING
WO2019048624A1	SYSTEMS AND METHODS FOR INSPECTION OF ENCAPSULATION AND COMPONENTS IN SENSOR EQUIPPED WOUND DRESSINGS	SMITH & NEPHEW PLC	2017-09-10	WO2019048624A1	Very relevant! Relates to coating of the flexible circuit board or sensor sheet and inspection of coating	High	PENDING
EP3449882A1	SYSTEMS FOR MONITORING WOUNDS AND WOUND DRESSING	Hill-Rom Services Inc.	2017-08-30 | 2018-07-27	EP3449882A1 | US20190060126A1	Data focus: receiving, analyzing and managing, output based on	High	PENDING

	STATUS AND SYSTEMS FOR PROTECTING WOUNDS				data. Also: there is an output!!		
WO2019020666A1	RESTRICTION OF SENSOR-MONITORED REGION FOR SENSOR-ENABLED WOUND DRESSINGS	SMITH & NEPHEW PLC	2017-07-25 | 2018-06-01	WO2019020666A1 | GB201809007D0	Very relevant! Relates to restricting the sensor to read in the right direction	High	PENDING
WO2019020551A1	SKEWING PADS FOR IMPEDANCE MEASUREMENT	SMITH & NEPHEW PLC	2017-07-25 | 2018-03-05	WO2019020551A1 | GB201803496D0	Very relevant	High	PENDING
WO2018169734A1	SMART BANDAGE	CALIFORNIA INSTITUTE OF TECHNOLOGY	2017-03-15	WO2018169734A1 | US20180267012A1	Focus on the sensor components and the function of it, as well as it communicates wirelessly	High	PENDING
WO2018115461A1	A DRESSING SYSTEM	FLEMING MEDICAL LTD. | UNIVERSITY COLLEGE CORK - NATIONAL UNIVERSITY OF IRELAND CORK	2016-12-22	WO2018115461A1	"Management of data and big data. Regards the dressing, the sensors integrated in dressing and that it should wirelessly communicate with clinicians. Dependent claims include different type of sensors, how they should be powered and positioned. "	High	PENDING
US20180049923A1	DRESSING APPARATUS AND METHODS FOR FACILITATING HEALING		2016-08-16	US20180049923A1 | CA2950967A1	Indicates infections and alerts if too moist, too high pressure, etc	High	PENDING
US20170347940A1	SMART BANDAGE	Occammd LLC	2016-06-06	US20170347940A1	Data management included. Relates to a dressing system where communication device can output alerts based on signals from sensors	High	PENDING
US20170202711A1	WOUND TREATMENT SYSTEM AND METHOD	CERNASOV Andrei | CERNASOV Nathalie | CERNASOV Andre	2016-01-19	US20170202711A1	Bandage which can be opened and several sensors can be plugged into the bandage.	High	PENDING

US20180055359A1	WOUND DRESSING WITH REUSABLE ELECTRONICS FOR WIRELESS MONITORING	KING ABDULLAH UNIVERSITY OF SCIENCE AND TECHNOLOGY	2015-04-15 | 2016-04-15	US20180055359A1 | EP3283029A1 | WO2016166731A1	Blood sensor electrode, a pH level sensing electrode, a blood glucose level sensing electrode, a pressure sensing electrode, and combinations thereof.	High	PENDING
US20160228049A1	WOUND MONITORING	NXP B.V.	2015-02-06	US20160228049A1 | CN105852802A | EP3054389A2 | EP3054389A3	Using NFC circuit.	High	PENDING
EP2836269A1	METHOD AND SYSTEM FOR MONITORING A WOUND DRESSINGS	Elwha LLC	2012-04-12 | 2012-04-12 | 2012-06-08 | 2013-03-12 | 2013-04-10	EP2836269A1 | EP2836177A1 | EP2836177A4 | EP2836269A4 | US10130518B2 | US10158928B2 | US10226212B2 | US20130271278A1 | US20130274563A1 | US20130274629A1 | US20130274630A1 | US20140298927A1 | US20140298928A1 | US20150208961A1 | US20150264452A1 | US20190082242A1 | US9024751B2 | US9084530B2 | US9451340B2 | US9510781B2 | WO2013155193A1 | WO2013155199A1		High	GRANTED
US20140298928A1	WOUND DRESSING MONITORING SYSTEMS INCLUDING APPURTENANCES FOR WOUND DRESSINGS	Elwha LLC	2012-04-12 | 2012-04-12	US20140298928A1 | EP2836177A1 | EP2836177A4 | EP2836269A1 | EP2836269A4 | US10130518B2 | US10158928B2 | US10226212B2 | US20130271278A1 | US20130274563A1 | US20130274629A1 | US20130274630A1 | US20140298927A1 | US20150208961A1 | US20150264452A1 | US20190082242A1 | US9024751B2 | US9084530B2 | US9451340B2 | US9510781B2 | WO2013155193A1 | WO2013155199A1	Data management. Relates to monitor the dressing rather than the wound, but it is still a dressing with sensors that will transmit data that will be analyzed and a signal will be outputted as a response.	High	GRANTED

US20190082242A1	APPURTENANCES FOR REPORTING INFORMATION REGARDING WOUND DRESSINGS	Elwha LLC	2012-04-12	US20190082242A1 | EP2836177A1 | EP2836177A4 | EP2836269A1 | EP2836269A4 | US10130518B2 | US10158928B2 | US10226212B2 | US20130271278A1 | US20130274563A1 | US20130274629A1 | US20130274630A1 | US20140298927A1 | US20140298928A1 | US20150208961A1 | US20150264452A1 | US9024751B2 | US9084530B2 | US9451340B2 | US9510781B2 | WO2013155193A1 | WO2013155199A1		High	GRANTED
EP2809232B1	SENSORS, INTERFACES AND SENSOR SYSTEMS FOR DATA COLLECTION AND INTEGRATED REMOTE MONITORING OF CONDITIONS AT OR NEAR BODY SURFACES	Sensoria Inc.	2012-01-30 | 2012-12-31 | 2013-01-29	EP2809232B1 | AU2013215287A1 | CA2862732A1 | CN104219999A | EP2809232A2 | EP2809232A4 | ES2618728T3 | HK1204898A1 | JP06272238B2 | JP2015509028A | KR2014123977A | US20130192071A1 | US20150177080A1 | US20150182843A1 | US20160206242A1 | US20160367191A1 | US20170086519A1 | US20180003579A1 | US20190094088A1 | US8925392B2 | WO2013116242A2 | WO2013116242A3 | WO2015017712A1 | WO2015103442A1 | WO2015175838A1 | WO2016109744A1 | WO2017120063A1 | WO2017185050A1	Could potentially aim for prevention of pressure ulcers on feet; does also cover data collection.	High	GRANTED

US10130518B2	Appurtenances including sensors for reporting information regarding wound dressings	ELWHA LLC	2012-04-12 | 2012-04-12	US10130518B2 | EP2836177A1 | EP2836177A4 | EP2836269A1 | EP2836269A4 | US10158928B2 | US10226212B2 | US20130271278A1 | US20130274563A1 | US20130274629A1 | US20130274630A1 | US20140298927A1 | US20140298928A1 | US20150208961A1 | US20150264452A1 | US20190082242A1 | US9024751B2 | US9084530B2 | US9451340B2 | US9510781B2 | WO2013155193A1 | WO2013155199A1	Data, continuously transmission are saved in a memory, can be used as a monitoring trajectory. Not mentioning any output, no healing only monitoring. This is a combination with other Elwha patents.	High	GRANTED
EP3034054A1	Wound dressing with a sensor and method for manufacturing the same	Absorbest AB	2014-12-16	EP3034054A1 | US20160166438A1	Indicate: moisture, a moisture level, a pressure, a temperature, and a pH level.	High	PENDING
EP3167008A2	IMPROVEMENTS IN AND RELATING TO DEVICES	Smith & Nephew PLC	2014-07-10 | 2014-07-10 | 2014-07-10 | 2015-04-16 | 2015-04-16 | 2015-04-16 | 2015-07-03	EP3167008A2 | CA2954465A1 | CA2954467A1 | CN106687150A | CN106687801A | EP3167007A1 | GB201412332D0 | GB201412345D0 | GB201412427D0 | GB201506451D0 | GB201506453D0 | GB201506463D0 | JP2017523280A | JP2017526907A | US20170183705A1 | US20170234802A1 | WO2016005288A1 | WO2016012219A2 | WO2016012219A3 | WO2016012219A9	Indicator can be a pH sensor.	High	PENDING
US20190008694A1	SYSTEMS AND METHODS FOR WOUND HEALING	Piotrowski Zdzislaw Harry | Piotrowski Adam E. | Piotrowski Anna A.	2014-06-02 | 2015-06-02	US20190008694A1 | US10022274B1	Granted as US10022274 B1. More narrow scope.	High	GRANTED

US20150177080A1	SENSORS, INTERFACES AND SENSOR SYSTEMS FOR DATA COLLECTION AND INTEGRATED REMOTE MONITORING OF CONDITIONS AT OR NEAR BODY SURFACES	Sensoria Inc.	2012-01-30 | 2012-12-31 | 2013-01-29	US20150177080A1 | AU2013215287A1 | CA2862732A1 | CN104219999A | EP2809232A2 | EP2809232A4 | EP2809232B1 | ES2618728T3 | HK1204898A1 | JP06272238B2 | JP2015509028A | KR2014123977A | US20130192071A1 | US20150182843A1 | US20160206242A1 | US20160367191A1 | US20170086519A1 | US20180003579A1 | US20190094088A1 | US8925392B2 | WO2013116242A2 | WO2013116242A3 | WO2015017712A1 | WO2015103442A1 | WO2015175838A1 | WO2016109744A1 | WO2017120063A1 | WO2017185050A1		High	GRANTED
US10105265B2	Dressing for wound treatment	ELECTROCHEMICAL OXYGEN CONCEPTS INC.	2013-02-12 | 2014-02-11	US10105265B2 | AU2014216501A1 | AU2014216501A8 | AU2014216501B2 | AU2014216501B8 | CA2900771A1 | CN105073077A | EP2956101A2 | EP2956101A4 | EP2956101B1 | HK1219221A1 | JP2016511029A | US20160000611A1 | WO2014126888A2 | WO2014126888A3 | WO2014126888A8	Provides an output	High	GRANTED
US20180369582A9	Integrated Surface Stimulation Device for Wound Therapy and Infection Control	The United States Government as represented by the Department of Veterans Affairs | Case Western Reserve University	2012-02-02 | 2013-01-18 | 2014-06-05	"US20180369582A9 | US10201703B2 | US20140324120A1 | US20160287868A1 | US9320907B2 | WO2013116013A1 | US20190111256A1"	"Is a subpart to a smart dressing. CONTINUATION US20190111256A1 - new application claiming a method (published 2019-04-21)"	High	GRANTED
US20180357763A1	SYSTEM AND METHOD FOR ASSESSING WOUND	WORCESTER POLYTECHNIC INSTITUTE	2013-10-30 | 2013-11-01 | 2014-10-30 | 2015-08-18 |	US20180357763A1 | US10032287B2 | US20150119721A1 | US20170076446A1 | US20180330522A1 | US9996925B2 | WO2015066297A1		High	GRANTED

			2016-08-15 | 2016-08-17				
WO2018161005A1	ENERGY GENERATION FROM FABRIC ELECTROCHEMISTRY	OHIO STATE INNOVATION FOUNDATION	2017-03-03	WO2018161005A1	Relates to energy generation in a fabric with sensors, but that it is a dressing is in dependent claims; no focus on measuring wound characteristics	Medium	PENDING
EP3439598A1	PRESSURE SENSOR	SFH Oxford Ltd.	2016-04-05 | 2017-04-05	EP3439598A1 | CA3020676A1 | CN109152666A | WO2017174984A1	Relates to pressure measurement and describes the construction of the sensor dressing mostly	Medium	PENDING
US20180207301A1	ELECTROCHEMICAL REDUCTION OR PREVENTION OF INFECTIONS	WASHINGTON STATE UNIVERSITY	2015-07-14 | 2016-03-22 | 2016-07-14	US20180207301A1 | EP3322451A1 | EP3322451A4 | WO2017011635A1	No data gathering but an output in voltage change after a sensor reading.	Medium	PENDING
US9433711B2	Dressings, systems, and methods for treating a wound on a patient's limb employing liquid control	KCI Licensing Inc.	2011-11-11	US9433711B2 | AU2012335000A1 | AU2012335000B2 | AU2018200097A1 | AU2018200097B2 | CA2850958A1 | CN103889377A | CN103889377B | EP2775974A1 | EP2775974B1 | JP06158202B2 | JP2014533182A | US10179196B2 | US20130123722A1 | US20160339155A1 | WO2013071253A1	Control system activating a pressure source, limited to liquid control.	Medium	GRANTED
WO2012078556A2	WOUND HEALING APPARATUS FOR PROMOTING GRANULATION AND EPITHELIALISATION AT A TISSUE SITE	KCI LICENSING INC. | ROBINSON Timothy Mark | LOCKE Christopher Brian | COULTHARD Richard Daniel John	2010-12-07	WO2012078556A2 | TW201233373A | US20120143113A1 | US20120143114A1 | US20160220742A1 | US20160346134A1 | US9352075B2 | US9440010B2 | WO2012078556A3 | WO2012078561A2 | WO2012078561A3	Reduced pressure but with an alarm system; - alarm when a drape needs to be changed.	Medium	GRANTED

US10121070B2	Video monitoring system	Stryker Corporation	2010-09-23 | 2011-09-23 | 2014-12-22	US10121070B2 | EP2619724A2 | US20120075464A1 | US20150077534A1 | US20150109442A1 | US20160065909A1 | US20180068179A1 | US20180227547A1 | US9204823B2 | US9934427B2 | WO2012040554A2 | WO2012040554A3	Relates to compliance	Medium	GRANTED
US20130085462A1	ELECTROKINETIC PUMP BASED WOUND TREATMENT SYSTEM AND METHODS	NIP Kenneth Kei-ho | Strohmann Jessica L. | Shieh Doris Sun-Chia | Mai Tuan Quoc | Lewis Robert B. | Hencken Kenneth R. | Bryant Craig S.	2011-09-30 | 2011-12-16	US20130085462A1 | CA2851495A1 | CN104114136A | EP2760406A2 | EP2760406A4 | JP2015501170A | WO2013049834A2 | WO2013049834A3	"Relates to a fluid circuit "	Medium	PENDING
US20160331257A1	Electrical Patch for Physiological Measurements	Baumann Eric | Homayoun Habib | Korzinov Lev | Churchville David	2015-05-15 | 2016-03-16 | 2016-03-16 | 2016-03-21	US20160331257A1	Physiological measurements, not directed specifically towards wounds.	Medium	PENDING
US20130018112A1	CELLULOSE NANOPARTICLE AEROGELS, HYDROGELS AND ORGANOGELS	University of Nottingham	2009-09-14 | 2010-09-14	US20130018112A1 | CN102666669A | EP2478039A1 | GB200916031D0 | WO2011030170A1		Medium	PENDING
CN105250075A	SYSTEM AND METHOD FOR MONITORING EXTENT OF WOUND HEALING	SHENZHEN QIANHAIYILAO SCIENCE AND TECHNOLOGY CO. LTD.	2015-09-12	CN105250075A	"No direct output but give a reminder to user to change the dressing, not indicated how the healing degree of wounds are determined. Includes monitoring and a display device, however undefined claims. "	Medium	PENDING
US20180140817A1	BANDAGE WITH MICRONEEDLES FOR ANTIMICROBIAL DELIVERY AND FLUID ABSORPTION FROM A WOUND	SPECTOR Donald	2010-03-04 | 2010-04-01 | 2013-03-12 | 2015-03-04 | 2015-04-22 |	US20180140817A1 | US20110245745A1 | US20130204171A1 | US20150223988A1 | US8419668B2	A moisture sensor, displays a message when a moisture exceeds a permitted level.	Medium	GRANTED

			2017-10-16				
US20140228686A1	EXTRAVASATION AND INFILTRATION DETECTION DEVICE	Bouton Chad E.	2011-09-02 | 2011-09-02 | 2011-09-02 | 2012-08-29	US20140228686A1 | EP2750594A1 | EP2750595A1 | US20140371588A1 | US20150011876A1 | WO2013033162A1 | WO2013033166A1 | WO2013033174A1	Processor and receiver and wireless interface. No provided output to wound. Only measure fluid level changes.	Medium	PENDING
US10028676B2	Hyperspectral technology for assessing and treating diabetic foot and tissue disease	Hypermed Imaging Inc.	2005-04-04 | 2005-08-19 | 2006-03-27 | 2006-04-04 | 2006-08-21	US10028676B2 | CA2604829A1 | CA2604829C | CA2631564A1 | CA2656016A1 | CA2656016C | CA2947613A1 | CA3031088A1 | US10117582B2 | US20060247514A1 | US20070016079A1 | US20070038042A1 | US20070232930A1 | US20070249913A1 | US20130131517A1 | US20130137949A1 | US20130245455A1 | US20140012135A1 | US20140012140A1 | US20140112559A1 | US20150133754A1 | US20160220119A1 | US20180116526A1 | US20190059787A1 | US8224425B2 | US8320996B2 | US8374682B2 | US8548570B2 | US8655433B2 | US8971984B2 | US9204805B2 | US9345428B2 | US9795303B2 | WO2006058306A2 | WO2006058306A3 | WO2006107947A2 | WO2006107947A3 | WO2007022508A2 | WO2007022508A3	Data collection. Relevant for prevention and data collection of tissue	Medium	GRANTED

US10226610B2	Apparatus and methods for controlling tissue oxygenation for wound healing and promoting tissue viability	ELECTROCHEMICAL OXYGEN CONCEPTS INC.	2007-10-26 | 2008-10-24 | 2009-04-23 | 2010-11-11	US10226610B2 | AU2009307077A1 | AU2009307077B2 | AU2016366165A1 | CA2681155A1 | CA2681155C | CA3005473A1 | CN102202618A | CN102202618B | CN108367139A | EP2340001A1 | EP2340001A4 | EP3386581A1 | JP05579188B2 | JP2012506292A | JP2018536528A | US20090112170A1 | US20110054388A1 | US20160082238A1 | US20170296392A1 | US8287506B2 | US9730838B2 | WO2010047732A1 | WO2017100320A1	Mentions a microprocessor which can receive user input data. The microprocessor regulated the oxygen flow rate delivered to the damaged tissue using any combination of temperature data, pressure data and user input data. Relevant for providing an output and data collection of tissue	Medium	GRANTED
US8905983B2	System and method for utilizing exudate with a reduced pressure treatment system to generate electricity	KCI Licensing Inc. | Locke Christopher Brian | Coulthard Richard Daniel John	2010-04-22	US8905983B2 | AU2011242623A1 | CA2792946A1 | CN102811761A | EP2560725A1 | JP2013529357A | TW201141564A | US20110264062A1 | WO2011133844A1	Related to a sensor (ph, pressure); data is collected.	Medium	GRANTED

US9023002B2	Reduced-pressure interfaces, systems, and methods employing a Coanda device	Robinson Timothy Mark | Locke Christopher Brian	2011-08-31 | 2011-08-31 | 2011-08-31 | 2011-08-31	US9023002B2 | AU2011239545A1 | AU2011239545B2 | AU2011239552A1 | AU2011239552B2 | AU2011239573A1 | AU2011239573B2 | AU2011256214A1 | AU2011256214B2 | AU2011256217A1 | AU2011256217B2 | AU2011256218A1 | AU2011256218B2 | AU2011256220A1 | AU2012243056A1 | AU2012243056B2 | AU2012294897A1 | AU2012294897B2 | AU2012294897C1 | AU2012302238A1 | AU2012302238B2 | CA2791381A1 | CA2795232A1 | CA2795233A1 | CA2795233C | CA2795234A1 | CA2795234C | CA2796893A1 | CA2796893C | CA2800987A1 | CA2800987C | CA2800993A1 | CA2800993C | CA2827086A1 | CA2827124A1 | CA2827124C | CA2844924A1 | CN102844055A | CN102844055B | CN102869406A | CN102883756A | CN102883756B | CN102883771A | CN102883771B | CN102883772A | CN102883772B | CN102933181A | CN102933181B | CN102939116A | CN102939116B | CN103402469A | CN103402469B | CN103635165A | CN103635165B | CN103764187A | CN103764187B | EP2558045A1 | EP2558045B1 | EP2558139A1 | EP2558139B1 | EP2558140A1 | EP2558140B1 | EP2571544A1 | EP2571544B1 | EP2571544B2 | EP2571557A1 | EP2571557B1 | EP2571558A2 |		Medium	GRANTED

				EP2571558B1 | EP2571559A1 | EP2571559B1 | EP2666489A2 | EP2666489A3 | EP2666489B1 | EP2696825A1 | EP2696826A1 | EP2696826B1 | EP2750728A1 | EP2750728B1 | EP2944298A1 | EP2944298B1 | EP3009154A2 | EP3009154A3 | EP3009154B1 | EP3072542A2 | EP3072542A3 | EP3085407A1 | EP3192540A2 | EP3192540A3 | EP3284489A1 | EP3332758A1 | JP05778277B2 | JP05850469B2 | JP05850535B2 | JP05877545B2 | JP05939646B2 | JP06075651B2 | JP06083762B2 | JP06103657B2 | JP06347950B2 | JP06430548B2 | JP2013524887A | JP2013526372A | JP2013526373A | JP2013526942A | JP2013526943A | JP2014511109A | JP2014511110A | JP2014514089A | JP2014516294A | JP2014525318A | JP2015211870A | JP2017099915A | TW201141448A | TW201141562A | TW201143822A | TW201200178A | TW201200179A | TW201200180A | TW201210644A | US10085891B2 | US10245358B2 | US20110257572A1 | US20110257612A1 | US20110257613A1 | US20110288510A1 | US20110288511A1 | US20110288512A1 | US20110288535A1 | US20130053795A1 | US20130053796A1 | US20130053797A1 | US20130053798A1 | US20130053799A1 | US20130186826A1 | US20130190707A1 | US20130317406A1 | US20140066867A1 | US20140121617A1 |		

				US20140200534A1 | US20140350498A1 | US20150230990A1 | US20160058925A1 | US20170000989A1 | US20170080133A1 | US20180125718A1 | US20180243696A1 | US20190015256A1 | US8403902B2 | US8409160B2 | US8604265B2 | US8641693B2 | US8702665B2 | US8821458B2 | US9028459B2 | US9295586B2 | US9314377B2 | US9345821B2 | US9433712B2 | US9446176B2 | US9474836B2 | US9492325B2 | US9877873B2 | US9975091B2 | WO2011130542A1 | WO2011130549A1 | WO2011130570A1 | WO2011146529A1 | WO2011146532A2 | WO2011146532A3 | WO2011146533A1 | WO2011146535A1 | WO2012141999A1 | WO2012142001A1 | WO2012142002A1 | WO2013022498A1 | WO2013032539A1			
US20160106577A1	Thermal Self Regulating Wound Dressing	Moreshead Wylie	2010-12-07 | 2012-07-09	US20160106577A1 | AT467361T | AU2006250080A1 | CA2632878A1 | CN100558265C | CN101198262A | DE602006014277D1 | EP1915065A2 | EP1915065B1 | JP2008542063A | US20060280948A1 | US20080109941A1 | US20090151043A1 | US20110127248A1 | US20110128686A1 | US20110128726A1 | US20110130813A1 | US20120311885A1 | US7494945B2 | WO2006127769A2 | WO2006127769A3 | WO2006127769B1 | WO2009089378A1	No data but an action from an thermal indication. thermal action without providing information	Medium	GRANTED

US20120190956A1	WOUND DRESSING WITH IMPEDANCE SENSOR	UNIVERSITY OF STRATHCLYDE	2009-07-10 | 2010-07-09	US20120190956A1 | CA2767292A1 | CN102481112A | CN102481112B | EP2451349A1 | EP2451349B1 | ES2584312T3 | GB200912009D0 | JP2012532642A | WO2011004165A1	Relates to wound sensor, can have a dependency on this patent in other solutions. No described output however.	Medium	GRANTED
WO2017222748A1	MEDICAL TUBE SAFETY DEVICE	INNOVATIONS UNLIMITED LLC.	2016-06-20	WO2017222748A1 | CA3028963A1 | US9788583B1	Relates to sensors in dressing, but the application is off	Medium	GRANTED
EP2565630B1	Dye-doped gelatin-coated optical fibers for in situ monitoring of protease activity in wounds	CSEM Centre Suisse d'Electronique et de Microtechnique SA	2011-09-02	EP2565630B1 | EP2565630A1	Only indication and monitoring, no output to wound	Medium	GRANTED

APPENDIX V

Top assignee analysis - Smith & Nephew

Table 19. The patent filings from Smith & Nephew in the High Relevance Patent Landscape are presented by patent publication number, related applications and designated states, title, legal status, application and publication dates and a summary of the technical scope from the patent claims.

Publication Application number	Applications and designated states	Title	Legal Status	Application date	Publication date	Technical scope
WO201920551	US provisional patent GB patent application (pending) PCT application designating EP	Skewing pads for impedance measurement	Pending	2018-07-23	2019-01-31	Electrical signals from sensors in a dressing. Product/system and method – describes the apparatus of wound monitoring as a product, but also the method of usage (application) and the method of conducting what the apparatus does (instead of an apparatus of determining wound characteristics it's a method of determining wound characteristics). Indicators: Biological impedance.
WO201963488	US provisional patent GB patent application (pending) PCT application designating EP	Sensor positioning and optical sensing for sensor enabled wound therapy dressings and systems	Pending	2018-09-24	2019-04-04	Positioning of sensors. Product/system and method – describes a product (a wound dressing) and a system, but also the method of operations and/or usage of product/system (not method of manufacturing).
WO201948638	Cross-related to three US provisional patents. GB patent application (pending) PCT application designating EP	Sensor enabled wound therapy dressings and systems implementing cybersecurity	Pending	2018-09-07	2019-03-14	Cybersecurity and data management. Product/system and method - describes product and system, method of operations and usage.
WO201948626	US provisional patent GB patent application (pending) PCT application designating EP	Electrostatic discharge protection for sensors in wound therapy	Pending	2019-09-07	2019-03-14	Electrostatic discharge protection. Product and process – describes the product and the method of manufacturing the product by putting the components together. Indicators: physiological parameter of the patient.
WO201948624	US provisional patent PCT application designating EP	Systems and methods for inspection of encapsulation and components in sensor equipped wound dressings	Pending	2018-09-07	2019-03-14	Coating of sensor sheet. Product, method and process – describes product, but foremost a method of inspection, but also method of manufacturing by putting components together.
WO201920666	US provisional patent GB patent application (pending) PCT application designating EP	Restriction of sensor-monitored region for sensor-enabled wound dressings	Pending	2018-07-25	2019-01-31	Restricting direction of sensor. Product and method – describe a product and the method of operations.

APPENDIX VI

Top assignee analysis - Elwha

Table 20. The patent filing from Elwha, in sub-patent family 1, are presented by patent application and publication number, title, legal status, application and publication dates and a summary of the technical scope from the patent claims.

Publication Application number	Publication granted number	Title	Legal Status	Application date	Publication date	Technical scope
US20130274629A1	US10158928B2	Appurtenances for reporting information regarding wound dressings	Granted	2012-04-12	2018-12-18	An appurtenance to an unpenetrated wound dressing, sampling of fluid associated with a wound through a projection into an interior region of the wound dressing. Measure fluid.
US20130271278A1	US9084530B2	Computational methods and systems for reporting information regarding appurtenances to wound dressings	Granted	2012-04-12	2015-07-21	A system for monitoring a wound dressing which includes a remote hardware. Sense at least one wound characteristics, sampling of wound fluid. Communicate with a remote system. A communication device configured to send the signals to the central assembly and receive signals from the central assembly. A local unit configured to receive signals from a plurality of appurtenances and interact with a computer system. Includes a central assembly with a processor configured to determine a suggested response to be taken by a caregiver. (Clinical decision support)
US20190082242A1	No	Appurtenances for reporting information regarding wound dressings	Pending	2018-11-13	2019-03-14	An appurtenance to a wound dressing, Wherein the transmission unit is configured to transmit a signal including information identifying the appurtenance which provide a unique identifier for the appurtenance and an indicator signal of visual, vibration or auditory response. Measures pressure and capacitance changes.

Table 21. The patent filing from Elwha, in sub-patent family 2, are presented by patent application and publication number, title, legal status, application and publication dates and a summary of the technical scope from the patent claims.

Publication Application number	Publication granted number	Title	Legal Status	Application date	Publication date	Technical scope
US20130274630A1	US9024751B2	Dormant to active appurtenances for reporting information regarding wound dressings	Granted	2012-06-18	2015-05-05	An Appurtenance to a wound dressing with a fluid-activated voltaic cell which send an electrical response when in contact with fluids, and a radiofrequency identification (RFID) unit attached to the fluid-activated voltaic cell and configured to operate in response to the electrical power generated by the fluid-activated voltaic cell.

US20130274563A1	US10226212B2	Appurtenances to cavity wound dressings	Granted	2013-03-12	2019-03-12	Claims the substrate and the sensor units on the substrate. A substrate configured to be positioned inside the cavity wound, the substrate including, at least one wound-facing surface, the wound-facing surface configured to be oriented facing a wound surface of the cavity wound; a plurality of sensor units attached to the substrate. Sensors: a plurality of sensor units of at least two distinct types. detect physical pressure, temperature, elapsed time value, analytes of wound exudate, a chemical-based sensor, optically resolvable detection indicator.
US20140298927A1	US10130518B2	Appurtenances including sensors for reporting information regarding wound dressings	Granted	2014-04-14	2018-11-20	A substrate in an appurtenance with a plurality of projections attached to the substrate and positioned to secure the substrate to the wound dressing, a fluid transport and control film affixed to the substrate. One or more sensor units attached to the substrate, the one or more sensor (chemical, resonance) units configured to sense a condition of the wound dressing; and a transmission unit attached to the substrate and operably coupled to the one or more sensor units, the transmission unit including circuitry configured to transmit information associated with the sensed condition of the wound dressing sensed by the one or more sensor units.
US20150208961A1	US9510781B2	Dormant to active appurtenances for reporting information regarding wound dressing	Granted	2015-04-10	2016-12-06	An appurtenance to a wound dressing and a **method** of monitoring a wound.
US20150264452A1	US9451340B2	Computational methods and systems for reporting information regarding appurtenances to wound dressings	Granted	2015-05-22	2016-09-20	The signaling within the appurtenance not claiming the remote system. A method of monitoring an appurtenance on a wound dressing, transmitting a first signal configured to be received by the appurtenance on the wound dressing, the appurtenance including a region extending into an interior region of the wound dressing at a selected depth which samples a fluid associated with a wound; receiving a first appurtenance signal from the appurtenance, the first appurtenance signal from the appurtenance modulated by the fluid contacting an antenna of the appurtenance when a moisture level of the wound dressing is at a level sufficient to cause the fluid to contact the antenna, associating a second time point with the receipt of the second appurtenance signal; comparing the second appurtenance signal from the appurtenance with the first appurtenance signal from the appurtenance to form a signal comparison; comparing the signal comparison with a preset table; and

						activating an indicator in accord with the preset table.
US20140298928A1	No	Wound dressing monitoring systems including appurtenances for wound dressings	Pending	2014-04-14	2014-10-09	Tried to cover all aspects in one patent. Claiming; An appurtenance to a wound dressing. A wound dressing monitoring system and a method of monitoring a wound dressing.

Table 22. The patent filing from Elwha, in sub-patent family 3, are presented by PCT application number and publication application number of designated states, title, legal status, application and publication dates and a summary of the technical scope from the patent claims.

PCT application number	**Publication application number**	**Title**	**Legal Status**	**Application date**	**Publication date**	**Technical Scope**
WO2013155193	EP2836177A1	Appurtenances for reporting information regarding wound dressings	Pending	2013-04-10	2015-02-18	Combining all previous patents in claims with focus on an appurtenance to a wound dressing and a system for monitoring a cavity wound medical dressing. The system has an appurtenance attached to a wound dressing, where the appurtenance includes projections positioned into the wound dressing and samples a fluid associated with a wound, processor, and transmitter attached to the processor. A local unit includes a receiver for the transmitter, where the processor is attached to the receiver, and the communication unit is attached to the processor. Focus on indicators within the wound.
	EP2836177A4	Computational methods and systems for reporting information regarding appurtenances to wound dressings	Pending	2013-04-10	2016-04-06	
WO2013155199	EP2836269A1	Appurtenances for reporting information regarding wound dressings	Pending	2013-04-10	2015-02-18	Combining all previous patents in claims with focus on the method of monitoring the appurtenance attached to a wound dressing, the communication to a remote device and signaling between components. The appurtenance includes sensors attached to the processor, where the projections of the appurtenance include fluid conduits between an interior of the wound dressing and the appurtenance.
	EP2836269A4	Appurtenances for reporting information regarding wound dressings	Pending	2013-04-10	2016-04-06	

APPENDIX VII

Top assignee analysis - Hill Rom Services

Table 24. The patent filings in Patent family 1, from Hill Rom Services are presented by patent publication number, related applications and designated states, title, legal status, application and publication dates and a summary of the technical scope from the patent claims.

Publication Application number	Title	Legal Status	Application date	Publication date	Technical scope
EP3449882	Systems for monitoring wounds and wound dressing status and systems for protecting wounds	Pending	2018-08-22	2019-03-06	Product/system patent. No claim of method or application, but only how it is constructed and what it does at what time point and environment. Indicators: temperature, pH, moisture, biomarker (unspecified biomarker)
US20190060126A1		Pending	2018-07-27	2019-02-28	More detailed than the EP application with more claims. More specific and definite wording (e.g. first predetermined temperature vs. desired temperature).

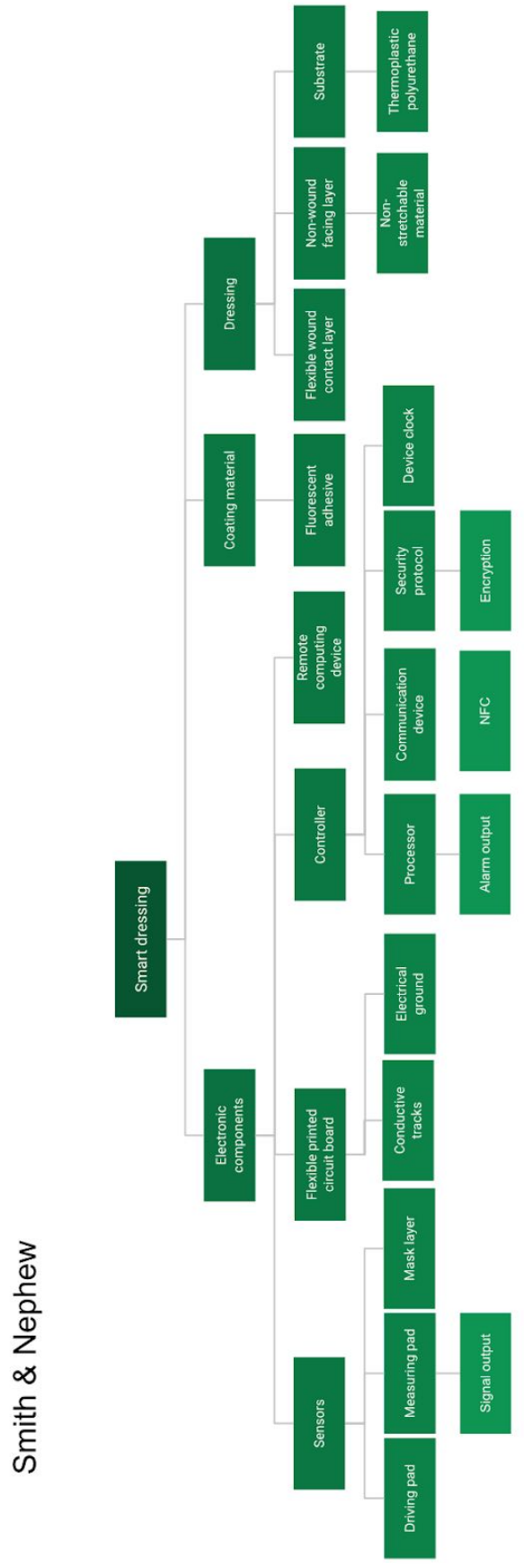
Table 25. The patent filings in Patent family 2, from Hill Rom Services in the High Relevance Patent Landscape, are presented by patent publication number, related applications and designated states, title, legal status, application and publication dates and a summary of the technical scope from the patent claims.

Publication Application number	Title	Legal Status	Application date	Publication date	Technical scope
EP3454340	Devices, systems, and methods for monitoring wounds	Pending	2018-09-10	2019-03-13	Product/system patent. No claim of method or application, but only how it is constructed and what it does. Indicators: size, tissue, exudate amount.
US20190083025A1		Pending	2018-09-04	2019-03-21	More detailed than the EP application with more claims. Includes executable instructions (interpreted as algorithms) and more focus/details of the storage medium (interpreted as a database).

APPENDIX VIII

Figures from the report with better resolution

Figure 14

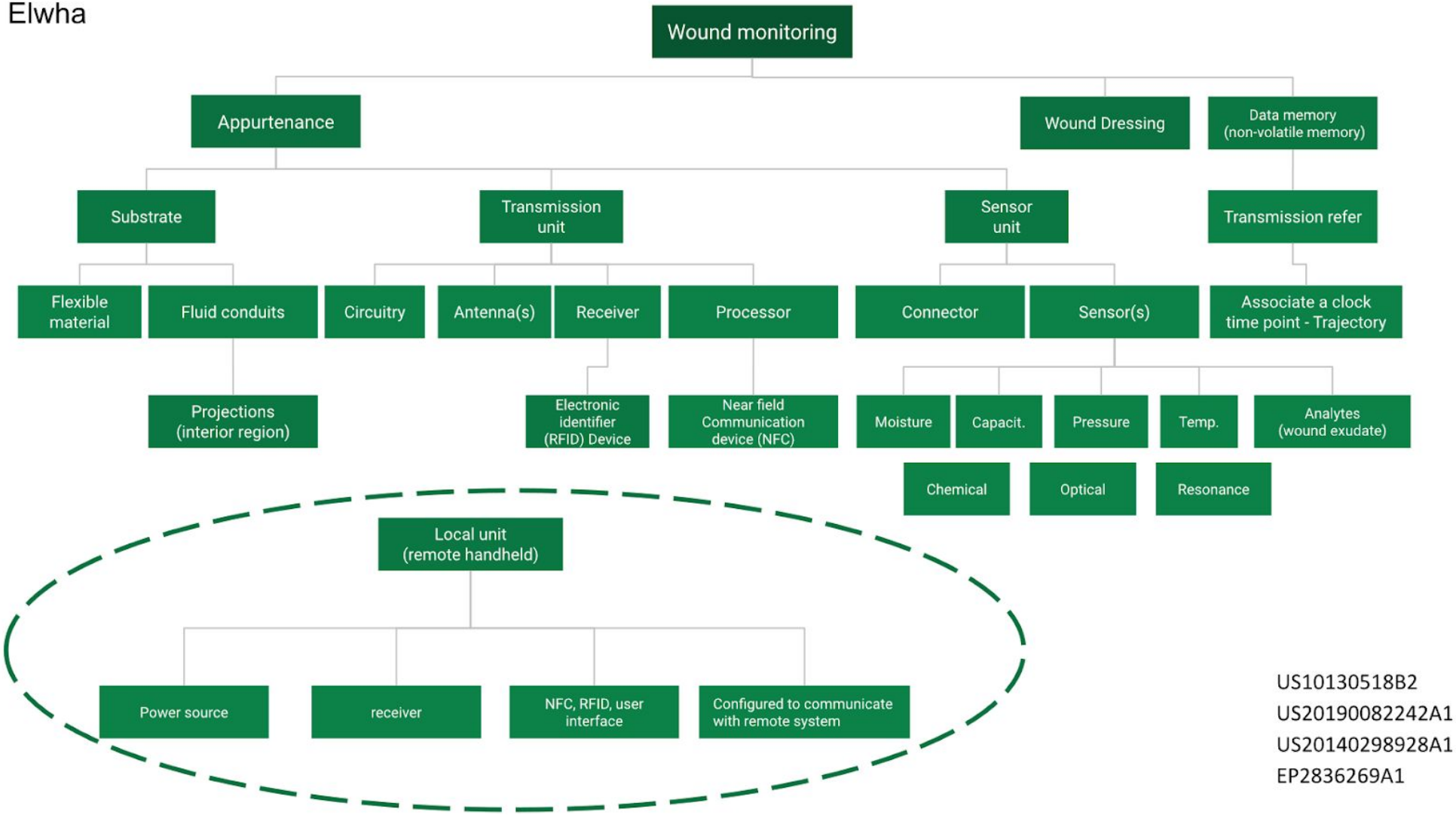


Smith & Nephew

WO2019063488A2
WO2019048626A1
WO2019048638A1
WO2019048624A1
WO2019020666A1
WO2019020551A1

Figure 15

Elwha



US10130518B2
US20190082242A1
US20140298928A1
EP2836269A1

Figure 16

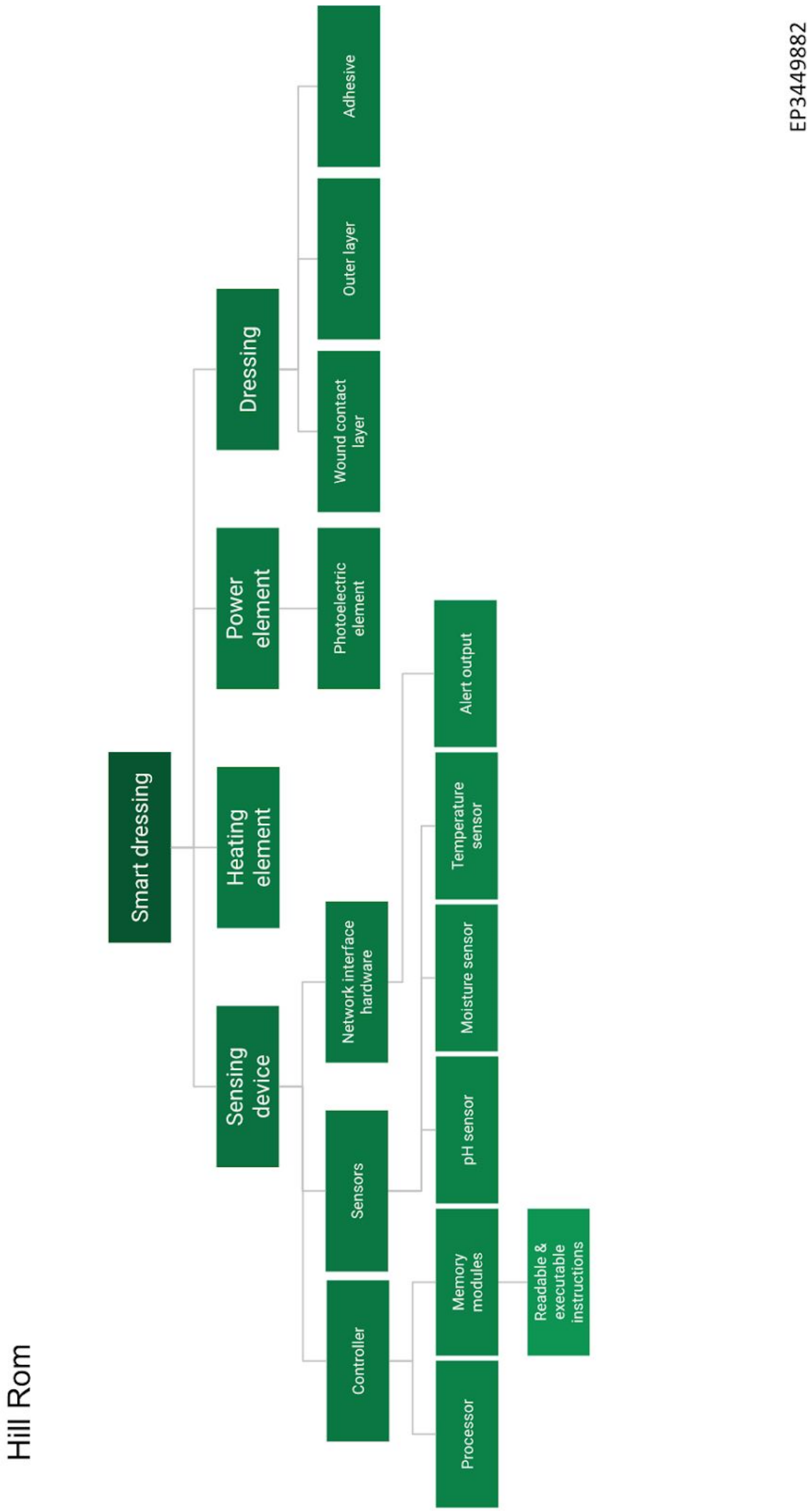
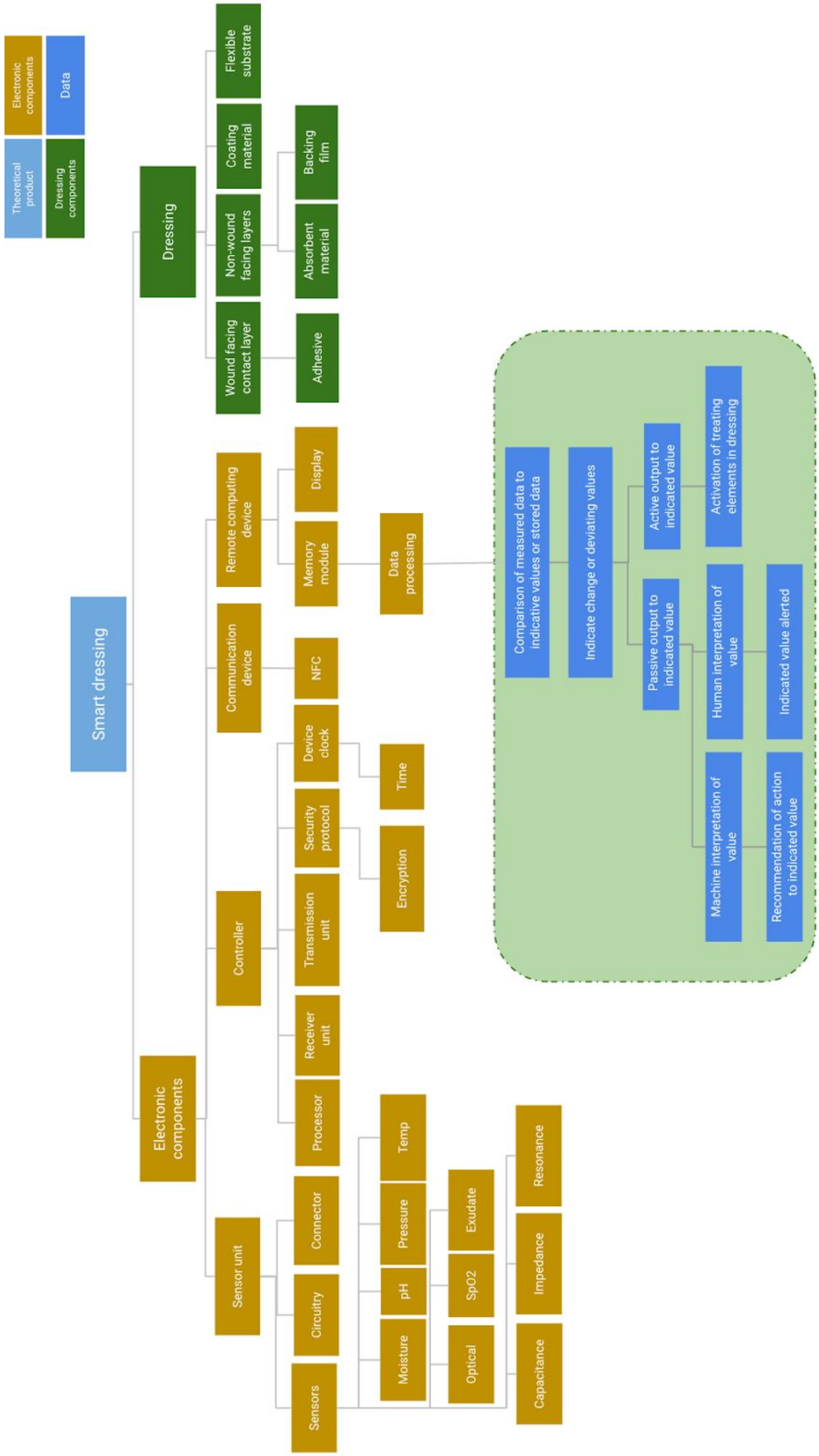
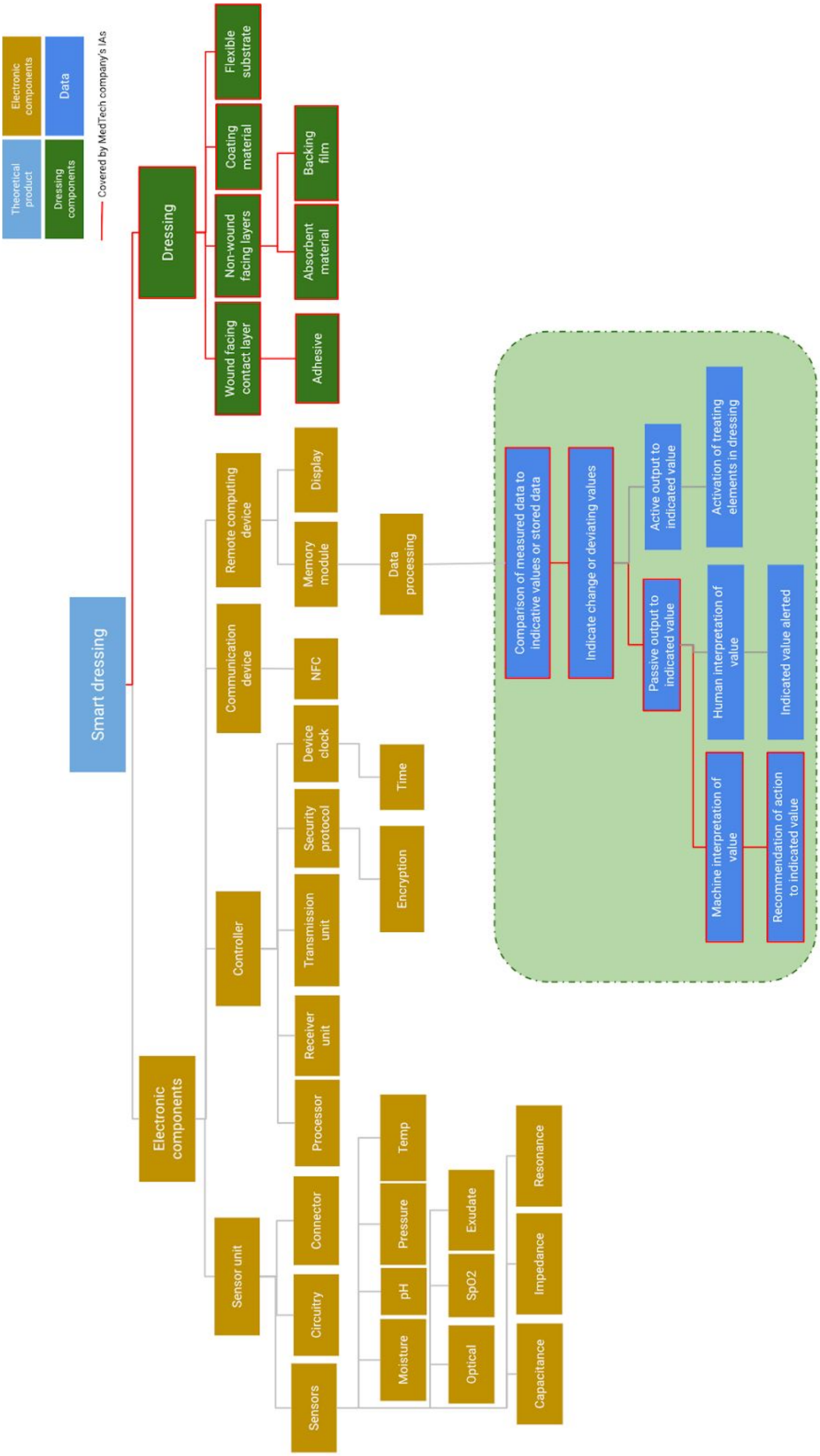

Hill Rom
Smart dressing
Sensing device
Heating element
Power element
Dressing
Controller
Sensors
Network interface hardware
Photoelectric element
Wound contact layer
Outer layer
Adhesive
Processor
Memory modules
pH sensor
Moisture sensor
Temperature sensor
Alert output
Readable & executable instructions
EP3449882

Figure 17



Theoretical product
Electronic components
Dressing components
Data
Smart dressing
Dressing
Electronic components
Wound facing contact layer
Non-wound facing layers
Coating material
Flexible substrate
Adhesive
Absorbent material
Backing film
Sensor unit
Controller
Communication device
Remote computing device
Sensors
Circuitry
Connector
Processor
Receiver unit
Transmission unit
Security protocol
Device clock
NFC
Memory module
Display
Moisture
pH
Pressure
Temp
Optical
SpO2
Exudate
Capacitance
Impedance
Resonance
Encryption
Time
Data processing
Comparison of measured data to indicative values or stored data
Indicate change or deviating values
Passive output to indicated value
Active output to indicated value
Machine interpretation of value
Human interpretation of value
Activation of treating elements in dressing
Recommendation of action to indicated value
Indicated value alerted

Figure 18



Theoretical product
Dressing components
Electronic components
Data
Covered by MedTech company's IAs
Smart dressing
Dressing
Wound facing contact layer
Non-wound facing layers
Coating material
Flexible substrate
Adhesive
Absorbent material
Backing film
Electronic components
Sensor unit
Controller
Communication device
Remote computing device
Sensors
Circuitry
Connector
Processor
Receiver unit
Transmission unit
Security protocol
Device clock
NFC
Memory module
Display
Moisture
pH
Pressure
Temp
Encryption
Time
Data processing
Optical
SpO2
Exudate
Capacitance
Impedance
Resonance
Comparison of measured data to indicative values or stored data
Indicate change or deviating values
Passive output to indicated value
Active output to indicated value
Human interpretation of value
Activation of treating elements in dressing
Machine interpretation of value
Indicated value alerted
Recommendation of action to indicated value

Figure 20

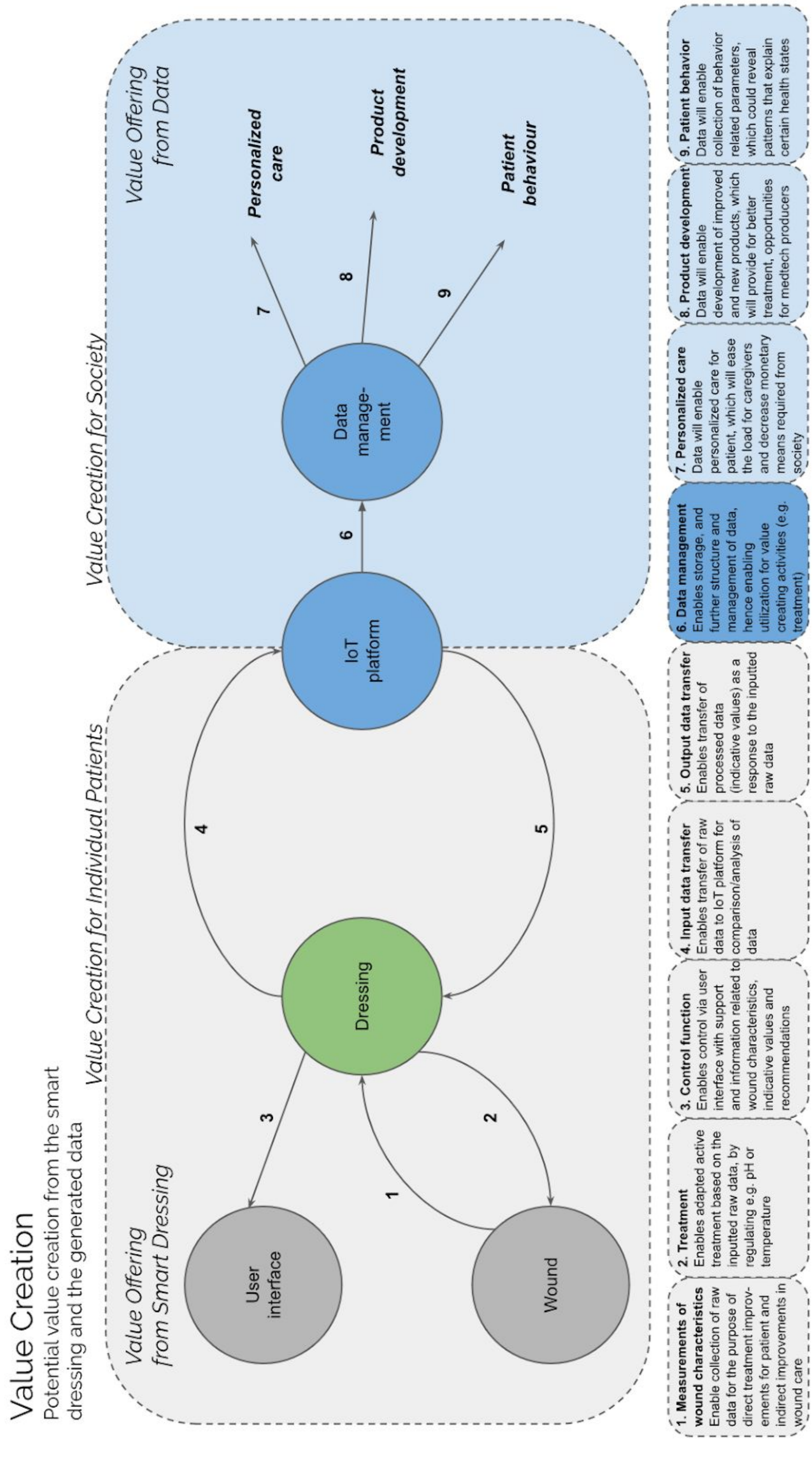
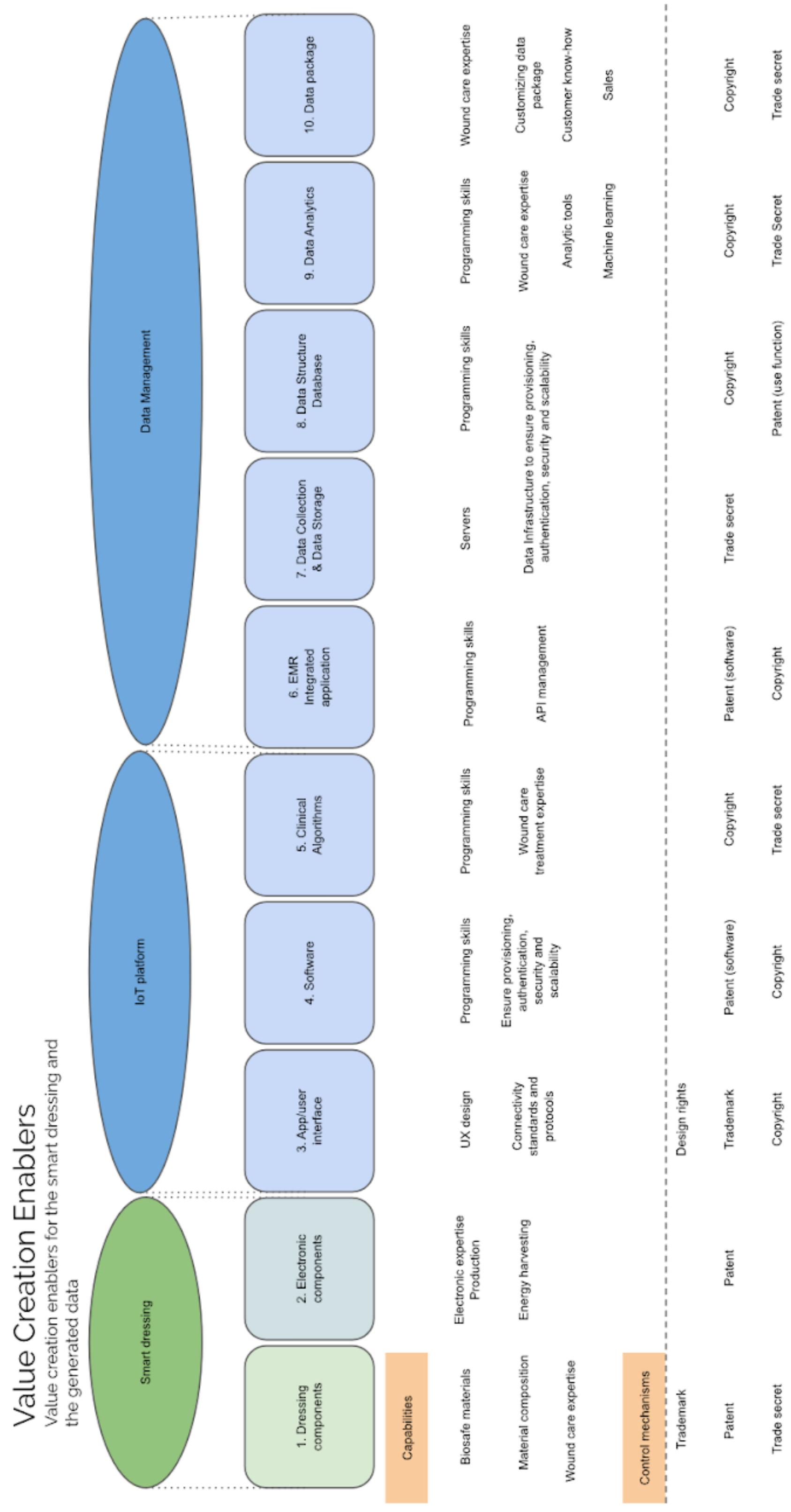

Value Creation
Potential value creation from the smart dressing and the generated data
Value Creation for Individual Patients
Value Creation for Society
Value Offering from Smart Dressing
Value Offering from Data
User interface
Wound
Dressing
IoT platform
Data manage-ment
Personalized care
Product development
Patient behaviour
1
2
3
4
5
6
7
8
9
1. Measurements of wound characteristics Enable collection of raw data for the purpose of direct treatment improv-ements for patient and indirect improvements in wound care
2. Treatment Enables adapted active treatment based on the inputted raw data, by regulating e.g. pH or temperature
3. Control function Enables control via user interface with support and information related to wound characteristics, indicative values and recommendations
4. Input data transfer Enables transfer of raw data to IoT platform for comparison/analysis of data
5. Output data transfer Enables transfer of processed data (indicative values) as a response to the inputted raw data
6. Data management Enables storage, and further structure and management of data, hence enabling utilization for value creating activities (e.g. treatment)
7. Personalized care Data will enable personalized care for patient, which will ease the load for caregivers and decrease monetary means required from society
8. Product development Data will enable development of improved and new products, which will provide for better treatment, opportunities for medtech producers
9. Patient behavior Data will enable collection of behavior related parameters, which could reveal patterns that explain certain health states

Figure 21



Value Creation Enablers
Value creation enablers for the smart dressing and the generated data
Smart dressing
IoT platform
Data Management
1. Dressing components
2. Electronic components
3. App/user interface
4. Software
5. Clinical Algorithms
6. EMR Integrated application
7. Data Collection & Data Storage
8. Data Structure Database
9. Data Analytics
10. Data package
Capabilities
Biosafe materials
Material composition
Wound care expertise
Electronic expertise Production
Energy harvesting
UX design
Connectivity standards and protocols
Programming skills
Ensure provisioning, authentication, security and scalability
Programming skills
Wound care treatment expertise
Programming skills
API management
Servers
Data Infrastructure to ensure provisioning, authentication, security and scalability
Programming skills
Programming skills
Wound care expertise
Analytic tools
Machine learning
Wound care expertise
Customizing data package
Customer know-how
Sales
Control mechanisms
Trademark
Patent
Trade secret
Patent
Design rights
Trademark
Copyright
Patent (software)
Copyright
Copyright
Trade secret
Patent (software)
Copyright
Trade secret
Copyright
Patent (use function)
Copyright
Trade Secret
Copyright
Trade secret