Smartbag

An Entrepreneurial Adventure Using Exponential Technologies.

AALBORG UNIVERSITET

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Abstract:

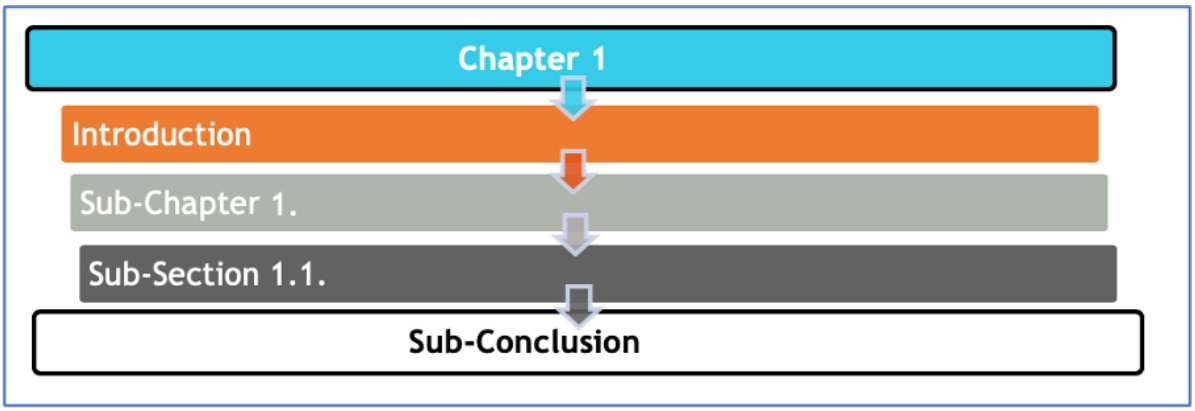
The report describes a solution targeting the healthcare market. Notably, a medical device innovation called Smartbag for the private healthcare market, with potential also for the public one. The process starts with the conception of the idea and discovery effort to understand the perspective of prospective customers using the device. The second phase is a proposed prototype of Smartbag, supported by design thinking theory that built on observations using the job to be done viewpoint. The third part is the business proposal to sustain the venture, secured by a subscription business model that takes into consideration aspects of exponential organizations, such as crowdsourcing and crowdfunding. The subscription business model and exponential organization are the perfect fit for a product that would use data as an asset. Specifically, Smartbag is the automation of the monitoring process around the indwelling catheter system, through sensors, AI, and data of patients with incontinence issues over 65 years old.

Reading Guide

1. Report Design

This paragraph is a description and reported example of the chapter's structure that I decided to adopt. The supportive and reasoning material expressed in the citations is written and placed in quotes using *"italic character."* The bibliographic material throughout the text is set inside brackets in the following form: (Name of the Author, Year, Page/s), according to this reference format, the full list of the bibliographic material in use in the report is placed in the reference section. The footnotes are used for biographical material that does not have a specific author, for instance, definitions, reports, and comments for clarification. An example of the organization of the chapters is as below.

Table 0. Example of Chapter Structure.



When possible, I employed figures and tables that (hopefully) will help the reader to get a visual understanding of the concepts. I made most visual works, such as figures, tables, and design. When taken from external sources, the source is cited under the picture or the text. Figures and tables are numbered in ascending order that ends in the Appendix section. The Appendix is an integral part of the report (especially for the prototype process and business plan).

2. Publication Design

The publication design follows a formal assembly that uses the insights of engaged scholarship regarding the organization of the elements for the research and problem sets of the research question (Mathiassen, 2017, p. 22). Moreover, to give a deeper understanding and clarification of the process, work questions, sub-work questions, and sub-goals have been established. The conceptual model for the current report is represented below.

Table 1. Report Publication Structure, (an adaptation of) (Mathiassen, 2017).

<table>
<tr><th colspan="3">Title</th></tr>
<tr><th colspan="3">Abstract</th></tr>
<tr><td>Outline and Background</td><td colspan="2">Description of the conception of Smartbag in the context.</td></tr>
<tr><td>Research and Methodology</td><td colspan="2">Framing of the report, data collection, methods and, theories in use.</td></tr>
<tr><th colspan="3">Research Question</th></tr>
<tr><td colspan="3">How to transform the Smartbag concept into an exponential technology prototype with design thinking for selected target customers? And on top of that, what is the initial business plan for Smartbag?</td></tr>
<tr><th>Work Questions</th><th colspan="2">Sub-Goals</th></tr>
<tr><td>WQ.1: What is the design thinking?

SWQ.1. What is design thinking method?

SWQ.2. How it was applied to Smartbag?</td><td>To study the impact of innovation factors while applying design thinking approach in the developing of the process.</td><td>Chapter 1</td></tr>
</table>

WQ.2: What is exponential technology? *SWQ.1. Which exponential technologies to use for Smartbag?* *SWQ.2. Why use exponential technology in Smartbag?*	Address the advantages of using specific exponential technologies in Smartbag.	**Chapter 2**
WQ.3: What market to address? *SWQ.1. What are the tendencies in the U.S and domestic healthcare market?* *SWQ.2. What market Smartbag is in?* *SWQ.3. What market dynamics are important for Smartbag?*	To identify potential markets and/or opportunities for the sale of the Smartbag product.	**Chapter 3**
WQ.4: Why should the target customers hire Smartbag? *SWQ.1. Which healthcare segment to select as target customers?* *SWQ.2. Which healthcare sector to select for market penetration?* *SWQ.3. What is the job that Smartbag does?*	To analyse patient's perceptions with detail to the indwelling catheter system and monitoring/management efficiency concerning the different environments.	**Chapter 4**

WQ.5: How is Smartbag concept transformed into a prototype? *SWQ.1. What are the medical reasons for the product?* *SWQ.2. What is Smartbag concept?* *SWQ.3. What products or prototypes can do similar jobs as Smartbag?* *SWQ.4. How to build the prototype for the job to be done?*	Propose a solution to the problem related to time management and monitoring, namely the Smartbag system solution.	**Chapter 5**
WQ.6: What is the initial business plan for Smartbag? *SWQ.1. What is the business model?* *SWQ.2. What is the market strategy?* *SWQ.3. What resources are needed?*	To detect product opportunities, potential financial funding and describe the succeeding action plan for Smartbag.	**Chapter 6**
Conclusion and Discussion	Justify the RQ and how it has been addressed. To report future outcomes on the business points of the start-up venture Smartbag.	
Appendix	The extended version of the work process and data collected during the report.	

Outline:

The Smartbag Conception

Introduction

This section introduces the project's considerations about the development of a start-up venture attempting to successfully unveil a new type of product as an integration of the existing urinary catheter system. Additionally, the present part embraces areas such as reasoning and background behind the idea, research definition, and objectives. This is intentional to provide a context and a basis for sympathetic with the product environment for the primary purpose of defining the Smartbag proposal.

1. Background

The reason behind the development of the current project from the writer's standpoint is personal and logic. In brief, I witnessed patients, especially the bedridden ones in hospitals and homes, and experienced some inefficiencies and pain regarding the hospital management system. Focusing (for now) on the catheter system makes it easy to understand the logical reason for the latter's improvement. For example, in my specific experience, my dear grandma was laying in the hospital's bed, when visiting her, the catheter bag was hanging around, people were stepping on it, and when it was full, nobody was going to change it. Why? Why letting people suffer that if previously hospitalized are in general already in pain?

No logical reason comes in mind. The actual nurses have to go to check, control the patient's conditions and machinery, and if something is wrong, then try to fix it, and in the case of her catheter bag, change it. According to this viewpoint, it is an inefficient system, isn't it?

Today's technology empowers us to exchange information almost instantaneously, thus the idea of developing a product with sensors that will update in real-time the "status" of the patient's catheter bag. Specifically, which status is the liquid "volume" inside the bag and when it has to be changed, avoiding the hassle for the patient to call the hospital staff, and the trouble for the nurses to go to check the patients without knowing the importance of the problem before

the check/call[1]. Besides, Smartbag would decrease the human error in collecting data on urine outputs and patients' conditions.

1.1. Motivations

As generally stated before, the new enterprise is focused on the development of a better monitoring method for patients and actors within the indwelling catheter system and, with attention to the private and public healthcare industry. The idea is to enter the market through private clients, starting with the considerations of different strategies (further explanation will be given in chapter 3). Among the factors explored, there are difficulties, advantages related to selling to the public and private customers, namely hospitals, communities, and hospices, and where/how to start the potential business. The results reported acknowledgments on how to solve the significant problems for the most appropriate target group of customers, if the market is viable and how to sell them the product. Furthermore, the writer described the development of a sustainable business model and the requirements for a product ready for sale.

1.2. Studies Guide

The master's programme in Entrepreneurial Engineering (EE, Aalborg University, 2020)[2], ceremonies that during the study, students should have knowledge and competencies within the fields of business development, innovation, entrepreneurship, agile processes, prototyping, design thinking, and creativity. Therefore, at the end of the educational path, students should dynamically develop innovative solutions for real problems. Target apposite customer segments and implement products. Moreover, being a master's thesis, the approach should be scientific and supported by theories to enhance the integrity and substance of the work. In this regard, I decided to focus on developing a solution for the automation of the infirmary monitoring system. While concurrently developing it, using prototyping and design thinking learned in the previous semesters of EE. The outcomes turned out to be legitimately promising based on feedbacks and market potential, especially within Europe and U.S. During this research period, I reached a reasonable market understanding, significant identification of

[1] In the observations from the writer the patients call the nursing staff pushing a bottom, or the nurses check one by one the patients which in the case of the indwelling catheter system they don't know when to change the liquid bag.

[2] Aalborg University, Master in Entrepreneurial Engineering, available at: https://www.en.aau.dk/education/master/entrepreneurial-engineering

relevant actor's pains, a business proposal, and an understanding for further development of Smartbag.

2. Introduction to the Context and the Name

The name Smartbag, for the potential venture, is pretty straightforward; it reflects the job done by the product (Christensen et al., 2016, p. 43), which is the contraposition that answer to the question previously explored in the introduction *("isn't a pretty inefficient system?"*).

It has been discovered through careful observation, and hand to hand experience. Theoretically supported by the process of questioning and observing (Dyer et al., 2011, p. 65, p. 89), that in today hospitals and private clinics, the staff, such as nurses and nurses' assistants go to make the job done of monitoring (and act upon), basically if two different conditions are satisfied:

1. The patient calls voluntarily through a bottom the staff requesting help or assistance for every kind of need.

2. The nurses' staff go for an "Inspection tour" and check the room's patient one by one, and remedy to the problems along the way.

The conditions above are put in an act in the hospitals' normal status, namely when no urgent calls have to be satisfied—for example, relevant "emergency codes" or other urgencies. When the staff receives the order from an audio input would require the staff to prioritize those kinds of jobs over the "normal" treatments (Hillier, 2012, pp. 31-64).

The way the staff receives the input data is usually audio or video. In the scenarios depicted in the conditions above, many problems occur. For the nurses, chiefly, in the first scenario, patients can push the button for every need from "change the TV's channels" to decrease the blood drainage. This brings not to prioritize the importance of the needs and inefficient movements of the staff from different points of the hospital (or other healthcare infrastructures). In the second condition, going around and checking the patient's parameter one by one can be overwhelming and time-wasting, creating inoperable movements where/when in reality, the patient may not need any treatment/help.

From a patient perspective, especially in the case of a catheter bag, other than the problems observed of the bag stepped on by others, the patient can feel irritation, cause the pee cannot

get out of the body. Secondly, the tube inside (the body) has to be changed at least every 15 days, which means that somebody has to remember when it is the right time. Reality and interviews with patients and relatives show that sometimes it is not changed, resulting in bacteria growth and, thus, future problems (Mcgoldrick, 2016).

Generally speaking, then, the problem in the hospitals is in the management system of the staff. Different authors have developed probabilistic models and algorithms to fix the problem. Still, in the real world of everyday life, none of the solutions seems to be successfully implemented (Hillier 2012, pp. 31-64). However, my idea, focus (at least at this stage) only on the catheter bag system, to develop a hardware and software product to start to solve the described problem, with the possibility to implement other aspects (like urine color, blood status, drip system, pill reminder, temperature monitoring and so on) as the integration of the same to create a "healthcare platform economy." The literature also supports this idea. The citation below represents the view. The view is an integral part of the Smartbag Logo (Figure 1).

Figure 1. Smartbag Logo (Own made).

"The project might begin as a single customer initiative, then be targeted at multiple users, and finally end up being a platform for a new family of products" (Kahn et al., 2013, p.12).

2.1. Product Potential

Personal reasons for moving towards the health care segment are as mentioned the experiences witnessed in real-life hospitals. Without forgetting the importance of the business aspect of the project, I see the healthcare sector as a challenge and opportunity. The automation and IoT are already here (Diamandis - Kotler, 2016, pp. 97-145), millions of sensors will be connected to the internet, and us soon. Secondly, longer lives mean more people aging and problem-related with healthcare and the economics of it (Dall et al., 2013).

2.2. The Smartbag venture

Ultimately, as already mentioned, these dynamics will accelerate advancement and technologies also in healthcare. The integration or renovation of old systems will create new opportunities for entrepreneurs, including the Smartbag venture. The final part of the present project will focus on the other related possibilities connected to the development of the Smartbag monitoring system. Based on literature and contact with nurses, hospital staff, and companies' players, the insights for lacking signs of progress are transparent and summarised below.

- In general, the companies who sell products for healthcare lack of product innovation, focusing on the old business, people from the industry are afraid of long *legal* approves.
- The nursing staff is trained with old technology, and generations of employees will take time for *learning activities* related to new tools and procedures.
- Usually, the products are bought from the same suppliers, especially in public facilities, where doctors advise the same brands of quality that they previously used. This brings to hard *competition* and thus low innovation.
- *Failures* of similar products bring the actors on the buyer scene to have bios also on new technologies (Herzlinger, 2006).

However (in the specific case of the urinary catheter system), during the years, somebody else tried to develop solutions for the catheter bag system, and I will explore those in chapter 5 to understand where and how they failed.

3. Research Question

The research question represents the purpose of the research, shortly and clearly. To have a guideline through the process, along with the research question, work questions have been established, which will lead to superior development of the work. Every WQ (Work Question) is addressed in the chapters related to the topic.

Catheter patients and users across the healthcare context should be able to benefit from a system to get the job done effortlessly and efficiently, exploiting the data from an integrated system of sensors (My vision of Smartbag concept).

How to transform the Smartbag concept into an exponential technology prototype with design thinking for selected target customers? And on top of that, what is the initial business plan for Smartbag? (Research question).

I propose that Smartbag should deliver a better system of monitoring. Tailored for a specific target and supported by a robust business model and strategy for the healthcare market. The exploration of prototyping and funding will serve as a vehicle for impacting the majority of people in the value network (Proposed solution).
The research question includes the discovery of the target customer, which denoted a flexible adaptation of the Smartbag prototype. The prototype will serve as a tool for further product development, given a profitable business model in the healthcare market. Based on the elements above will be investigated the need for funding within the business plan adopted.

Work Questions

WQ.1: What is design thinking?

WQ.2: What is an exponential technology?

WQ.3: What market to address?

WQ.4: Why should the target customers hire Smartbag?

WQ.5: How is Smartbag concept transformed into a prototype?

WQ.6: What is the initial business plan for Smartbag?

4. The Concept in Brief

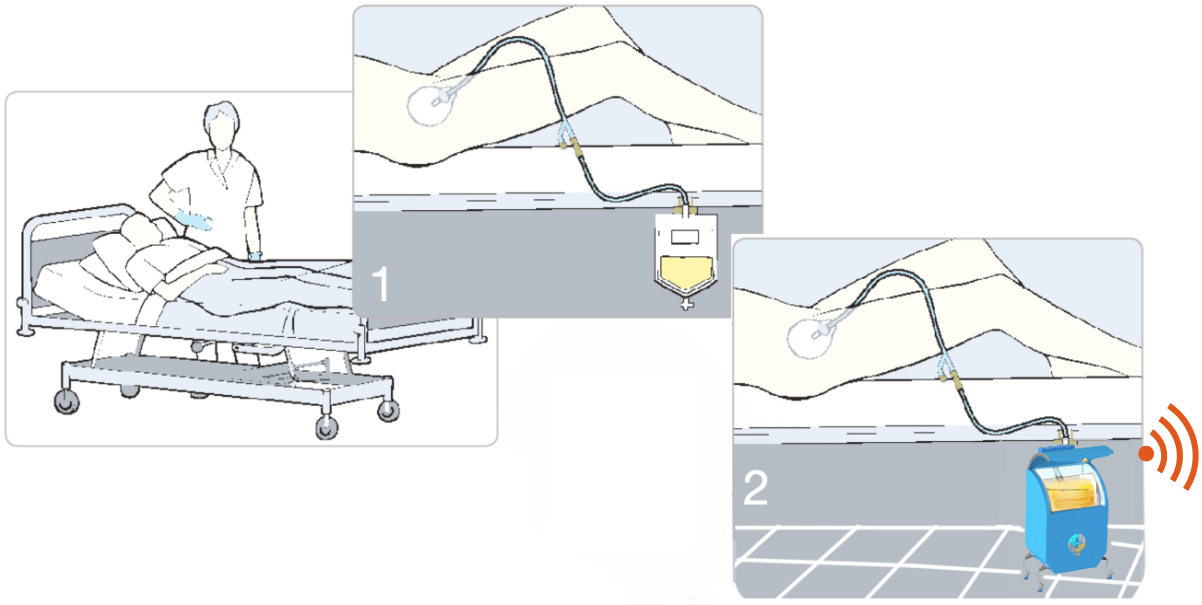


Figure 2. Catheter system 1. and Smartbag integration 2 (Modified from, Statenserum Institut, 2015)

Having in mind the context, in this section of the report, it is possible to give a brief explanation of what the Smartbag concept is. The images will support the reader in understanding.

The proposed concept is founded on careful considerations of market research and prototyping development (see chapters 4 and 5). The idea is to put the urine bag inside the Smartbag, a "cover box," with sensors connected through Wi-Fi technology and send data to a phone. The phone will receive the liquid status in a platform and alert the users through the app if the bag needs to be changed.

Besides, the daily data collected will serve as a monitoring method for medical purposes. In conclusion, the Smartbag concept is a monitoring solution that exploits a few exponential technologies (sensors, networks, data) that will eventually be integrated around the indwelling catheter system value chain.

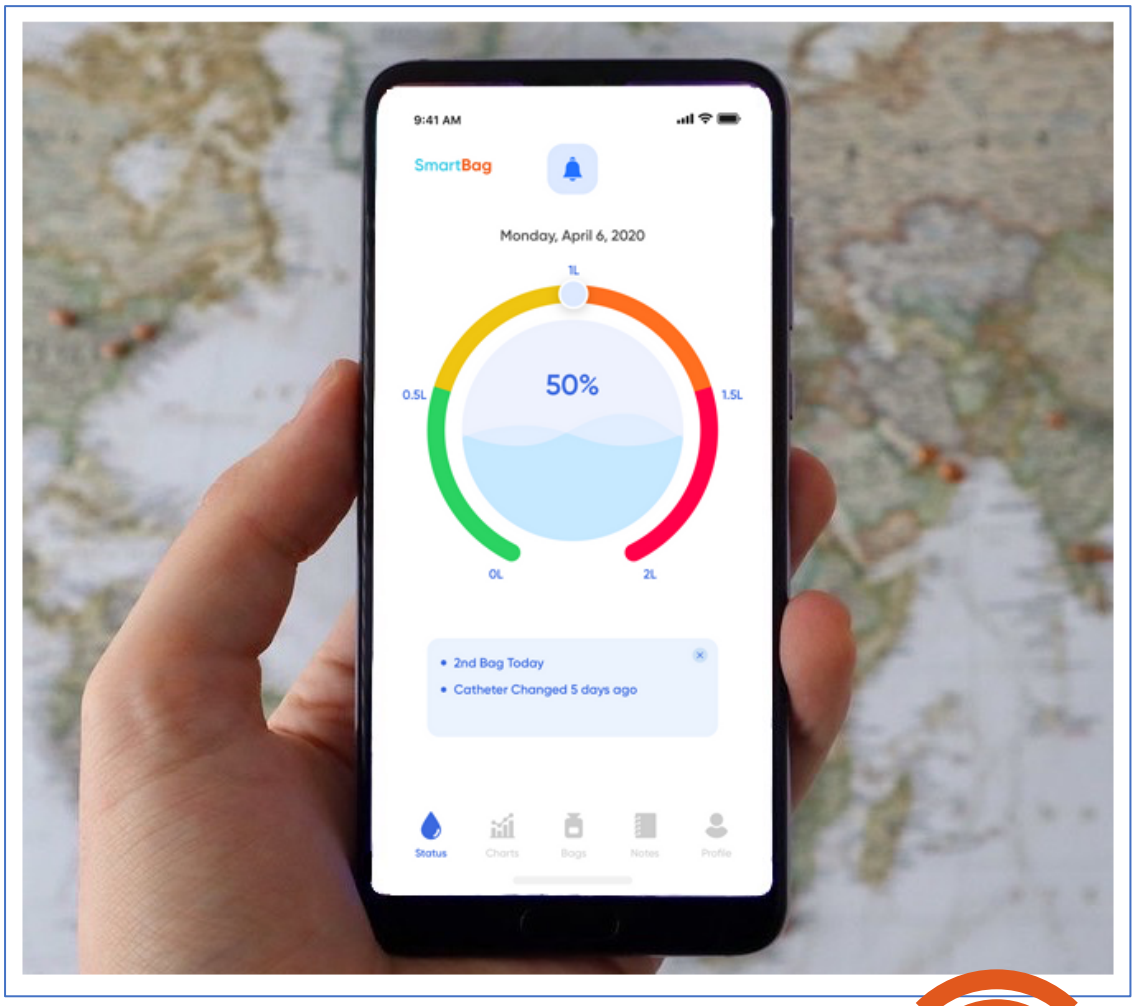


Figure 3. Smartbag, App Concept (Own made).

Figure 4. Smartbag, Structure Concept (Own made).

Introduction

In this section, I explain in what way the methodology of the research is used to answer the working questions and elucidate the structure around the research question. The study's construction is based on a highly comprehensible style and sound structure inspired by Mathiassen (2017), while the methodological aspect is planned according to Aulet (2013). The used work is the basis for designing an engaged scholarship type of research, where stakeholders are included in understanding real-world problems while also developing theoretical insights.

1. Structure of Research

In line with the literature Mathiassen (2017), the research is built upon the perspectives and understandings of critical participants to have a more supporting theory and realistic results to address the research question. The chosen process of engaged scholarship allows structuring creative and iterative development while evaluating ideas and making discoveries. Among the four[3] different forms of interested scholars, I have chosen the (adaptation[4] of an) *action research* which addresses a customer's problem and aims to contribute to academic knowledge. Therefore, action research implies the possibility of using both qualitative and quantitative approaches. The research design and publication design differences were carried out by the iterative change of both the research questions, work questions, and publication design desired, to converge the two processes. The central objective of every chapter was to address the work questions building over the elements of the research (real-world problematic, area of concern in the literature, method of inquiry, conceptual framework, contributions to knowledge) to give a groundwork to address the research question and provide a substantial contribution to the problem (Mathiassen, 2017).

[3] Informed basic research; Collaborative basic research; Design and evaluation research; Action research.

[4] My adaptation (permitted in the application of the literature), transforms the A (Area of Concern of the literature) in a "Area of Concern of the Entrepreneur" being directly linked to the area of concern of medical literature, innovation and entrepreneurship (Mathiassen, 2017). What makes the research "engaged" is anchoring the problem to P (Problem Setting) with a specific "designed" A (Table 2, p.16).

More specifically, the project is mainly designed to develop a competitive strategy for Smartbag to support the start-up sales and market penetration into the various opportunities available at the initial stage of a start-up venture in the Danish environment. Thus, solving the real-world problem in the medical field with an entrepreneurial perspective. While the research is engaged in the issue around the catheter system, the report could lead the project to the conclusion that the plan to market has a well-designed form, scope, or significant possibility for failure. The investigation is assumed on product and market development effectiveness on private and non-private validation. Thus, the study will be valuable for both academic and professional players, as it glances at the perception of patients, consumers, and industry leaders, providing principles for academic and directives for executives and professionals. The methods and theories used for addressing the specific work questions are described in the proper section of the relative chapters[5].

The general attitude is to use theories that will support the objectives of the research. A practical roadmap guides the possible construction of the thesis for entrepreneurs who are willing to build innovation-driven enterprises (Aulet, 2013, pp. 3-7). To support the creation of an innovative, disruptive product, I also took advantage of the job to be done theory, which will be an underlying framework in the examination of the work questions (Christensen et al., 2016, pp. 4-18).

Table 2. Engaged Scholar Smartbag, Mathiassen (2017) (Adaptation).

Components	Definition
P: Problem Setting	Elderly people lack adequate access to medical treatments in specific relation to the indwelling catheter system. Although nurses/assistants can address the problem, technology can increase patients' efficiency and well-being.
A: The Area of Concern	Adoption of Smartbag as an innovative solution in healthcare.
F: The (Main) Conceptual Framing	Design Thinking (Diderich, 2020). Job to be done theory (Christensen, 2011). Disruptive theory (Christensen, 1997). Blue Ocean Strategy (Chan – Mauborgne, 2017).
M: The Method	Qualitative case study of how people involved in helping patients with a catheter can benefit from a solution using exponential technologies.

[5] Every chapter is built to answer the work questions stated in the Introduction.

RQ: The Research Question	How to transform the Smartbag concept into an exponential technology prototype with design thinking for selected target customers? And on top of that, what is the initial business plan for Smartbag?
C: Contributions **Cp**: *Contribution to the Real Problem* **Ca**: *Contribution to Area of Concern in the Literature*	*Cp*: Guide and realise a potential product to solve the related problem of catheter monitoring and improved efficiency for the target customer. *Ca*: A comprehensive guide to making successful innovation (in healthcare) while developing a prototype[6] with higher market potential within a business opportunity.

1.1. Objectives

The objectives follow a pattern of exploration that goes to answer questions as "*to what the current system is*? and *how It can be changed?"*
Moreover, inside the specific environment, the observation brought to insight about the job to be done and a potential solution to do it better (Christensen, 2011, p. 92)[7].
The ultimate purpose is to solve the inefficiency around the catheter system while using entrepreneurship as a vehicle to impact the users positively. The *sub-goals* of the research associated with the WQ and SWQ and structure of the report is reported in Table 1 (at the beginning of the thesis). The *sub-conclusion* that will follow every chapter is meant to simplify the understanding and summarise how the WQ and Sub-WQ have been addressed.

1.2. Method Section

To define the job to be done and understand the market was necessary to collect data on people's behaviors, needs, and practices around the catheter system. I looked-for to interview the proper people in the specific context (Christensen et al., 2016, p. 56) patients, doctors, nurses' staff

[6] See the solution propose in Prototype Development Literature, chapter 5.

[7] In the book "The Innovator's DNA," the authors emphasise the importance of questioning, which is one of the discovery skills that works as a catalyst for the other (observing, networking, and experimenting). However, logical steps for the writer, the studies confirm that this process brings higher and innovative results in the creation of new disruptive products.

(potential beneficiaries), and industry experts. The intent was to learn from people's experiences. It has been studied how different "nurses" in the private and public sectors deal with the catheter system, urine output calculations, and task management. It was useful to emphasize the real value proposition (help patients and increase efficiency), which will serve to deliver the most reliable market strategy for Smartbag. The survey method (Jackson, 2011, p. 17), was used to find out how the healthcare businesses deal with problem-related to staff shortage, bed assistance, and catheter bag checking. This was done mainly to understand how the current job is carried and to look for "workarounds," which is a term to an incomplete or partial solution to the job to be done (Christensen, 2011, p. 98). Besides, it was questioned if it would be positive for patients to benefit from the Smartbag features. This data will be the foundation of the strategy design, where the business development based on customers' pains and insights was gained while researching users' needs. Finally, as the term suggests, quantitative method research implies surveying a large group of individuals, using a structured form that includes mostly closed or premade choice. Consequently, the findings may be communicated numerically. However, at this stage of the project, I considered suitable to deselect the quantitative method and using it when I will have more quantitative data to (de)verify specific (yes/no/percentage) hypotheses. Therefore, the *qualitative method* is chosen for the explorative situation coming out of the discovery phase, where there is not data from a market foothold. The quantitative approach can be a suitable method later when the Smartbag application is deployed, and information from the market could be easily collected.

1.3. Key Assumptions

Based on a severe literature examination, cited throughout the text, and according to the intents of the study, recognizing key assumptions is the first part of the process to validate the primary market research activities (Aulet, 2013, p. 227).

1. There is a substantial relationship concerning the patient's well-being and efficiency of staff management[8] (McKinsey&Company, 2009).

[8] There is a substantial relationship between financial performances, management and healthcare of patients, McKinsey & Company, (2009), "Management in Healthcare: Why good practice really matters", available at: http://worldmanagementsurvey.org/wp-content/images/2010/10/Management_in_Healthcare_Report_2010.pdf

2. Technology and remarkably sensors can help to develop a prototype that would save time to the nurses, deal with staff scarcity and more important benefit incapacitated patients (see chapter 4).
3. Smartbag could succeed taking opportunities, in the Danish (Digital Health Strategy 2018-2020)[9], and U.S[10] healthcare markets, regarding the automation process of ordinary tasks with IT solutions (Khanna et al., 2016).

4. There is a meaningful difference between the private and public assisting of bedridden patients in the healthcare industry (see chapter 4).

5. There is a need for different sources of funding the venture and develop the product for sale (Van Balen et al., 2018).

These key assumptions will be further elaborated through the research to understand the consumer and increase the likelihood of success for the Smartbag product. Every key assumption is debated in the proper chapter.

2. Data Collection Procedures

The design of the research project is based on a combination of two categories of processes, which are descriptive and as well as investigative. The descriptive method would answer questions such as *how*, *when*, *where*, but not why.
"The use of a qualitative description approach is particularly relevant where information is required directly from those experiencing the phenomenon under investigation, where time and resources are limited and perhaps as part of a mixed methods approach." (Neergaard et al., 2009). In contrast, the investigative type is suitable for the early stages of the decision-making process. It is often used to permit the preparation of robust problem recognition and definition, to be able to define the problems or opportunities. According to the authors, Yau Fai Oh et al., 2006, other than generate new knowledge and answering the *why* questions, *"Investigative research has the advantage of bringing the investigator to observe closely and directly phenomena of interest, relying on disciplined, naturalistic, and in-depth observations over time in diverse contexts."* (Yau Fai Oh et al., 2006).

[9] Digital Health Strategy 2018-2020, available at: https://sundhedsdatastyrelsen.dk/da/diverse/download

[10] It has been proved in a recent study that the healthcare system is one of the least digitalised industry, making it less productive, while big data and IoT systems help to maximise performances (Khanna et al. 2016).

2.1. Data Sources

I have used secondary and primary data sources to gain the required information for the foundation of the present work. In particular, through *secondary data sources*, such as desk research, I learned from books, articles, websites, and statistics about the healthcare approach to the problem set, players involved, industry trends, and competitors. This information helped me to achieve an overall understanding of the topic in the U.S and Danish market, which is investigated through the report. Whereas, the field research of *primary data sources* is based on mixed methods, where there was a chance to use more than one (data) gathering technique and analysis procedures to define the problem statement, helped to understand the Danish market, real experiences and current stages of the market and more importantly the environment where Smartbag would be positioned.

2.2. Interview

Interviews are the most common qualitative data collection method (Muhammad, 2016, pp. 201-275). Therefore, it has been chosen as a tool for making "average" conclusions on the management process and patient experiences related to the catheter' system.

In short, asking the targeted respondent different questions to which they will answer, most of the inquiries being open questions. The results can be hard to analyse, but it has the advantage of being possible to conduct in various ways. Hence, my choices are:

- *In-person:* I consider the approach to real active data and interviews to build a robust picture of the situations of the customer's struggle the most effective way to understand people (Christensen et al., 2011, p. 325-336). The investigator collects information not only from the verbal language but also from the non-verbal communication.

- *Phone interviews*[11]*:* Regarded as faster than the previous method, it is also less prolific (Gill et al., 2008).

[11] Mostly uses for U.S market research and understanding of the healthcare infrastructure.

The approach followed for the condensation of meaning that guided in the capture and documentation of the data analysed is the *Systematic text condensation* for qualitative analysis. In line with the literature Malterud (2012), the method applied consists of the following stages:

1) From a broader view to key themes;
2) Classifying and organising the topics making models or sub-themes;
3) Analysing the data for the extrapolation of the meaning;
4) Summarise, from condensation to explanations and concepts (Malterud, 2012).

A model of the related questions asked in the interviews is shown in Appendix 1, 1.7.

2.3. Survey

The survey grounded on a specific sample can gather a sizable quantity of data from a lot of respondents. Hence, the polls can represent the average opinion of the whole selected group. Although the surveys contain quantitative data, such as the number of cheeking per day/hour, importance of the specific problem (compare to other tasks), the distance[12] between the needing patients represented by numbers, more emphasis was given to people's subjective points of views and personal thoughts which was used to support the interpretation of the qualitative information. I have carefully studied the perspectives of the root causes of the monitoring problem and mechanism. According to the literature, a way to drive innovation is to understand the causal mechanism and the progress that people are trying to make (Christensen et al., 2016, p. 45) in their environment.

2.4. Closing

Reasons for the choice of the survey and interviews are the considerations for the process to be a more fruitful approach in terms of the rate of information/time. In practice, I founded the work of primary data collection (when possible) especially on the face to face interviews and the surveys, carrying out the research in a more qualitative process. In fact, according to the literature for the research, it was Investigated attitudes and concepts regarding the catheter system, behaviours of the actors, views on the defined topic and when possible key institutional

[12] From patient A to patient B (how much is the distance in terms of time and meters?). Knowing that it is possible to roughly understand how much time the medical staff does a specific tour and calculating the time wasted if the patients do not need assistance.

perspectives within depth conversations and semi-structured open interviews (Jamshed, 2014, p. 87-88). Important insights were given mostly by personal observation and networking, as already mentioned considering the discovery phases while working on the subject and asking people about their pains and jobs within the healthcare system (Christensen et al., 2011, pp. 89-113).

3. Respondents

The primary ambition was to find beneficiaries (patients) and the real potential users, namely nurses and staff hospitals in Denmark and the United States (see limitation for this choice), which seems to have difficulties accomplishing and claim for a superior data-driven tool of monitoring[13]. I explored enterprises in the healthcare industry in Denmark and the US. that could profit from the idea (being sellers of medical devices or catheter bags, see competitor analysis). As was stated earlier, the research type is more qualitative than quantitative. Therefore, I preferred the most suitable sampling method to find indispensable data for the analysis. Hence, the final choice (for private patients) of sampling is the "Simple Random Sampling (SRS)" type (Groves et al., 2009, p. 103). While the method used for medical staff is known as cluster sampling. The intention was to find people who are generally interested in Smartbag's product and able to provide insights into their ordinary operations. The patients were chosen based on characteristics such as bedridden problems, urine issues, and mobility issues and mostly found thanks to assisting agencies who deal with private healthcare businesses. The second part of the research has attentive medical staff, especially nursing and assisting staff, which are the ones dealing with urine checking and catheter systems. Most of them were found while working in Danish hospitals such as University Hospital (Rigshospitalet), Entrance 69, Bisperbjerg Hospital, and Amager Hospital. Instead, the U.S. market was explored, thanks to phone calls and mail correspondence with nurses and medical assistants found mainly in nursing groups online and in personal networks.
The most significant insights from the interviews are cited throughout the test, while some of the extended version interviews are stated in Appendix 1.

[13] Ministry of Health, in report, "Healthcare in Denmark", available at: https://www.sum.dk/English/~/media/Filer%20-%20Publikationer_i_pdf/2016/Healthcare-in-dk-16-dec/Healthcare-english-V16-dec.ashx

3.1. Processing Data

The analysis is designed to examine the respondents' habits and opinions of the patient's management/monitoring methods related to the catheter system. I tried to amplify the objectiveness through the data processing and examination, scrutinizing their answers as statistical data. In brief, when possible, treating and transform the answers into statistical information and numbers, which were further connected to tables and charts for organization and visual reasons. Pie charts (Appendix 1, 1.9) were used to show compressed information in percentage to visualise the results better.

3.2. Limitation

Different elements have limited the examination of the problem statements. The evaluation through analysis based on the data collected through interviews, surveys, and personal observations in the healthcare market was limited by the number of participants and context assumptions (example, Danish nurses, in Danish hospitals). As I experienced, not all people contacted were helpful to cooperate for interviews and surveys. Other limiting aspects were the lack of direct data from the companies' subject to related product sales. Moreover, different business environments other than the Danish and North American would not be considered in this report due to the length of the time frame.

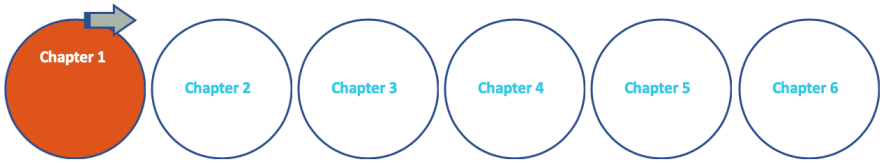
The choices of the markets are based on the initial hypothesises of business opportunities in the U.S.[14], easiness of contact with the user's object of the study found in my network (relatives and friends). I had the fortune to interact with people working in hospitals and private clinics in the U.S. market. While the Danish market is in the current country where I live, thus easiness in conduct tests, build a prototype, find advice (AAU Incubator) observe the environment and hand to hand market research.

Sub-Conclusion

This section provided an overview of the methodology Aulet (2013), and framework Mathiassen, 2017, employed in the current study to address the research problem. The approach was focused on the advance of items for the key assumptions using the literature. Besides, it

[14] The market research will confirm or disprove the hypothesis.

was provided with an argument for the qualitative approach at this stage, in line with the job to be done theory (Christensen et al., 2016, p. 38).



Chapter 1

Design Thinking and Smartbag

Introduction

The chapter explores the WQ.1 "What is design thinking?". Focusing on what the method is and how to use the process for the development of the Smartbag concept. The literature used goes to support the different phases of the design thinking process. Particularly useful are the "House of Quality" (Hauser – Clausing, 1988) used in translating user needs in product specification, the type of prototyping methods (Christie et al., 2012) used for Smartbag and why they are used. A brief introduction to the process development of Smartbag with Agile methodology is mentioned (Lukasik – Saylor, 2018).

The chapter is organized in order to answer the sub-work questions:
1. What is the design thinking method?
2. How it was applied to Smartbag?

The explanation and application of the following section's methods are theoretical support for both the report process and prototype strategies. The Smartbag prototype chapter (5) will take up some of the aspects of the design thinking approach, but with practical applications for the making of the product.

1. Overview of Design Thinking

The present paragraph is a brief explanation of the design thinking (DT) process building a base for the subsequent chapters while answering the *first* sub-work question "*What is design thinking method?*". Moreover, to have a complete overview, I will explain why it is essential and how the DT process can benefit the Smartbag proposal.

Design thinking is a formidable method of problem-solving that starts with considerate unmet customer necessities. From this vision arises a process for innovation that embraces idea development, practical creativity, prototyping, and testing. Besides, putting the customer at the

center, using design thinking, it is possible to increase the rate of innovation of the final object (Diderich, 2020, pp. 10-11).

Companies such as IBM, Nike, P&G, Apple, and Whirlpool that are using the design thinking process and are included in the DVI (Design Value Index)[15] have beaten the S&P 500 Index[16] over the years. In conformity with the Design Management Institute, more companies are pursuing to build organisations to successfully implement the design thinking process.

"The Design Value Index Study shows 10-year returns yielding 2.11 times (211%) that of the S&P 500." (Rae, 2016).

Design thinking guides to a step by step process that is summarised in three main questions that are the foundation for the Smartbag development and outcome. Under the literature (Diderich, 2020, p. 175):

- Desirability: *Is Smartbag addressing a real customer need and support one or more jobs to be done?* (Diderich, 2020, p. 176)
- Feasibility: *Can Smartbag deliver a solution that is technologically feasible and respects the customer value proposition?* (Diderich, 2020, p. 177)
- Viability: *Is there a viable business model for Smartbag for a price that customers are willing to pay for the job to be done?* (Diderich, 2020, p. 177).

[15] DESI (2019), "The Digital Economy and Society Index (DESI)", in Policy, Shaping Europe's digital future, available at: https://ec.europa.eu/digital-single-market/desi

[16] The S&P 500 is commonly considered as the best single instrument of measurement for large-cap U.S. equities. The index includes 500 prominent firms and captures roughly 80% coverage of available market capitalization. It is also used for measuring the economic well-being (Investopedia (2020), "S&P 500 Index – Standard & Poor's 500 Index", available at: https://www.investopedia.com/terms/s/sp500.asp).

2. Smartbag Elaboration

The section is dedicated to the *second* sub-work question of the chapter to address "*How design thinking was applied to Smartbag?"*. In concordance with the literature, Linke, 2017, the design thinking practices facilitated the writer to recognise and evaluate opportunities through customer needs evaluation. Based on that, create a rich product specification that developed into a prototype. Besides, having considered desirable, feasible, and viable characteristics, I implemented the different prototyping methods for planning and execution. Finally, after having a complete design of the Smartbag porotype, an appraisal of the economics of the prospective business was conducted (Linke, 2017). The conceptual steps are reported in figure 5.

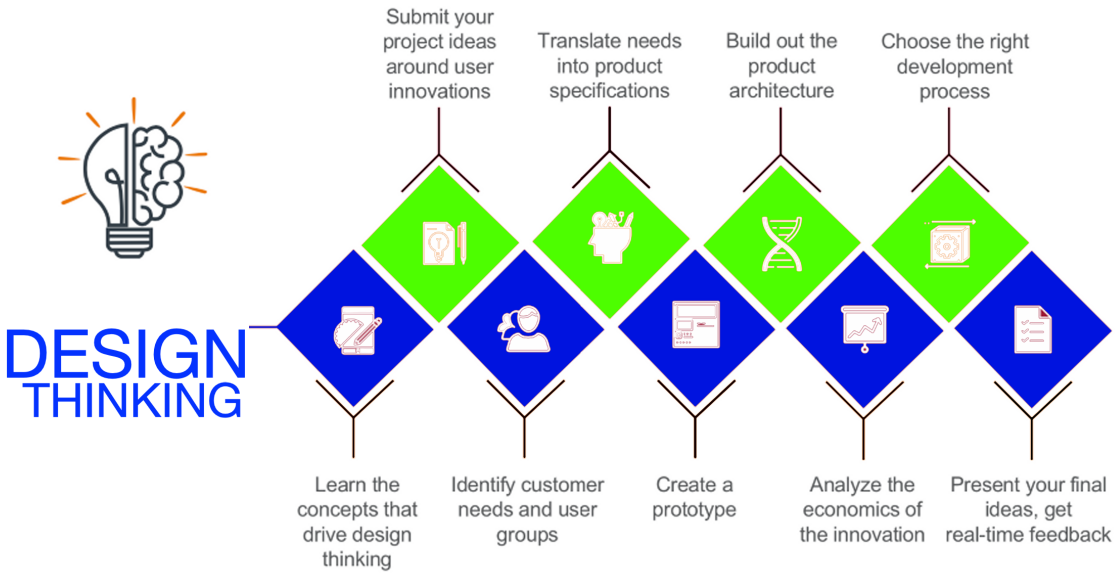


Figure 5. Design Thinking Process (Modified from, mit.edu, 2020).

The theoretical phases described above were applied in the Smartbag development. Every step has been supported by the biographical material in order to provide a more robust outcome.

2.1. Design Thinking Skills

To assess the innovation challenge of Smartbag, the Real-Win-Worth framework was applied and adapted to the stage of Smartbag (prototype development). The outline consists of weighing the opportunities, completeness, and risks associated with the development of the product (Day, 2007). Although the method was thought for large companies already in the

market, a version of the R-W-W can be used for the innovation process in this case. The three-fundamental question for the application of the method are:

1. How ***Real*** is the opportunity for Smartbag?
   (Find out market attractiveness and technical feasibility)
2. To what degree Smartbag can ***Win*** compared to competitive alternatives?
   (Understand product advantage and company's competencies)
3. Is the opportunity ***Worth*** pursuing?
   (Find the strategic fit with the market and assess the risk/reward ratio)

"The R-W-W (real-win-worth) screen is a simple but powerful tool built on a series of questions about the innovation concept or product, its potential market, and the company's capabilities and competition." (George Day, 2007).

The three questions above have been investigated along with the design thinking approach. In particular, question one is satisfied in the market research and prototype development (chapter 2, 3 and, 5), while the second question in understanding the advantage and competitiveness is supported in the investigation of the market research (chapter 3 and 4). Hence, the analysis is completed answering question three with the financial section and the consideration of resources with the assumption described in chapter 6. Appendix 1, 1.11 is dedicated to the extensive R-W-W matrix.

2.2. Identifying Customer Needs

As cited, it was essential to conduct a customer need analysis. Hence, making the Smartbag development according to design planning and identifying customer requires. As reported by the literature, the design thinking process is based on the observation that solving distinctive business problems involves a deep understanding of the customer's needs, pains, and consideration after eventual benefits proposed (Diderich, 2020, p. 17).

Rather than question the consumers on what they want, (as done by conventional market research), the method examines what clients do or do not do and what are their jobs-to-be-done. The observation gathered by real customer insight will be used to validate the prototype and customers' feedback (Diderich, 2020, p. 18). This revelation on the customer needs is also reinforced by the job to be done theory. In fact, in the process of observing and detecting the

customer needs, a question like *"why the customer would hire Smartbag for?"* is crucial, and this cannot be achieved if not by motivating causal mechanism such as the progress a user is trying to make under certain circumstances and find the causation for a specific action (Christensen et al., 2016, p. 45). The application of the design thinking method and documentation on the customer data analysis is exhaustively explained in the methodological aspects of the present report.

2.3. Translating in Product Specifications

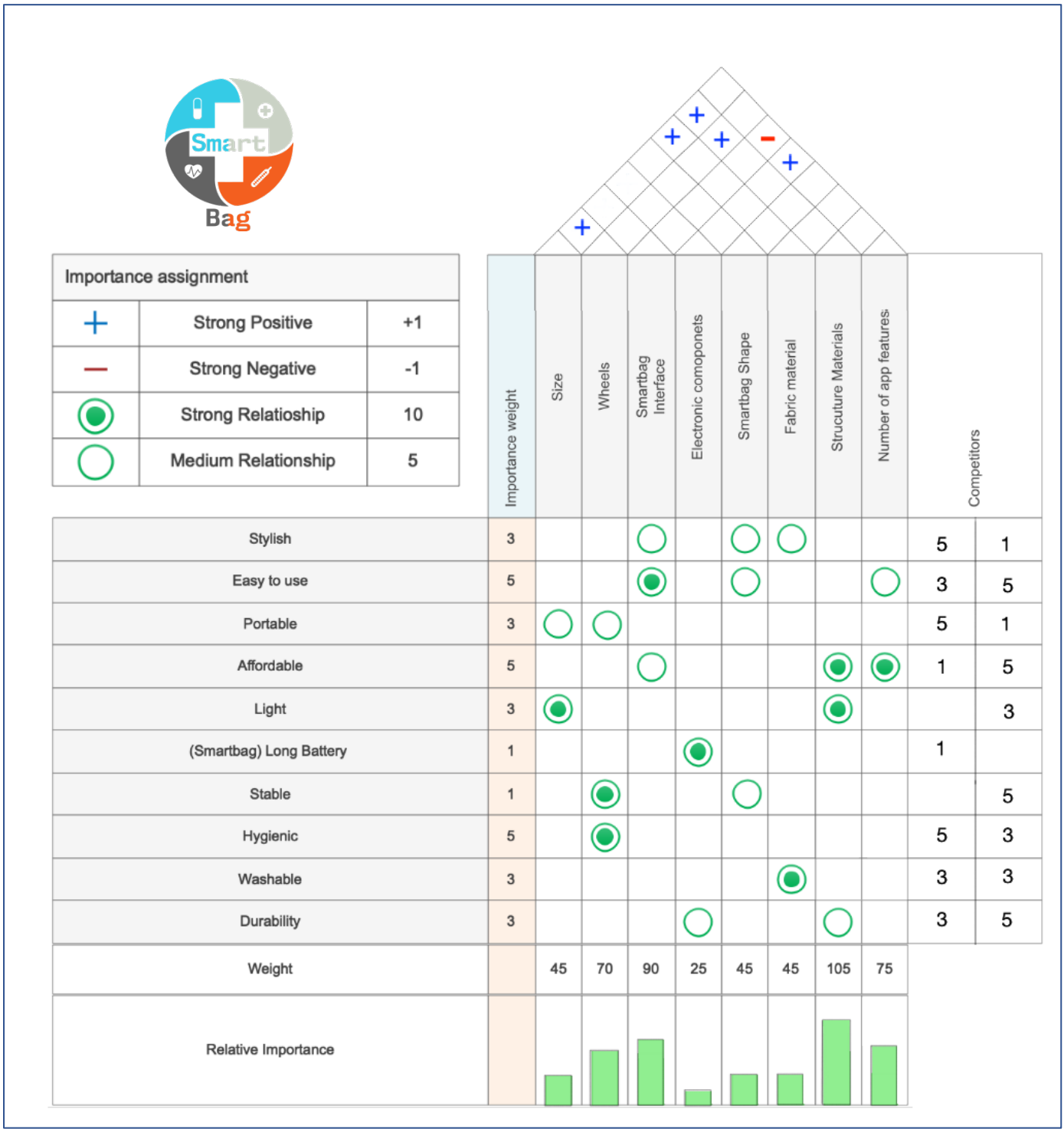


Figure 6. House of Quality of Smartbag (Own made).

To translate customer needs into (as much as possible) quantifiable specifications, I adopted the Quality Function Deployment (QFD) method. This helped in benchmarking the requirements *vs*. dynamics of product specification of Smartbag. The result is the understanding of which components and principles are more important in the development of

Smartbag. Furthermore, at the rooftop of the "house" are underlined the relationship between the elements. If one factor is correlated with another, the change of one will inevitably affect the other (for example, affordability and materials).

The steps for building a product using "house of quality" in the original Japanese theory are diverse and iterative. For example, they start with engineering characteristics, following the iteration with part deploying, process planning, and production planning (Hauser – Clausing, 1988). However, it is possible to build more or fewer iterations depending on the product stage and satisfaction of the results (Allan, 2019). The application of QFD in Smartbag is made in the view of future product development and for a better prototyping attitude. The table in figure 6 shows the explanation of the symbols in the legend and the final result of the analysis in Smartbag QFD.

There is not a direct competitor for the measurement of urine output with an external device like Smartbag. Although, to deliver the perceived needs and see if they lead Smartbag to a competitive advantage, (Hauser – Clausing, 1988) the column on the right describes two possible comparisons with smartwatches (like Apple watch and alike) and cover for urinary bags.

It is important to describe the assumptions made for the construction of the competitor column. The first column compares the job of Smartbag monitoring System with a similar product, while the second is aimed to compare Smartbag with cover and support bags.

- *Smartwatches*: I decided to compare the characteristics, leaving blank the spot of stability and lightness. The stability for the Smartbag is intended in the way that "the bag" stays up while moving, so there is no correlation with a smartwatch in this sense. The lightness, although the watch is light in the Smartbag System the weight is given by the urine bag, which is part of the problem into the system, thus, I considered not comparable this parameter due to the nature of what is monitored.
- *Cover/support bag:* In the second column regarding the commercial cover bags chosen as a competitor in the sense of covering the drainage bag (see the prototype, chapter 5). They have no battery; thus, the spot is left blank.

The remarkable results from the QFD[17] table considered for the prototype development are the ones represented by the real relative importance, as can be seen in the figure, the *structure material*, *Smartbag interface and the number of app features are in the top 3*. Thus, I gave more attention to these, because they would affect more the demanded characteristics of the final product (concerning the customer specifications, the column in the left).

2.4. Architecture and Prototyping

Prototyping is relevant in the concept development phase because it can test the feasibility and desire of the final product.

"...the value of prototypes resides less in the models themselves than in the interactions they invite." (Schrage, 1999, p. 20).

Although the statement, it is essential to remember that prototypes have limitations in the ways they are perceived, creating a possible bias in users and the results. The prototype developer should be aware of the potential user's bias and use prototyping techniques that are geared to what is needed to learn to minimize the distraction and inaccuracies that could mislead the outcome (Richardson, 2015).

2.5. Types of Prototyping

Prototype Representations
Proof of Principle Prototype: *It focuses to prove some central functional features of the proposed design but typically does not have all the characteristics or functionality of the ending invention.*
Working Prototype: *It expresses all or approximately entirely of the functionality of the ultimate result.*

[17] The QFD was compiled following a flexible approached allowed by the literature cited in the text.

- The scale 1-3-5 of importance (both in the left column of factor importance, and competitors) is assigning one of these numbers in relation to the factors in the left column.
- The green circle (full and void) have a value of 10 and 5 that multiple the scale sum of the 1-3-5 scale of the column, giving the importance of scale in the "relative importance".
- The controlled factors are the engineering and design factors in relation to the left column.
- The "rooftop" represents the correlations within factors, for example if the size increases also the wheels increase, so it is a positive correlation.

Visual Prototype: *It symbolises the size and look, but not the functionality, of the planned project. For example, in a visual prototype geometric features of a design can be represented, with less concern for colour, fabric, or other aspects of the finishing product.*
User Experience Prototype: *It shows adequate part of the appearance and purpose of the eventual product and it can be used for consumer examination for validation.*
Functional Prototype: *It includes equally function and exterior design of the envisioned product, it does not have to be in the precise size.*
Paper Prototype: *It is usually made by print or drawing for the customer interface of the software product. These models are normally beneficial for initial testing of software design, and decisions on what are the feature wanted by the user.*
The general types of prototyping[18].

It is essential to remind that the Smartbag "product" is divided into two parts in this description. The first part is the *physical* one, the "cover box," while the second is the *software* interface, the "Smartbag app." For the development of the final Smartbag prototype, different approaches were used for the physical and software application. This has been done for the efficiency of resource allocation and to fit the scope of prototyping in the different stages of the research. Mainly, for the Smartbag *physical development*, validation and representation of *the visual, working, and user-experience prototyping* have been used to finish the project, having as close as much a functional prototype (the fabric is not the same. Thus the appearance is not as intended). Regarding the *software app*, the *paper* and *functional prototyping* were applied. More details about the prototype evaluations are stated in chapter 5, while the most significant representations of the type of prototypes for Smartbag are in Appendix 4.

2.6. Prototyping Strategy

[18]ThomasNet (2015), "General Prototype Categories", available at: https://www.thomasnet.com/articles/engineering-consulting/general-prototypes/

There are two approaches to the prototyping strategy in conformity with the written work (Christie et al., 2012). Namely, business and engineering attitudes.

The business approach acknowledges the weight of innovation during design practice and the utility of prototyping for future product development. However, management does not necessarily comprehend how to build a physical product.

The other attitude is the engineering process. According to the author's Christie et al. (2012), engineers spend more time in analysing and testing the physics of virtual prototypes (CAD, CNC, etc.) and lack to define an ideal approach to move from concept to real product as stated in the project management literature (Christie et al., 2012). While testing is necessary from an engineering standpoint, the scarcity of real-world prototyping with real users could end up neglecting customer feedback and requirements, the feasibility of usage, and interfacing modelling.

Conforming to the literature, Christie et al. (2012), there are nine strategical factors to take into account to avoid the limitations of the two approaches (business and engineering) explained above (see Appendix 4, 4.0). The factors chosen[19] (number 4 and 8 in Appendix 4, 4.0) for the Smartbag process are the considerations on having a physical or virtual prototype and different material for the ideal Smartbag product. The reason for that is that the physical prototype served to gather user feedback and how they act in the presence of Smartbag. This leads to an increase in the tests on the number of features and requests that the *virtual prototype* was *not* able to offer[20]. The CAD concept served as a testing and creative lab for parameters as size, volume, material thickness and colour, wheel distance (for the equilibrium), and to give the writer a geometric and aspect view before assembling the physical prototype.

Moreover, Smartbag physical prototype is made out of materials that may be different from the specification of the users and industry. This was done for cost reasons and to try the size and functionality of Smartbag product with real users.

[19] 4. Considering having virtual prototype or physical, 8. Similar or different components for prototyping than the final design.

[20] For example, according to the observation and comments of the users, when she was pushed in the wheelchair, their refer to the prototype as “cumbersome” thus, wanted something to hook Smartbag to the wheel chair armrest, in order to free up the hand of the assistant to push their wheelchair.

2.7. Financial Analysis

The financial consideration is part of the development of the Smartbag solution. A business model was developed, following the design thinking process in analysing the economics of the innovation and accessing if the opportunity is worth pursuing because of future business. Furthermore, in Smartbag design thinking can be practical to the commercial purpose because in detecting and delineating the users clearly and approaching their needs sympathetically, the business model can also be shaped on that.

In this regard, the customer experience led me to discover the desired price range and shape the business model to benefit the users, giving value (to people often with limited mobility) through a subscription business model to receive the catheter bags directly at their homes when they run out of them. These discoveries are intersected with the Smartbag business and product development to have a more efficient balance between customer needs and financial outcomes. To demonstrate that the projected economic model, net present value, and cash flow analysis are stated in more detail in the last chapter 6 and the business plan in Appendix 5.

2.8. Smartbag Development Processes

The type of development process applied for Smartbag is the agile[21]. Both design thinking and agile include principles and frames to apply in activities of the product development. When attentively and simultaneously applied together, the dual approach helps to produce a better outcome, differentiated solutions that push growth and create new value to users. While the design thinking approach method helps to definite the *"Why"* of the Smartbag, the agile principles motivate the *"How"* (Lukasik – Saylor, 2018).

[21] Types of development processes can be classified in staged, spiral, and agile methodologies. The differences are based on the type of cycle the process takes before the product development. The agile method is more flexible and have shorter cycle in term of time compare to the other two. Regarding the staged delivery phase, although there is some similarities with the agile method, some of the key point is that the client does not have to be involved if they don't want (differently from agile that it is needed to deliver value) and the rework each component needs is minimised in the way to build it only once. While in agile during the process it is possible to change the implementation or the interface. Moreover, the variables for the Spiral method such as requirements known in advance, not changing during the process were not feasible with the Smartbag development (Osherove, 2005).

Agile method practices guide the delivery of the project in determining smaller components in the planning and objectives. Hence, the revision or adjustment of project iteration is made along the way upon real-time feedbacks from testing with users.

Although the Smartbag was developed only by me, the literature Hill, 2015, suggests synchronizing the two processes (Agile and Design Thinking) in a way that people involved in the project should attention on providing valuable results for customers rather than on productivity objectives such as financial, percentage of products success, the yield of defects (Hill, 2015). This was useful in Smartbag when assigning economic value and time constraints after the value and product specification were clear.

To apply Agile, certain conditions have to be present. As claimed in the literature (Rigby et al., 2016).

- **Marketplace conditions**: Consumer inclinations and solution options change often.
- **Consumer Participation**: The cooperation with users help the team to receive rapid feedback and make the customer understand better what they want as the development advance
- **Type of Innovation**: There are unidentified solutions, and the final object is not completely clear, product specifications may change. Furthermore, original revolutions and time to market are significant.
- **Work in building-blocks**: Developing the project in small cycles to conduct manageable mistakes and incremental iterations that create value.
- **Valuable Mistakes**: Breaking down the work can increase learning.
- **Enthusiastic members**: The project should be carried by determined contributors (Rigby et al., 2016).

In the Smartbag process development, all the conditions were present, with as mentioned the differences that one enthusiastic contributor formed the team. This fact made me learn more about all the aspects of development. The advantage is the achievement of a strong knowledge of product specification in the first stages of a prototype as the Smartbag. However, for more advancement, to bring Smartbag to market, a team[22] of three or four people would be ideal, including, accountant, software-developer, electronic-engineer, marketing/salespeople. The discussion on how to build the Smartbag is explained in prototyping, chapter 5.

[22] The team section and people required is in Appendix 5, 5.5.

Sub-Conclusion

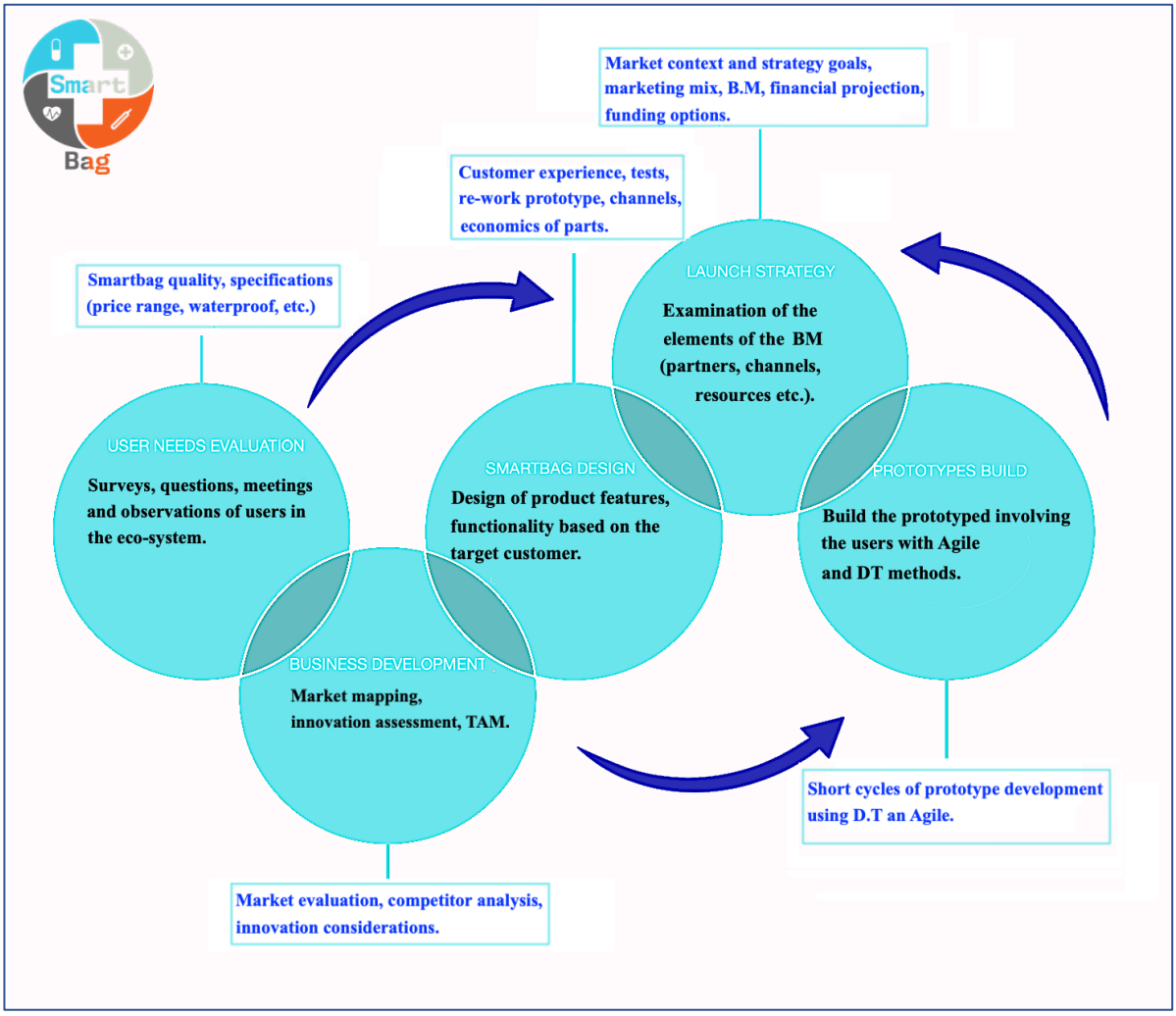
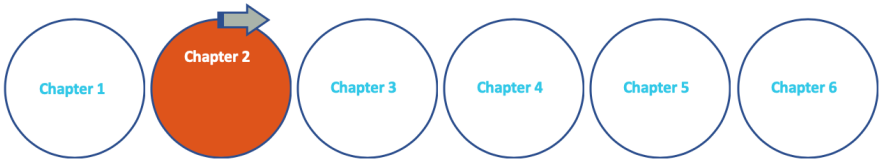


Figure 7. Smartbag Cycle Process (Own made).

The chapter served as an explanation for *WQ.1, "What is design thinking?"*. Specifically, the design thinking method facilitated the progression from customer's needs and the discovery of opportunities in the healthcare environment to the business model building. The three questions (desirability, feasibility, viability) that condense the approach are in deep re-examined in the subsequent chapters. The procedure turned out to be flexible and fitted the purpose of the Smartbag research problem. Figure 7. above represents the connected cycles of Smartbag, in the different phases of the design thinking process.

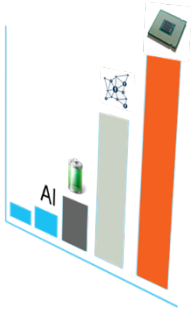


Chapter 2

Exponential Technologies

Introduction

In this chapter is clarified working question WQ.2 "What is exponential technology?" to understand how can be beneficial for the Smartbag business. The first part of the present chapter defines the technological tools available for Smartbag and, finally, how to use them to fulfill the user needs. The definition is facilitated by the original illustration of Ray Kurzweil (2015) of the law of accelerating returns (LOAR).



The chapter is sectioned in the two sub-work questions:

1. *Which exponential technologies to use for Smartbag?*
2. *Why use exponential technology in Smartbag?*

In line with the design thinking approach described in chapter 1, the current section is dedicated to exploring the technological feasibility[23] to deliver the value and requirements around the circumstances where Smartbag would be placed. Understanding the choice[24] of the technology behind the Smartbag opportunity is fundamental to deliver the desired values and build a viable and sustainable business model (Diderich, 2020, p. 177).

1. Vision and Technology Overview

While the Smartbag proposal is based only on a simple application of sensor technologies, the founder (me) has a broader vision for the Smartbag products and the healthcare system. It is worth to spend a few paragraphs to explain the concept and how exponential technology can help to get the vision to become real.

[23] Feasibility: can Smartbag deliver a solution that is technologically feasible and respects the customer value proposition? (chapter 1).

[24] This is also done by considering the medical usefulness (Medical Reason section, chapter 5) of the data such urine output, gender, age, illness and pathologies, bags consumption, healthcare number identification. Thus, Smartbag proposes to integrate the necessary technology into the Smartbag to collect the desired information.

"Soon, Smartbag's products will assault the healthcare market. Sensors will give real-time data to Robots and clinics 'staff. Computational power will allow machines to predict with mathematical models what patient needs help first, what resources to deploy, and how AI will monitor every single motion inside the healthcare environment, assisting the patients efficiently…" (Giovanni Amenta, Smartbag).

The statement above may seem ridiculous, but taking a look at today's technology permits, it is not even bold enough. It is not in the scope of this thesis to go deep into all the aspects of my vision. However, I think that a small introduction to exponential technologies, AI, and sensors are necessary.

2. Exponential Technologies

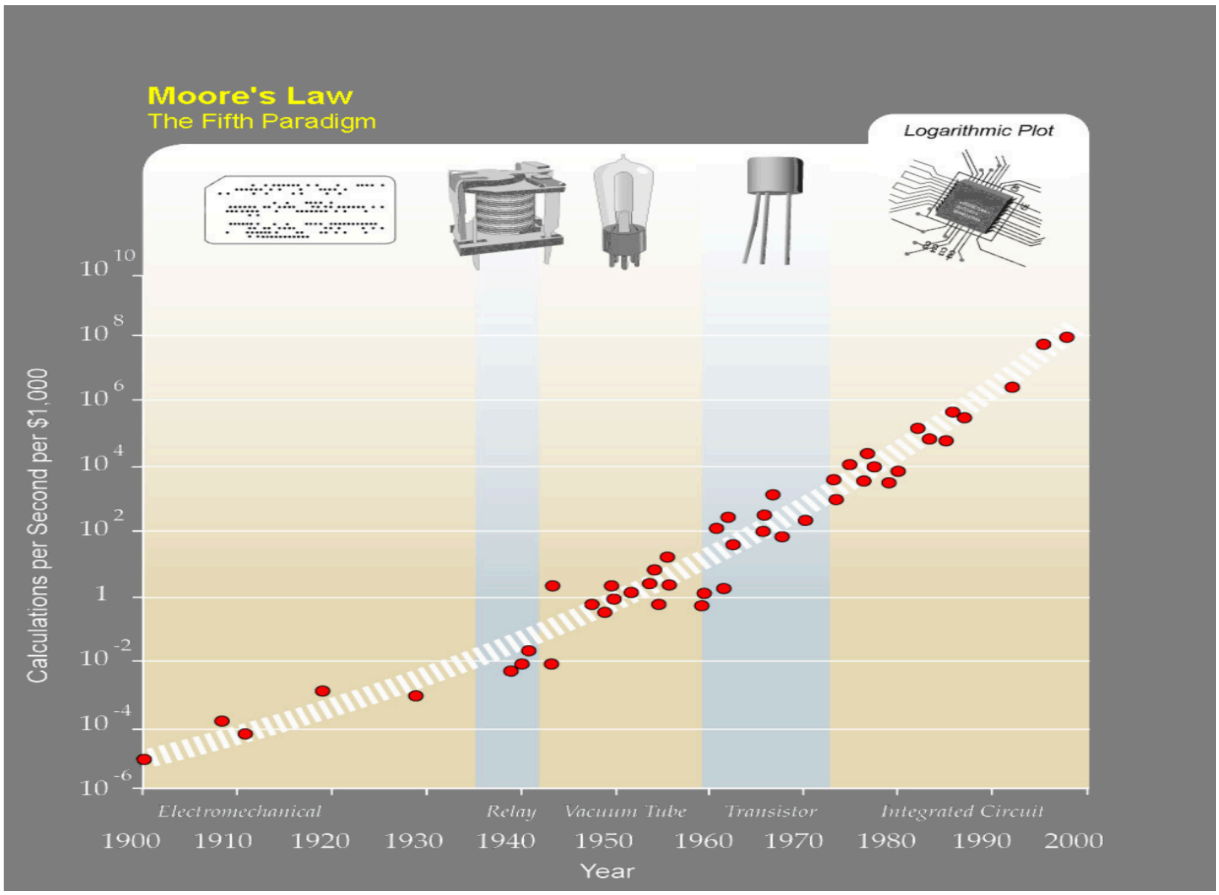


Figure 8. Moore's Law (Kurzweil, 2015).

This paragraph gives a brief explanation of exponential technology, addressing the *first* sub-work question, "*Which exponential technologies to use for Smartbag?"*. To understand the potential advantage in using some of the tools in Smartbag. As part of the new industrial revolution, better known as industry 4.0, the research has indicated that technologies, following

Moore's law, (the capacity of microchips, thus, computers doubles every 18 months, representing exponential growth), also relates to other technological advances (Deloitte, 2015)[25]. To better understand the concept, figure 8 shows how the exponential curve shapes the development of computing power technology. In addition to increased computational power, they also tend to become cheaper. Some of the exponential technologies are AI, VR, AR, data science, digital biology, biotechnology, robotics, networks, computing systems, and 3D printing.

The intersection of some of these exponential waves increases the velocity of progress, and converging technologies accelerate the process even more, also called the Law of Accelerating Return (Kurzweil, 2015). Simply said, humans use, for example, our new computers to design even quicker new computers, and this creates a progressive feedback loop that further fast-tracks our acceleration rate, as, for computers, scientists use computational power to design new drugs, simulate the weather, predict pandemics and so on. Once the information becomes digitalised and processed by machines, the developments become astonishing (Diamandis - Kotler, 2020, p. 25). To put the described notions in the vision and context related to Smartbag, I would like to cite a recent statement in the American Association of Critical-Care Nurses, 2018.

"Humans are incrementalists by nature, whereas technology increasingly is exponential. Thus, future changes, which are being led by technology, should be viewed as exponential and different from changes of the past 30 years" (Harrington, 2018, pp. 11-14).

What inspired me to sail on the Smartbag journey are, in particular sensors, connected through networks, where affordable AI will manage the information. The maturity of converging technologies suggests that this is the best time to create a healthcare business that is personalised, proactive, and prospective (Diamandis - Kotler, 2020, pp. 343-351).

2.1. Networks and Sensors

The most commonly known networks are the internet and the brain. A network such the internet exchanges information through *"electric nets"*, in the form of signals. In the industry, 4.0 more

[25] Deloitte (2015), "Industry 4.0, Challenges and solutions for the digital transformation and use of exponential technologies", available at: https://www2.deloitte.com/content/dam/Deloitte/ch/Documents/manufacturing/ch-en-manufacturing-industry-4-0-24102014.pdf

signals will come from devices called sensors (which measure weight, temperature, humidity and so on). If on one hand, 5G and telecommunication technologies will bring to connect 75.5 billion devices by 2025 (Statista, 2020)[26], on the other, thanks also to the smartphone industry, sensors technologies will become more inexpensive. What makes the time right, to start the Smartbag venture, are the fact that mutually access to networks and sensors are becoming incredibly cheaper and available (Diamandis – Kotler, 2016, pp. 98-112). The opportunity becomes more appealing if we think about the problem of nursing monitoring/management as a problem of Operational Research.

2.2. Management Science 

While applied mathematics and models have tried to solve management problems in the supply chain, financial engineering, simulations, and manufacturing, etc., they lacked a precious piece of information: detailed data about the elements of the models. Typical examples of problems solved with Operations Research (OR) are warehouse robotics optimization of Amazon Kiva (Jun-Tao Li - Hong-Jian Liu, 2016), and Walmart's inventory management (Greenspan, 2019). In brief OR is a subject that deals with advanced analytical techniques to help make better decisions with the scope of the systematic and analytical decision-making process and problem-solving (Rajgopal, 2020).

In the healthcare system, problems like bed occupancy[27], capacity planning, management of blood banks, the performance of patients, general allocation of resources (Brandeau et al., 2006) are solvable with OR algorithms, in specific the author (Hall, 2012, pp. 177-243) pointed out in what way predicting, queueing models, stochastic process models can be efficiently deployed. Mathematical coding can advance nurse scheduling, bed management, appointment setting, and many other healthcare processes. The facts stated above concurrently with the development of the technologies previously mentioned create a chance for the writer to solve the problem of the catheter bag system (sub-part of the bed assistance issue) with tools previously not readily available.

[26] Statista (2020), "Internet of Things - number of connected devices worldwide 2015-2025", available at: https://www.statista.com/statistics/471264/iot-number-of-connected-devices-worldwide/

[27] In Denmark counting the number of beds, number of the nurses, we can determine the ratio of occupancy, which is around nine patients to 1 nurse during the day and 11 to 1 during the night (Health Affair, 2014). This fact brings then to spot a problem of "staff shortage" (in Hospitals).

2.3. Artificial Intelligence 

According to scholars (Garbuio – Lin, 2018), AI can benefit patients by giving them access to tailored, confirmed, and actionable information. Furthermore, AI increases the diagnostic efficiency by providing a quicker and more accurate recognition of slight changes within the patient's health data and correlating such variations across similar patients. With the business model value creation through AI use (in healthcare), the literature has categorized seven archetypes[28]. With the lens of this description, in my vision, Smartbag would fall into two archetypes.

1. The *personal health companion archetype*, where AI technology assists patients in managing a preliminary analysis. In this way, the information asymmetry between medics and patients is reduced by offering patients the data-based examination and making use of the health care information collected.
2. The *promotor archetype*, which connects the appropriate health care medical specialist, in the diagnosis phase. Thus, facilitating the availability of data, treatment, and doctors. Moreover, it increases efficiency in directing promotion or sales for health care providers (Garbuio – Lin, 2018, p. 14).

3. Smartbag as Exponential Organisation

The present paragraph established a base for addressing the *second* sub-work question of the chapter, "*Why use exponential technology in Smartbag?".* An Exponential Organisation (ExO) is a new organization that uses tools and systems while leveraging accelerating technologies (Ismail et al., 2014, p. 36). Moreover, to build an ExO small teams leverage external resources to achieve their goals to increase flexibility and margins as opposed to a traditional business that tries to own physical assets. Transforming information in the ultimate asset of the company that will lead to exponential growth.

According to Ismail, both traditional assets and expertise can be supplied by external and temporary resources. To this end, it is possible to leverage communities and the crowd for

[28] 1. Information Provider Archetype; 2. Specialised Diagnostic; 3. Aggregator; 4. Personal Health Companion; 5. Smart Prevention Companion 6. Connectors Archetype; 7. Promotor (Garbuio – Lin, 2018, p. 10).

many traditional functions to run inside the enterprise, involving idea generation, funding, design, distribution, marketing and sales (Ismail et al., 2014, p. 143).

In the case of Smartbag, the experiences with the users suggest that the OR science and data can be combined to assist the nurses/assistants to do a better and efficient job[29] managing their time. While AI (machine learning) will be used to analyse patient's information over time, linking patient's information (CPR, age, location, illness) with urine data to deliver the best pre-diagnoses related to urinary issues (kidney/dehydration). Beyond the diagnostical purpose, the data will be used to provide the quantity needed for drainage urinary bags to the patients in the exact period. This would connect bag suppliers and consumers to get out the best value from both sides. The advantage of using the external platform for machine learning implementation tasks (such as Microsoft Azure, IBM Watson, Hadoop, and Cloudera) could give the chance to save money on the hardware and software infrastructure implementation.
In line with the literature, the steps to follow for the implementation of the Smartbag algorithm are as below:

Gather	Collect data via sensors and humans, or imported from available datasets
Organise	Organise the data, extracting, transforming and loading them into the platform
Apply	Use machine learning to recognise patterns and adjust algorithm systems.
Expose	Make available the data as an open platform so *"the ExO's community to develop valuable services, new functionalities and innovation."* (Ismail et al., 2014, p. 158).

All of this above would be possible also thanks to the physical vehicle where the data is collected, namely network and sensor technology. Given, the exponential technology trend will continue the costs of buying the parts for Smartbag and implement technologies (AI chip,

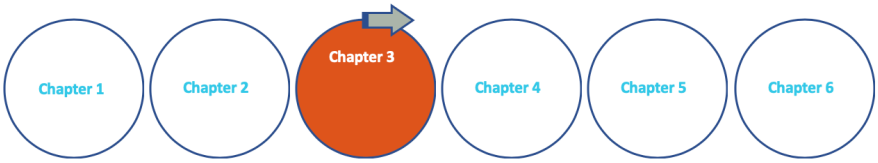
[29] For example, during the observations, the writer notices that some of the private sector nurses can have more than one patient. In the specific condition, they go to visit their patients routinely to change the catheter bag at a particular hour of the day. Smartbag could let them know which patients are closer and have more urgency based on the data collection of all the patients the nurses manage.

sensors, and even batteries)[30] would further decrease exponential, increasing the Smartbag margins from a supply perspective. Once a significant number of customers will get into the Smartbag system will be possible to implement other products using the information collected or merging that information with other exponential information-based products to create the "healthcare economy platform" mentioned in the introduction.

Sub-Conclusion

The chapter served to specify WQ.2 better *"What is exponential technology?"*. The vision for Smartbag is to create a healthcare platform economy, starting with a niche market, as mentioned in the introduction. The ample opportunities connected to exponential technologies leave open doors for the future of Smartbag integration in the healthcare infrastructure.
Moreover, the choice on how to build the prototype and future product has been justified based on the above circumstances and to solve in a different way the problems mentioned (management, monitoring). More in specific, I believe it was essential to explore the features that would make the product the perfect fit for the job to be done while exploiting the data, the sensors, and the AI technology. Additionally, having an idea of what tech-equipment to use will simplify the understanding of the supply chain for the components and people's expertise to hire for the creation of the Smartbag business model. The specific Smartbag components are described in the prototype development. At the same time, the implication for building Smartbag as an ExO start-up with consequences also in the business model (Crowdfunding, Crowdsourcing, Team, Channels, etc.), are better explored in the last chapter (6) about the business plan.

[30] Sensors: The average price for IoT sensors has declined from $1.30 in 2004 to $0.38 in 2020 (Microsoft Trend Reports, (2019), Manufacturing Trends Report, available at: https://info.microsoft.com/rs/157-GQE-382/images/EN-US-CNTNT-Report-2019-Manufacturing-Trends.pdf. Batteries: Battery prices, have fallen 87% from 2010 to 2019. By 2023, another 30% to 40% increased efficiency is expected to bring the average cost to $100/kWh (Henze, in Bloomberg NEF, 2019).



Chapter 3

Understanding the Marketplace

Introduction

The chapter is a result of the investigation of WQ.3 "What market to address?". The first part is a summary of trends in healthcare in the U.S and Denmark. The reasons for that are to give a glance to market opportunities or constraints that could afflict or benefit the Smartbag business development in the chosen markets. The second part focus on the market sizes and potential. Finally, the last section emphases the perspective about old and new competitors.

The chapter is partitioned in the tree sub-work questions:

1. *What are the tendencies in the U.S. and domestic healthcare market?*
2. *What market Smartbag is in?*
3. *What market dynamics are important for Smartbag?*

The exploration of the market options for Smartbag is vital for finding a smart and reachable market opportunity. The understanding of the type of innovation possible with a device for people with a urinary problem should reflect the trends of the aging population (thus, more potential customers), capital allocation, and concern in data security. The information collected and summarised below considers these factors that will be used for building the business plan.

1. Summary Healthcare Tendencies

The material presented in this section would be useful to answer the *first* sub-work question, *"What are the tendencies in the U.S. and domestic healthcare market?"*.

In this section, the first sub-work question on the U.S.[31] and Danish market tendencies are addressed. For the U.S. outlook, information is taken by robust and as possible recent reports from PwC and Deloitte (2020). The information for the domestic (Danish) market is mainly

[31] The general view and predictions for the U.S healthcare, hopefully, can help the reader to get a point of view and direction for capital allocation, limitations and expectations in the overall picture and how these tendencies and similarities could affect or are present also in the Danish markets.

collected from Statistiks.dk, reports from the Danish Ministry of Health. The extended explanation on trends, drivers and constraints are in Appendix 2. The data analysed for the healthcare marketplace show good opportunities, with some limitation in capital spending, competition and legal policies[32].

U.S Market Trends 

1. Managers willing to automate repetitive jobs with technology (AI, IoT, Data).

2. Increasing in the aging population will increase the need for a more efficient healthcare system.

3. Privacy policy concerns related to data from patients (PwC, 2020).

U.S Market Drivers

1. Home health (Allen, 2020).

2. Private equity as the accelerator (PwC's Health Research Institute, 2020).

3. Need to control healthcare costs will fast-track analytics (investments), (Marketwatch, 2018)[33].

U.S Market Restrictions

1. Legal and Capital entrance difficulties (Clarke, 2016).

2. Slowing down spending on Healthcare (short-term) (Deloitte, 2020).

[32] Concerning user's data privacy policies to be addressed and legal complication in market entrance due to the different laws applied in the various countries.

[33] MarketWatch, "Healthcare Analytics Market Drivers of Growth Analysed in a New Research Report", available at: https://www.marketwatch.com/press-release/healthcare-analytics-market-drivers-of-growth-analyzed-in-a-new-research-report-2018-11-08

3. Increased competition from (established) technological companies (Chen, 2019)[34].

Summary of Denmark Healthcare 

Mutually stimulating for the development of the Smartbag venture, it is also the potential business starting point, which is the Danish market[35].

- Increased life expectancy, thus growing aging population (Denmark Statistics, 2020).
- Government ambition toward the digitalisation of healthcare (The Ministry of Health, 2017)[36].
- Policy and culture are more focused on public spending rather than private healthcare, 2.8% GDP for the elderly (The Ministry of Health, 2017).
- One of the most appealing countries for capital investment in the world (Forbes, 2018)[37].
- European legal policy and domestic limitations on medical devices commercialisation (Ørndrup - Federspiel, 2019).

2. Smartbag Opportunities

This section is dedicated to the understanding of the *second* sub-work question, *"What market Smartbag is in?"*. The opportunities at this stage are evaluated, considering both business aspects and personal objectives and resources at the time of writing.

[34] Among them, Apple which updated its healthcare app, using the electrocardiogram (EKG) feature in the apple watch, while Alphabet helps Physicians taking note of information during a hospital appointment and connects home company Nest, to monitor patients in nursing homes (Chen, 2019).

[35] The Danish market object of exploration has been chosen mainly because I'm located in the Danish environment and it was easier to reach companies, hospitals, and players for the development of the Smartbag project start with a niche foothold to test the market.

[36] The Ministry of Health (2017), "Healthcare in Denmark an Overview", available at: https://www.sum.dk/English/~/media/Filer%20-%20Publikationer_i_pdf/2016/Healthcare-in-dk-16-dec/Healthcare-english-V16-dec.ashx

[37] Forbes (2018), "Best countries for Business", available at: https://www.forbes.com/best-countries-for-business/list/#tab:overall

It seems clear that Smartbag is in the healthcare market. The healthcare industry includes pharmaceutical, biotechnology, health insurance, medical devices and equipment, healthcare services, and facilities (Wilston, 2019). Smartbag would fall into medical devices and equipment sub-sector. Specifically, the Smartbag devices will serve people with urinary problems using the catheter system. Thus, it stays in the intersection between the medical device (market) for people who use urine bags (market). In this regard, it is useful to analyse the market potential for this segment of the patient, starting from a broader medical device perspective, narrowing down to the target market.

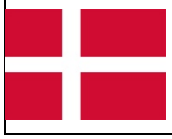
Healthcare Sector	Market Potential	Source
Global Medical Devices	Valuation of $425 bn (2018) ($613bn by 2025)	Fortune Business Insights[38]
Global Urinary Catheter Market	Valuation of $3.45 bn (2015) ($4.18 bn by 2026), 200 to 400 million of patients[39]	Markets and Markets, Fortune Business Insights
U.S Medical Devices	169.3bn (2018)	Markets and Markets[40]
U.S Catheter Market 	1.45 bn (2017), 25 million of patients (Around 40% of the tot. Market share)	Markets and Markets,
European Medical Devices	115 bn (2017)	MedTech Europe[41]
European Catheter Market	1.08bn, (projected 1.76 bn in 2026)	Fortune Business Insights

[38] The report is available in Fortune Business Insight (2018), at: https://www.fortunebusinessinsights.com/enquiry/request-sample-pdf/medical-devices-market-100085

[39] The number changes because different references have different numbers.

[40] The report is available in Markets and Markets, (2017), at: https://www.marketsandmarkets.com/Market-Reports/urinary-catheter-market-132934629.html

[41] The report is available in MedTech Europe, (2017), at: https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-1.pdf

Danish Catheter Market 	Less than 1m of patients for people +65.	(Sørbye et al., 2005)

2.1. TAM and SAM 

In view of answering the research question on building the initial business plan for Smartbag, based on the data, it is now possible to estimate the Total Addressable Market (TAM) and the Serviceable Available Market (SAM). The TAM is defined as the potential global market, while SAM is a segment of the TAM that can be reached. Specifically, it is the targeted market by Smartbag products and services, which is within the reachable geographical area.

- TAM: 200 million people
- SAM U.S: 25 million people
- SAM DK: Less than 1 million people (17, 700)

From a business standpoint, the U.S market looks more appealing, due to growth factors and size. However, other factors (such easiness of business development, exploration research, resource's reachability, etc.) at the current stage have to be taken into account in the business plan.

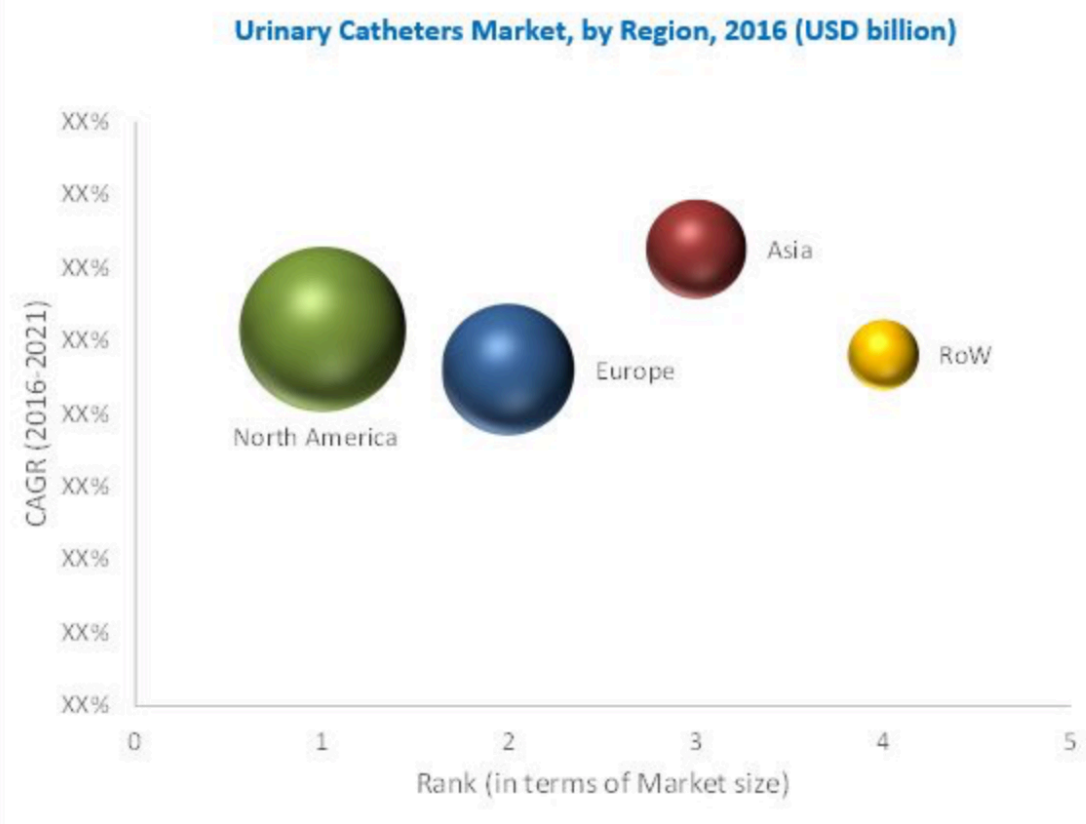


Figure 9. Geographical Distribution of Urinary Market Potential (Markets and Markets, 2017).

3. Measuring the Competitiveness

The last and *third* sub-work question has mainly a strategic purpose *"What market dynamics are important for Smartbag?"*. Addressing this will help to navigate in the writing of the next chapters, particularly in finding the ideal customer and building the business plan. Consistent with Credit Suisse on creating sustainable value creation (Maubossin - Callahan, 2013, p. 10), the industry analysis is divided into three parts:

I. *Creating an industry map*: assessing industry strength and categorising the industry to improve awareness of the main topics and prospects.
II. *Evaluate industry attractiveness*: using an analysis of the five forces.
III. *Reflect on the probability of being disrupted by innovation*: considering disruptive innovation that plays an important role.

The industry map is a useful tool to start a competitive analysis. It should include all the elements and firms that could impact future profitability and comprehend the present and possible relations that eventually shape the sustainable value creation (Maubossin - Callahan, 2013, p. 11).

3.1. Frameworks and Tools for the Analysis

Before going into the practical research of finding out competitors in Denmark, it is necessary to answer a few questions and understand the framework and the battleground in which Smartbag may move in the analysis of the competition. The popular tools available for competitors and strategy analysis are PEST, SWOT, Growth-Share-Strategy, Balanced Scorecard, and Porter five forces. While the PEST analysis has not been done directly, some of the aspect such the legal, technological, and economical has already been explored above, therefore it is not used in this section of the report. The Growth-Share-Strategy is more advised for already established companies (Henderson, 2013), that have the possibilities to differentiate their products. In a more extended vision where finance, customer relationship, business process, and growth are already in place, the Balanced Scorecard (Kaplan - Norton, 1992, pp. 71-79) would fit the purpose. However, at the stage, of Smartbag the strategy for achievement is still in progress. In specific, at this stage, Smartbag must address how to get a niche market foothold and create positive cash flow, without dealing with significant competition with more capabilities[42] than Smarbag. The more general frameworks that can be used at the current Smartbag phase are SWOT and Five Forces.

3.2. Competitor Analysis and Industry Map

For a theoretical explanation of Porter's framework, Appendix 3, 3.1. Regarding the medical sector, Denmark has many domestic producers that also occupy fair shares globally. The companies are most focused on the manufacture of devices for hearings, diagnostics, prosthetics, and orthopaedics. Conforming with the theory the industry map development should include these points:

Firms in order of power (defined by market share, size).

- Reflection on possible new entrants.

[42] Such as: capital, knowledge, time, experience and channels.

- Economic interactions.
- Estimate any other reasons that could impact profitability or success (regulations, labours (Maubossin - Callahan, 2013, p. 11).

The biggest companies in this landscape of the medical devices and pharmaceutical are:

Coloplast, Ambu, Bavarian Nordic, GN ReSound, H. Lundbeck, Novo Nordisk, Oticon, Widex and smaller companies such as Apodan, CimpaxApS, Continence Care ApS, and Codan Medical Aps.

The extended competitor analysis is reported in Appendix 3.2.

However, I considered important for the research to report the company who has major market share and global advantage (Coloplast.com, 2020), thus could become a bigger threat for Smartbag[43]. In order, to understand where the competitors face risks and could be vulnerable, according to Porter's framework (Porter, 2008, p. 68), I reported the risk assessment matrix of the company.

Coloplast, the company manufactures and deliveries products to hospitals and institutions as well as wholesalers and retailers. The category of products ranges from ostomy, continence, wound, skin, and interventional urology. Considered particularly innovative the company produces different catheter system and innovative products for incontinence. Moreover, their market is 63% in Europe following the remained U.S and rest of the world. They have production in 8 different countries, included Denmark. According to the brochure of the company the objective is to "make lives easier" using customer experiences and specialist supports (Coloplast.com, 2020).
At this point, it is interesting to look at their last annual report in the section of the business "continence care". The useful information for Smartbag are the followings:
They stated they have 40% (1st position in the world) of the global market incontinence care, the same market is growing at 5-6% per year, (due to increase in old population) and according to them is worth DKK 14 billion, (the market includes catheter bags), the increase is also due to different patterns from users and medical staff toward more efficient solutions.

[43] If they implement a similar product, given that they already have a big share (of the drainage bags) of the market and established channels.

From the same report their risk assessment matrix assigned a high level and likelihood to "Production and business continuity" as in the figure. In a specific example in a factory in Costa Rica:

"During 2018/19 Coloplast has seen an increasing number of cyberattacks e.g. phishing from hackers and other cyber criminals against the company, that in worst case scenario can affect the production and delivery performance." (Coloplast, Annual Report, 2018-2019).

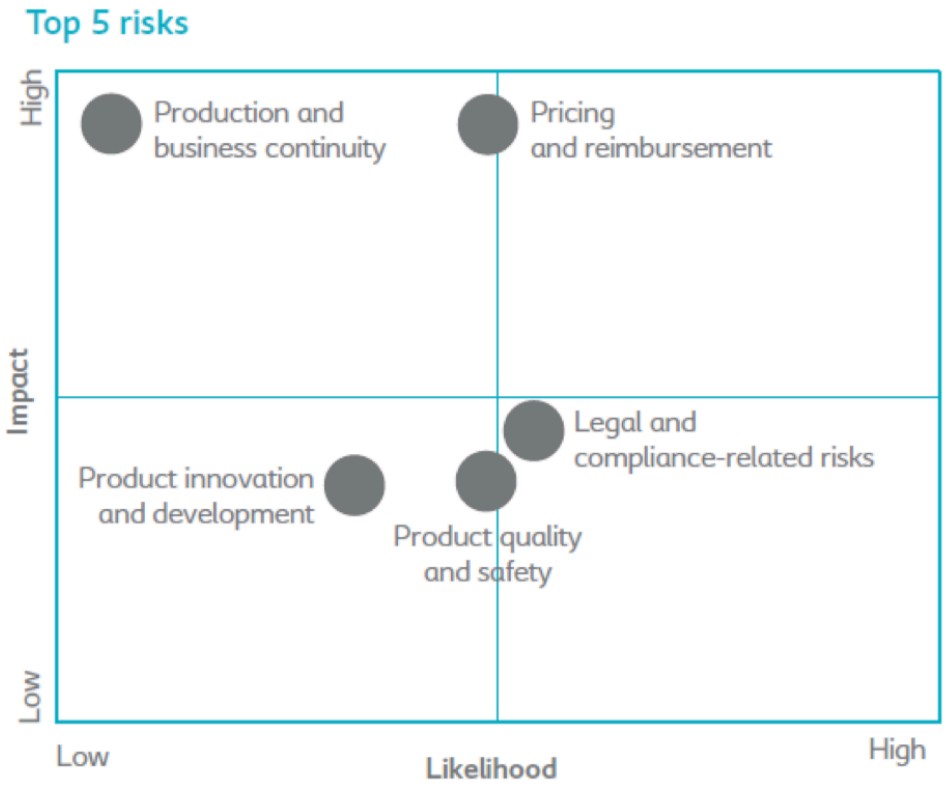


Figure 10. Coloplast's Five most Significant Risk Categories (Coloplast.com, 2020).

The threats for similar or same devices can come literally from everywhere; however, as it can be noted I gave more weight to the companies in the same category of Smartbag which are more obvious players in the same market such as Coloplast, where the possible aspects defined by "Porter Frameworks" where investigated. It is possible to find all the healthcare companies that are approved to operate, from the Danish Ministry of healthcare, because they have certain certifications such DS/EN 13485:2016, DS/EN ISO 9001:2015 standards (presafe.dk)[44]. For more information about legal requirements, Appendix 2, 2.8.

[44] Presafe.dk (2020), available at: http://www.presafe.dk/valid-presafe-certificates

I. Industry Classification

Supported by the literature, I consider it essential to *categorise* the industry, structure, and strategic opportunities (Maubossin - Callahan, 2013, p. 17). This is done because a different industry may have various opportunities or threats that Smartbag could associate with. The classification is based on the author's broad framework (Barney, 2002, p. 110).

Grounded on these categories and regarding Smartbag as in the medical devices market, it could be considered as a *fragmented* and international *industry* with the following opportunities: *discover new economies of scale, alter ownership structure, and multinational opportunities.* It is reported below a citation from Fortune Business Insight.

"The global medical devices market size was valued at USD 425.5 Billion in 2018 and is expected to reach USD 612.7 Billion by 2025, growing at CAGR of 5.4% 2018 to 2025" (Fortune Business Insight, 2018).

II. Porter's Five Forces

A valuable tool for addressing the capabilities and opportunities of the start-up venture is Porter's five forces (Porter, 2008, pp. 78-93). The analysis cantered in the Danish market and with attention on the Smartbag proposition is subordinate to understanding the level of competitive dynamism in the marketplace and evaluating the attractiveness of the Smartbag venture. The five forces are described as:

1. The threat of new entrants
2. Threat of substitutes
3. Bargain power of customer
4. Bargain power of suppliers
5. Competitive rivalry.

Notes: For convenience and logical sense, the information about the relationship between supply and demand (points 3 and 4) is put in the same column. The reasoned reflections on the Five Forces are reported in Appendix 3.

New entrants (Low)	Substitutes (Medium-low)	Demand-Offer (Medium)	Rivalry (Medium-high)
-Legal policies *-Distribution channels* *-Capital requirements*	*-Perceived level of product differentiation* *-Low switching cost*	*-Loyalty plans* *-Symmetric information* *-Design manufacturing* *-A large number of suppliers*	*-Brand loyalty* *-Market growth* *-Number of potential competitors*

III. Disruptive Innovation

After an overlook at what are the industry opportunities and which companies are well-positioned, it is interesting to investigate through the lens of disruptive innovation why a simple product as Smartbag could be a new entry threat also for "incumbent" with considerable resources and smart management (Maubossin - Callahan, 2013, p. 27).

Along with Christensen's theory, there are two forms of disruptive innovation: low-end disruptions and new-market disruptions. Smaller companies, who have fewer resources and offer a product that already exists is called low-end disruptors. Whereas a new-market disruption, enters the non-consumption market initially, it pleases customers who previously did not buy or use a product. In general, a new-market disruptive product is inexpensive or straightforward enough to empower a new group to benefit from it (Christensen, 2015).

"Generally, disruptive innovations were technologically straightforward, consisting of off-the-shelf components put together in a product architecture that was often simpler than prior approaches. They offered less of what customers in established markets wanted and so could rarely be initially employed there. They offered a different package of attributes valued only in

emerging markets remote from, and unimportant to, the mainstream." (Christensen, 1997, p. 15).

In my view, Smartbag falls into the "disruptive innovation" category, having defined Smartbag as a simple product and targeting a market that hopefully don't appeal to incumbents (because of the size, and not focus on their core business). Targeting this unserved market with Smartbag products and meeting their (customers) needs should allow Smartbag to have time to develop other services/products that will appeal to the incumbent's ordinary customers. This vision, of expanding in different sectors by starting with a niche market, is built into the Smartbag's logo, as mentioned in the introduction[45].

From a monitoring standpoint, no product connects patient and assistant/relative as Smartbag proposal. This delineates Smartbag as a new market entrant disruptor, and people that cannot afford to pay an assistant 24/7 will now have part of the solution that comes in their aid. However, if Smartbag is seen from another perspective, it does not compete with any other products and will be an integration of a system. Nursing and assistant will do the same job more efficiently. This point of view can fit into the blue ocean theory, considering Smartbag, a *non-disruptive market creation*, where no product or system in place will be disrupted. According to the theory, in fact, *"disruptive innovation is limiting and captures only a partial picture of how new markets are created."* (Chan – Mauborgne, 2017, p. 52). To be considered a disruptive product a displacement of current offerings and jobs, as the old is disrupted by the new. Instead, Smartbag will answer to new markets beyond existing industry limitations (Chan – Mauborgne, 2017, p. 72).

Notes: The disruptive innovation theory may not explain Smartbag current product as "disruptive" at this point of entry, but following the theory and my long-term vision, Smartbag will enhance its product/service portfolio, disrupting companies that don't consider it as a current competitor. In the aggregate, it will be the starting point for disruption.

3.3. SWOT

[45] Generally speaking, Smartbag solution is simple and anyone could build it, especially large companies, the question "why they did not do it yet?" have two main responses: 1. There is no need for the 2. The business is not appealing for the players already in the game. The first option has been explored through meeting, interview and observation and the need (in the limit of the research) have been validated by the writer. The second option is an open question that will be explored better in the business section in chapter 6.

The SWOT represents a valuable tool for addressing the conditions where Smartbag is positioned at this stage. In the figure below are listed the more significant points (in my view). An extended version of the SWOT analysis is in Appendix 3, 3.4.

The SWOT analysis is comprising of external and internal factors, which, according to the literature, will help in addressing the strategic considerations in making the business plan (Gurel, 2017).

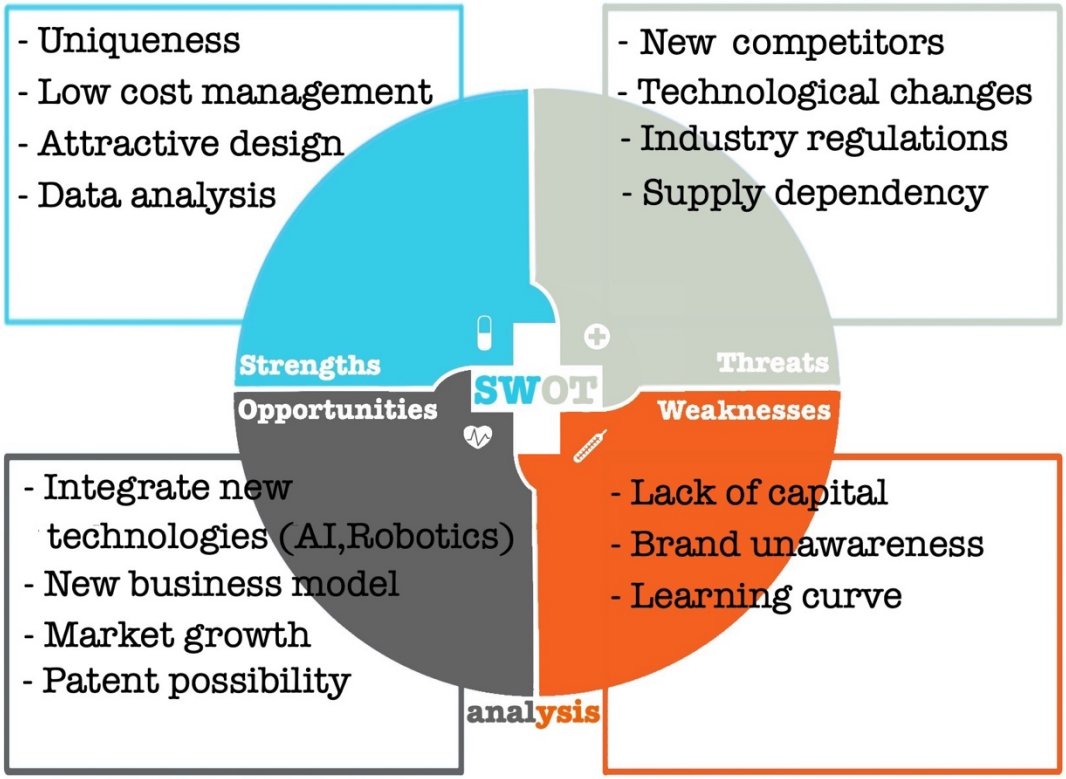


Figure 11. Smartbag SWOT (Own made).

Sub-Conclusion

The work question of this chapter, *WQ.3*, "*What market to address?"* was aimed to give a better understanding of which market to find the ideal customer. The data show that the U.S market has more potential in terms of market share. However, at the time of writing, I'm located in the Danish environment, and finding insights and observation about potential users in the U.S is more complicated than in the place I'm situated. Besides, in my view, the Danish market

can be an opportunity for a niche foothold, a starting point with highly technology adoptive users where Smartbag product can be tested[46].

"…excellent IT infrastructure, some of the world's highest penetration rates for mobile, broadband and computers, and progressive consumers who are quick to adopt new technologies." (Ministry of Foreign Affair Denmark, 2020)[47].

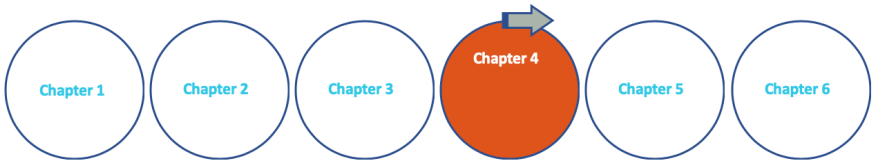
The study on the potential customers of the next chapter is consequently carried in Denmark. The business plan will take into consideration the possibility of expanding in the U.S market, contemplating the limitations of the user's research factor. The possible competitors listed in the current report could take the market more easily than Smartbag, however grounding the strategy and way of thinking as ExO start-up, it is more probable that new innovative products for the healthcare environment will come from other enterprises not yet in the market. As Ismail says:

"As young people and start-ups have plenty of ideals and ideas, the competitive advantage, as well as the field of competition, migrates towards their game and strong points. This is one of the key reasons why disruption today is more likely to come from start-ups than from existing direct competitors." (Ismail et al., 2014, p. 286).

This implies that a threat of new entrant from a small start-up like Smartbag that uses exponential technologies, flexible organisation, and (according to disruptive theory) focuses on a niche market that "incumbents" neglect can have huge advantages over the big companies.

[46] Denmark scored the highest ratings in DESI (Digital Economy and Society Index) 2019 and it is among the global leaders in digitalisation (DESI, 2019).

[47] Ministry of Foreign Affair Denmark, (2020), available at: https://investindk.com/set-up-a-business/test-and-innovation



Chapter 4

Finding the Potential Customers

Introduction

In this chapter, WQ.4, "Why should the target customers hire Smartbag?" is investigated. The primary attitude is to find the target customers and understand the healthcare environment where Smartbag will be distributed. To conduct the study, the core literature for the framework is Aulet (2013, pp. 23-69).

The chapter is structured in the following sub-work questions:

1. *Which healthcare segment to select as target customer?*
2. *Which healthcare sector to select for market penetration?*
3. *What is the job that Smartbag does?*

This chapter, concurrently with the design thinking approach, aims to discover the desirability: Is Smartbag addressing a real customer need and supporting one or more jobs to be done? (Diderich, 2020, p. 176). In the previous chapter, the potential size of the U.S market resulted in a positive perspective for the Smartbag starting point. However, at this stage of experimentation and uncertainty for the Smartbag product, I needed to be in the environment with potential customers to build a user profile. Thus, the study is shaped in the Danish environment.

1. Segments

To understand the potential segments in the Danish market (the choice is stated in the previous chapter) for Smartbag, the *first* sub-work question *"Which healthcare segment to select as target customer?"* has been addressed in the paragraphs below.

There are different categories of customers that could benefit from the Smartbag idea, from partial/total paralyzed people, to hospitalized patients with all the kinds of problem that affects the urinary system. The most appealing, because larger market segments are however the ones where it is possible to find these end-users. From a study conducted for understanding the catheter use in-home care, resulted that the issue is afflicting and overly affects older people. Approximately *50% of those who receive home care and obtains formal services are*

incontinent. Moreover, Denmark, as a result of the same study in the second place in Europe (for use of IUC by gender and by site among the home care clients in 11 European countries, Sørbye et al., 2005).

Another study on the most probable places where the catheter system is used are hospices/ nursing homes, hospitals or communities intended as normal residential houses, (Shackley et al., 2017), (Figure below). In this regard it is worth taking a look at the statistics for the considered categories of the population in Denmark, creating a profile of the potential user's base. Thus, below, three ideal segments of the market have been studied, explicitly *hospitals, nursing homes, and private customers.*

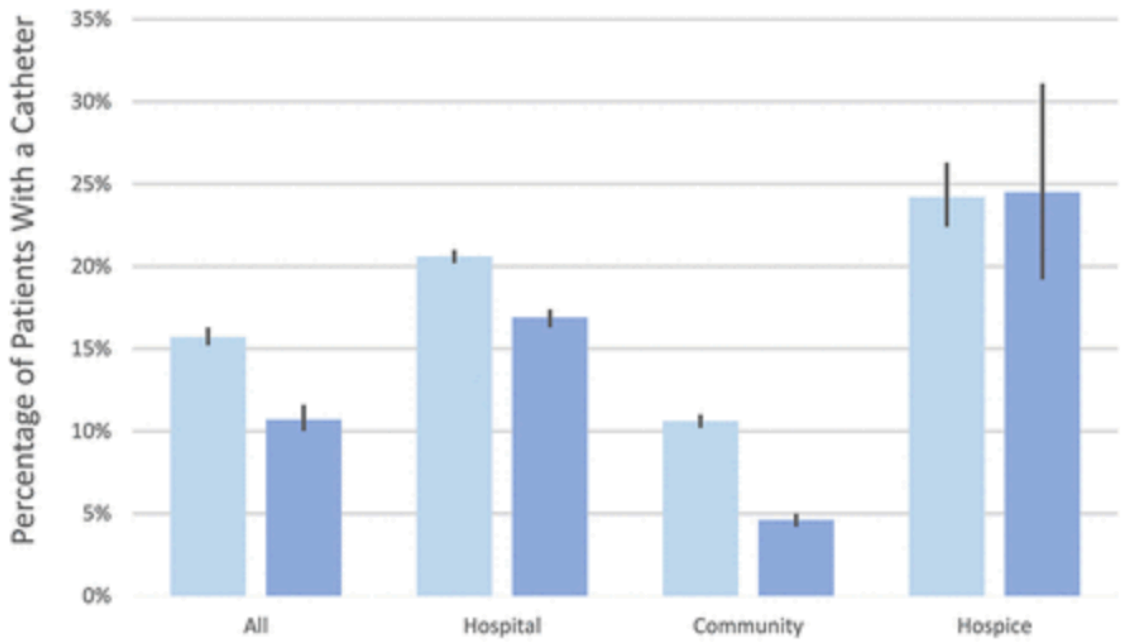


Figure 12. Percentage of Patients with Catheter (Shackley et al., 2017).

1.1. Hospitals

The second bigger portion, on where are people using indwelling catheter systems is the hospitals, where the idea started, and the problem was defined. The Smartbag idea includes both hardware and software parts, which based on the environments (hospitals or privates) would take shape differently. It is difficult to estimate or find data on, how many patients use the indwelling catheter system in a Danish hospital[48]. An idea to find a reliable estimation is to

[48] The experiences to gather data in the different hospitals showed that the medical staff does not count the catheter bag they use, thus they do not know. A better understanding is given reading interview A, Hospital experience, Appendix 1.

go in few hospitals in the city and calculate the average inventory per day (given that the catheter bag is usually changed every day), calculate the ratio of catheter bag per day/ total hospitalized patients, having that percentage would allow calculating the percentage on the total hospitalized national patients, thus finding the X number of catheterised patients. However, at the time I'm writing I could not access the information on inventory management of the hospitals (Due to COVID-19 all public facilities were closed, moreover the process of getting an appointment with the necessary people inside the hospitals turned out to be long and complicated).

Relying on another information source, from the National Board of Health, and data from the National Health Insurance, it was appraised that 8% of the patients are catheterized in public clinics, around 18 % of the patients are catheterized at their general practitioner and that roughly 74 % of the patients are catheterized by nurses in the home care of the municipalities. Besides, regarding the performance of the treatment and from a medical standpoint it was assessed that 86 % of all patients who need the catheter system can be accomplished by local home care units in nursing homes, the rest 10 % and only 4% by a specialist as a urologist (National Board of Health, 2009)[49].

1.2. Nursing Homes and Homecare

As elderly, it is common to consider people equal or above 65 years of age which in Denmark increased from 902, 859 people in 2010 to 1, 116, 062 people in 2018 (a growth of 23.6 %). In the same years, the number of individuals beyond 80 years has climbed from 227, 510 to 256, 694, 12.8 % growth). Despite the aging population increase, it is also a fact that the overall home help measured in hours went down about 18%. As a result, also the number of people getting home help declined by 12 %, from 162, 769 in 2011 to 142, 865 in 2016 (Danmarks Statistik, 2018). The fact can be explained because Danish elderly in general are having healthier well-being and functional capacities.

Worth looking is also the data about the share of the elderly living in nursing homes and care housing that is dropping. As in the global trends, for instance, from 2010 to 2016, the portion of the elderly above 75 years in institutional care decreased from 15 % to 12 %. (Danmark's

[49] National Board of Health (2009), "Shared care In Catheterization of patients with long term Urinary catheter need", available at: https://www.sst.dk/da/udgivelser/2009/~/media/4685D5353B714F80996DB337E6B0331C.ashx

Statistik, 2017)[50]. Similar declining trends are followed by other age elderly portions. This fact brings to think that more people are *taking care directly in their homes*, which is also supported by the Danish policy on providing nursing services by the municipalities. Consequently, conventional hospices are being slowly replaced by *home care*. In addition, a trend toward more social funding and investments in the elderly is rising in recent times.

1.3. Considerations

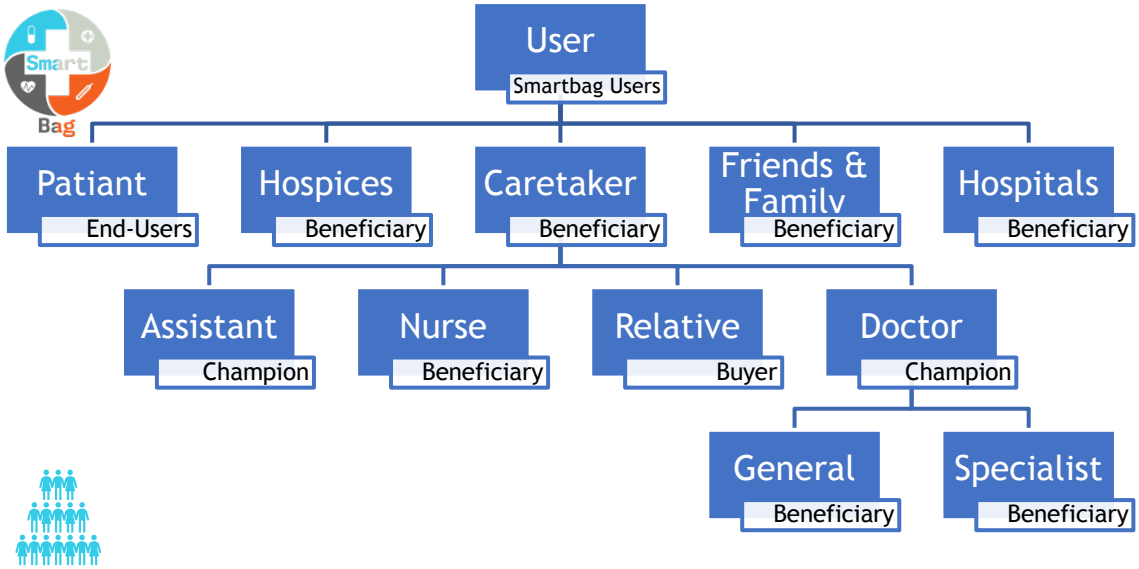
Even though the idea started with an inspiration from a hospital's pain, the data analysed so far suggests that a more significant percentage of beneficiaries of the Smartbag system would be present in the *nursing home and residentials*. Moreover, with a growing aging population and telemedicine home-care trends in Denmark, the future may look more brilliant for now to develop a solution for patients of the home care communities.

2. Customer Profile

In this section, the *second* sub-work question, *"Which health-care sector to select for market penetration?"* is explained.

Having defined the market segmentation, it is now possible to create a customer profile to tailor the Smartbag solution for their needs and market penetration. It is essential to build the business based on the customer the company is serving, rather than (as other authors suggest) pushing the products or services to sell onto the market (Aulet, 2013, pp. 51-56). To identify the people involved in the value chain, few distinctions have been made in line with the literature.

[50] Report: Denmark in Figures (2019), available at: https://www.dst.dk/Site/Dst/Udgivelser/GetPubFile.aspx?id=28924&sid=dkinfigures2019



Notes: The scheme is a simplification of the roles involved in the catheter system value chain. The combination of two or more roles or two or more attributes may belong to the same person. For example, the assistant and the relative can be the same person. Or the caretaker can be a friend inside the hospital infrastructure, or the patients themselves take the role of buyers.

In the Smartbag proposition, customers involve an end-user and a decision-making entity. The end-user in this case, the catheter system patients is probably a vital part of the decision-making process but could not be the most important element to take the decision. More explicitly:

1. End-User: The person who will benefit from the Smartbag, which I call the patient.

2. Decision-Making Unit: The people who choose whether the patient will purchase the product, comprising:

- Champion/Beneficiary[51]: The individual who desires the patient to purchase the product, can be identified as an assistant and medical staff.
- Primary Economic Buyer: The elements with the power to spend money on buying the product, that is usually a relative (Aulet, 2013, p. 51).

[51] The difference between Champion and Beneficiary is intended to reflect the simple model illustrated. For example, the assistant can desire that the patient purchase the product but at the same time the relative, doctors, hospitals or hospices could benefit from the service (directly or indirectly).

In the case of Smartbag, it is probably that the elderly doesn't have the full saying on what devices/products to use for their healthcare. In this regard, it is usually up to the relatives and assistants to take action on buying such products. In this scenario, it may be possible that the end-user is the old people, and the decision-maker with purchase authority is a close relative who supervises the person. At this point, it is possible to have an overall "persona" of the patient with the below characteristics.

The table below is based on desk research on data, statistics about patients with urinary problems in the Danish market, personal experiences, and observations. This is done to focus on a real customer and thus better addressing their pains (Aulet, 2013, pp.70-75).

Table 3. End-user's Characteristics

Factors	Characteristics	References/Motivations
Gender	Female[52] 60%, Male, 40%	Womenhealth.gov
Age Range	65-95	Based on statistics addressed in the current chapter (4).
Minimum Income	DKK 72, 756 per year (without benefit)	Social Security Program: ssa.gov
Geographic Location	Denmark	Easiness to reach the target customers (see introduction of current chapter 4).
Motivations	Urinary problems	Common denominator for the potential patients object of study.
Pains	Losing entirely mobility, neurological functions, dependence from others, etc	Based on my interviews and experiences.

[52] Urinary incontinence affects statistically more women than men. This is because reproductive health events unique to women, like pregnancy, childbirth, and menopause, affect the bladder, urethra, and other muscles that support these organs.

Reason for buying/using Smartbag	Fastest response to the catheter assistance, aesthetic	Based on the interviews and experiences.
Receiving Assistances from:	Home care services, General Practitioner, Nursing, Hospitals, Specialists.	Report: "Healthcare in Denmark", and personal interviews.

2.1. Customer's experience (B2C)

During the time of exploration on which is the best customer target, I discovered that the customers in private markets, specifically private houses, with one or two patients, catheter users are an excellent opportunity for Smarbag. Contrary to my initial thought that his/her dears always check the patient. Indeed, in some part of the day, for example, during the night the bag can become overfilled and explode, creating the apparent problems, another example is when relatives taking care of the patients are not in the immediate nearby. Furthermore, users and assistants made clear that the product would be considered a normal expense, for an aging population, associating the purchase as "ordinary" as the alike products: blood pressure monitor, drip system, cleaning, and monitoring merchandise for helping the patients to live a better life.

Relative's citation: *"I would buy a product like this…as I buy the other tools for checking the temperature or the blood pressure…"*

The interviews turn out to have "assembled" a customer request for the products, and the people involved (as defined by the literature, Aulet, 2013, p. 51) with the following wishes:

- Cost acceptable for the relative: around $20 to $80.
- Type of purchase: Preferably once every two years, within the cost range as above.
- Job to be done for the patient: Measure the urine output and notify the patient's assistant when the bag needs to be changed. Besides, from statistical numbers (Aoki et al., 2017) on female users and meetings, the secondary job is to cover the pee bag (aesthetic reasons).
- Data output for assistant and nursing staff: The data, eventually sent to a phone, would set the alarm when the condition of "full" is satisfied., with the option of predicting the time based on the liquid flow.

2.2. Reflection

From the interviews[53] and experiences, it seems that the market, both private and, in the hospital, has to be further segmented, from autonomous/dependable patients to critical/less critical. However, the difficulties in finding the data and on the research are also on progress for experts in the field. Especially the second experience[54] type brings to think that even if the Smartbag proposal would be tailored for the private market, in case the patients are in the hospital, they can still eventually benefit from relatives' remote monitoring (without any connection to the hospital infrastructure).

3. (New) Definition of the Job to be Done

According to the data (more patients in-home care), trends toward digital home (or telemedicine) care and growing aging population, experiences and lack of reliable information on the number of catheter users in the hospital's setting, the ideal starting point for Smartbag is the elderly home care system.

It is now possible to address the *third* and last sub-work question, *"What is the job that Smartbag does?"* to understand what progress the people involved in the process make with Smartbag. It is necessary to have an overlook of the circumstances and actors who get value from the Smartbag product and the amount they are getting related to the position of the layer (Christensen, 2016, p. 64).

- The first beneficiary of the Smartbag proposal is the home patient who has better monitoring services linked to the urinary catheter system, other than benefit from a more hygienic and aesthetic solution.
- The second actor to get value is the assistant who takes care of the elderly, who will benefit from Smartbag in receiving time alerts avoiding to overfill the bag, notification about urine levels analysis (for eventual treatment or to notify the doctor), and finally for moving the bag without dragging it onto the floor.
- The third (eventual but probable) participant is a relative who partially supervises the patient while the assistant takes care of them. In this case, they can monitor their dears remotely sharing information and data with the assistant.

[53] For an extended version see Appendix 1.

[54] See Appendix 1, Interview 2.

- The fourth player is the medical staff, who will receive the data regarding the patient and urine output instantaneously, simplifying the assisting and the diagnosis both in normal and emergencies[55].

Hence, based on this brief analysis and user interviews it is possible to answer the fourth sub-work question of the chapter. The users hire the Smartbag product for the main jobs:

1. *Functional job*: Patient monitoring and diagnostic, making the system hygienic, easily carry the bag and, saving time in bags (purchase) supply[56]. *(relative/assistant)*
2. *Emotional, Social job:* Feeling not embarrassed by having a catheter drainage system[57]. *(patient)*

Patient's citation: *"I feel embarrassed to show the urinary bag when my friends or nephews come to visit me…and it is a bothering problem when I move to have to carry around the bag".*

3.1. Reflection

At the beginning of the journey, I was initially inspired by an inefficiency in the hospital scenarios' indwelling catheter system. Even though the problem is still compelling to be solved, after new considerations on market aspects and customer experience, the Smartbag product seems to serve better and be positioned in a different kind of environment, the home of elderly people.

As the title of the section "Nursing *homes and home care"* suggests, it is resealable and time-saving to consider the profile of the ideal customer to be part of the elderly Danish population living in nursing homes or private residential properties and discerning the pattern of hospital's potential users. This is purposely done because the circumstances that separate the potential customers of nursing and private homes from the ones of the hospitals are operational and categorical different.

[55] In case the patient would be unconscious and the people around do not remember specific information (CPR, Drugs to take, past days treatments) or are far away from the situation, Smartbag App, gives the possibilities to record the pathologies, illness and type of catheter to be shared with the doctors instantly.

[56] The Smartbag app have integrated the automatic renewal of bags supply within the business model based on the experiences that the users with limited time have to go out to buy the catheter bags.

[57] The job to be done theory distinguish between functional, social and emotional job (Christensen, 2016, p.57).

In particular, the function of Smartbag to collect data for patients with urinary problems would be pretty much the same with the same pains, but who takes care of them and stays around is different, thus different circumstances. While in the hospital, the nursing staff and assistants cope with "many kinds" of patients, in-home care, the patients are the "same kind" and usually supervised by one assistant or relative, which will be the second beneficiary of the Smartbag idea. This change of perspective implies:

a) Different kind of software application that will be better explained in the next chapter.
b) Distinctive strategy and business plan to address the specific market.

Sub-Conclusion

The main goal of the chapter was to understand *WQ.4*, *"Why should the target customers hire Smartbag?"*, this has been clarified through consideration regarding where to find the patients, who are the users and finally why the primary beneficiaries (patient, assistant/relative, which in the private market have buyer power), should hire the product to improve their lives.

Chapter 5

Smartbag Prototype Development

Introduction

This chapter evaluates the construction of the Smartbag prototype system following a flexible design thinking approach. The WQ.5 "How is Smartbag concept transformed into a prototype?" is addressed in this chapter. A suggestion of software operations is also proposed based on the hardware and framework management of the patients' object of study. Finally, to create a future better version, I will analyse the prototype's boundaries and benefits.

The sub work questions of the chapter are:

1. *What are the medical reasons for the product?*
2. *What is Smartbag concept?*
3. *What products or prototypes can do similar jobs as Smartbag?*
4. *How to build the prototype for the jobs to be done?*

The evaluation of the prototype is useful for having an idea of what components, expertise, and team members will be helpful for the real product development of Smartbag. Thus, the prototypes help to build and evaluate both technical feasibility and desirability through the interactions and tests along the process. Besides, including potential users in the process benefits for assessing the innovation proposed of the final Smartbag (Diderich, 2020, pp. 10-11).

1. Medical Specification

While building a prototype is fun from an engineering standpoint, the product's usefulness has to respect the conditions for delivering value to customers. One of the requirements for Smartbag, (considering it a medical device) is the medical motivation for the existence of such equipment. Thus, in this paragraph, the *first* sub-work question is addressed "*What are the medical reasons for the product?*".

Measuring the urine yield is useful to know and understand the kidney status when the patient is treated, for example, with water solutions. It is fundamental to estimate *water balance* and use for multi-protocols to detect the patient's reaction toward the right treatment. Medical science suggests that among the most important,[58] related to urine output there are *kidney and dehydration/hydration* complications.

A satisfactory outcome translates into a well-oxygenated kidney (Brashear, 2011). Whereas if a patient's urine output is excessively low, in number approximately less than 0.5 mL/kg/h (a typical value is around 15 ml per hour), the patient could run into the disease called *Oliguria* (Boon et al., 2006, p. 475). Instead, if the liquid measured is almost zero/mL/Kg per hour, the illness called *Anuria* will be suspected in most cases. Equally, Oliguria and Anuria are usual complications in ICUs[59]. The problems related to the two issues described brings to symptoms like *Prerenal azotaemia, Postrenal azotaemia, Kidney damage*[60].

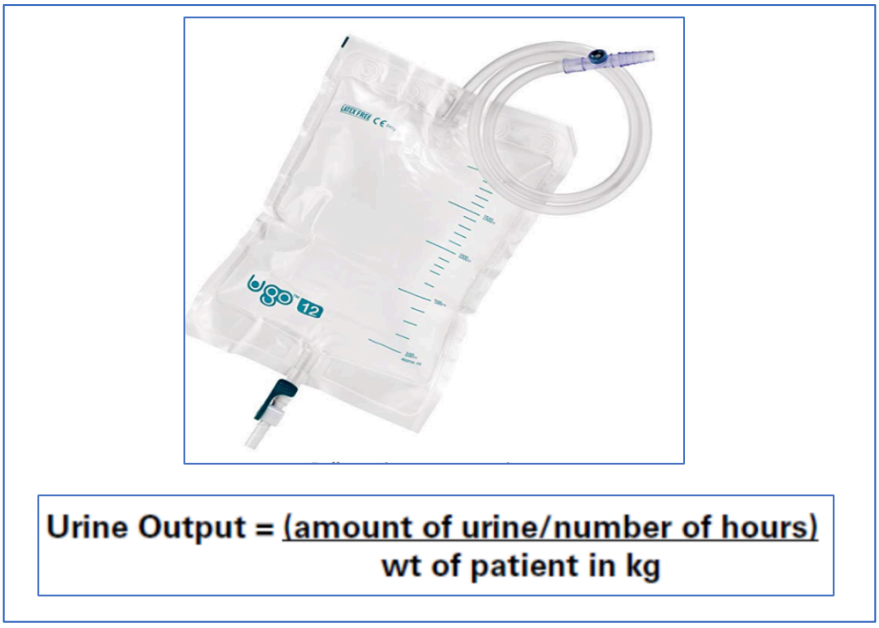


Figure 13. Catheter Bag (Scale Measurement in ml), Urine output Formula (Amazon.uk, 2020).

[58] There are other related medical problems linked to urine output, such diabetes, cancer, medical treatment, etc.

[59] The action of monitoring patients with a critical illness or difficult conditions is done by a specialist called "Intensive care units" (or ICUs). Danish intensive care units (ICUs) deliver government-funded intensive care to all Danish peoples. In Denmark, there are three different levels, founded on the level of staffing, equipment, and available professional specialties (The Danish Intensive Care Database, 2016).

[60] The different levels of importance imply that the care varies from level 1 to 3, thus, from monitoring every 4-2 hours to immediate help.

Regarding the dehydration issues, the principal parameters to be measured are volume and colour of the urine, thus, to be considered standard conditions, the colour should be pale, and the urine without odor. In contrast, less volume and darker colour, are signs of dehydration (Gunawan et al., 2018).

Just out of curiosity, the Medical Encyclopaedia[61] suggests that in normal condition an adult, daily urine product, is commonly about 800 to 2000 ml with a fluid entry of around 2 litres. As by now should be clear in the private and public healthcare facilities the urine output is still measured manually by notes using the scale and the weight of the patient, making it necessary to check the catheter bag every four hours and takes note at least twice a day.

So, using the intersection of data about body weight, colour, liquid millilitres and a workforce of nurses, it is possible to have an exceptional understanding of the urinary system conditions. The automation of the process with Smartbag could potentially use less labour, save time, register patient conditions instantly, and give more accuracy. Moreover, the data gathered could be used for better therapies and benefits for the patients. From a scientific standpoint, Smartbag would help to have a reliable dataset for scientific studies that analyse correlation within the data of the patients.

2. Overview of Smartbag

To have a clear understanding of how to realise the Smartbag prototype because of the Smartbag commercial product it is vital to grasp the essentials of Smartbag concept and vision. Thus, in this paragraph, it is appropriate to re-answer the *second* sub-work question, *"What is the Smartbag concept?"*.

Smartbag is a uniquely designed monitoring box in which a urinary bag can be placed. Smartbag will be equipped with sensors to monitor the urine bag level and will send data on urine volumes to a connected mobile device. Through a purpose-designed application, Smartbag will notify the patient/relative / medical assistant when the bag is close to full and needs to be changed. The data collected on the patient (illness, medical treatments, type of drugs taken) and on urine output are analysed over time to offer the best diagnostic and monitoring system. On top of that Smartbag can count the utilised drainage bags. This allows (as an option) the users to receive a new package every time they run out of them.

[61] Medical Encyclopaedia, available at: https://medlineplus.gov/ency/article/003425.htm

There is currently no similar product on the market that provides this monitoring solution. Longer-term, Smartbag will be integrated around the healthcare system value chain. Smartbag is the future of a medical device to be used as an integration of existing systems or new solutions, that will use data and computational power to coordinate the operations.

3. Prototypes and Products History Review

To have a better understanding of past and recent trials with similar objectives to the Smartbag (monitoring of the urine output), I considered it essential to investigate the *third* sub-work question "*What products or prototypes can do similar jobs? Smartbag?".*

During the last few years, different applications to solve the problem object of study have been created. The type of sensors available for the specific use can vary from optical, gravitational, pressure sensors, colour detector, to ultrasound, etc. It is essential to mention some previous significant work, to create something different and better.

Among the most relevant, similar products, it is possible to acknowledge the prototyping work in the development of a urine hydration system based on urine colour (Nusantara, 2018). In this prototyping work, the developers focused on the hydration problem, thus checking only the urine's colour, even though it is a relevant idea the paper does not apply the sensor to a catheter bag and does not address the customer and market problems, putting it only in an "algorithm" kind of solution.

Notes: The urine colour detection (possible with a colour sensor) will not be integrated in the first version of the Smartbag. The choice of not doing it is based on the reflections that the catheter bag is changed every day, thus the colour is detected anyway by the users. When detected and (if) necessary the users will use the Note Pad feature into the Smartbag app. Contrary to the volume that changes over time and needs a precise tool to be measured. Moreover, discussions with the doctors and patients made me realize that the colour is less important, and it is only checked in specific cases or during ordinary medical exams.

	Good
	Good
	Fair
	Dehydrated
	Dehydrated
	Very Dehydrated
	Severe Dehydrated

Figure 14. Hydration Scale for Urine Colour (Nusantara, 2018).

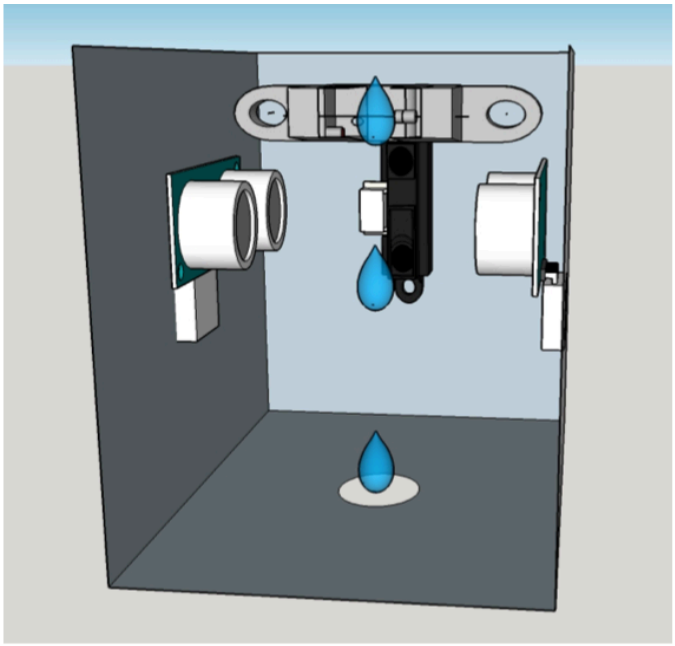


Figure 15. Design of Another Protype with Optical Sensors (Sanguansri, 2016).

Another sensor type prototype comes from an IT master thesis student, where he tries to solve the same problem (as Smartbag) of urine measurement output, using a different approach. This prototype developed uses an optical sensor, which measured the dripping flow between two parts of the tube connected to the catheter system. The idea, interesting from an engineering standpoint, changed the standard catheter design, making the commercialization and adaptation difficult. The student in question concluded to measure volume changes in the bag with the second version of his prototype. However, as the student's thesis says, it remains a "lab application" (Sanguansri, 2016). I consider the design over-complicated and difficult to implement in the real world. Figure 16. shows the receiver and emitter in the design of the master thesis mentioned.

Complementary prototyping work was published in the article with the title "A Low-Cost Device for Monitoring the Urine Output of Critical Care Patients" (Otero et al., 2010). In this work, the authors show the feasibility of a Bluetooth connecting the devices with a PC. However, they make a magnetic measurement of the liquid inside a tube integrated into the

system, as they state the legal and commercial feasibility didn't allow them to go further. Also commercial products were developed during the past years, most famous of the category is the Urinfo 2000, created and commercialised in 2009 (Medgadget, 2010), it was composed by three parts the digital monitor, the flow (infrared) sensor, and a disposable plastic bag. It was built to revolutionise the entire catheter system. Still, accurate the Urinfo did not transmit the data to a central unit where all the medical staff can go to check and analyse data.

Figure 16. Urinfo 2000 (researchgate.net, 2017).

The nurses have still to go to check the output measurement and takes notes manually. Urinfo 2000 is no longer offered in the marketplace. The company had been bought by Flowsense, and the developments had been dropped.

The proposal of a new monitoring system was built on the knowledge acquired during the market research, patients, and staff aspects. In general, the past products and prototypes lacked two fundamental things, either of them.

The first problem was the complex introduction or change of the entire catheter system, which seems to bring a learning, legal, and commercial challenge.

Second, some of the products as Urinfo 2000, although more accurate were lacking a central data collecting system that would allow to manage and use the data effectively and efficiently.

Thus, if the job of measuring were accurate, the complexity of entirely or partially new systems would not reach the market, or if it were simple enough, it would not be good enough for the job to be done of monitoring. Besides, as a third issue, maybe less relevant, all the previous

(business speaking) they were focusing on the hospital market, neglecting the potential also for a private opportunity.

3.1. Aesthetic Products Review

Figure 17. Ugo Stand, bag support and Inspired Comforts, Cover bag (Amazon.com,2020).

This paragraph will briefly discuss the functionalities and applications of other aspects of the catheter bag system, namely the support and aesthetic ones. As already discussed in chapter 4 of the present report, the end-users, especially women, would like to have something that covers the catheter's bag for hiding and supporting it rather than having the bag hanging around being visible. In the marketplace, there are already existing products with the functionality of stabilizing the bag and covering it from the view of others. Some of the products in question are made out of plastic, polymers, and simple rigid fabric. Among the most popular choices in the global market, it possible to buy brands as Ugo Stands (U.S.A) that make support and covers for bags or more simple solution in fabric such as from Inspired Comfort. Both solutions are sold for around $30, dependent on the market. Other products in the global market follow the lines of the design of the two companies described, with more or less simplicity of design with a price range from $15 to $50 (Amazon.com)[62]. Figure 18 shows the images of the products.

4. Prototype Development

[62]Amazon.com, 2020, available at: https://www.amazon.it/MEYLEE-Kit-incontinenza-catetere-urinario/

The *fourth* and last sub-question of the present chapter on *"How to build the prototype for the jobs to be done?"* is investigated in this section.

Thus, the aim is to go deeper into the process of prototyping the Smartbag concept. Reasons for prototyping are clear communication of the Smartbag product, making specifications, compare solutions, and ultimately test and develop user interaction in the segment chosen.

4.1. Design thinking and Lean Start-Up Methods

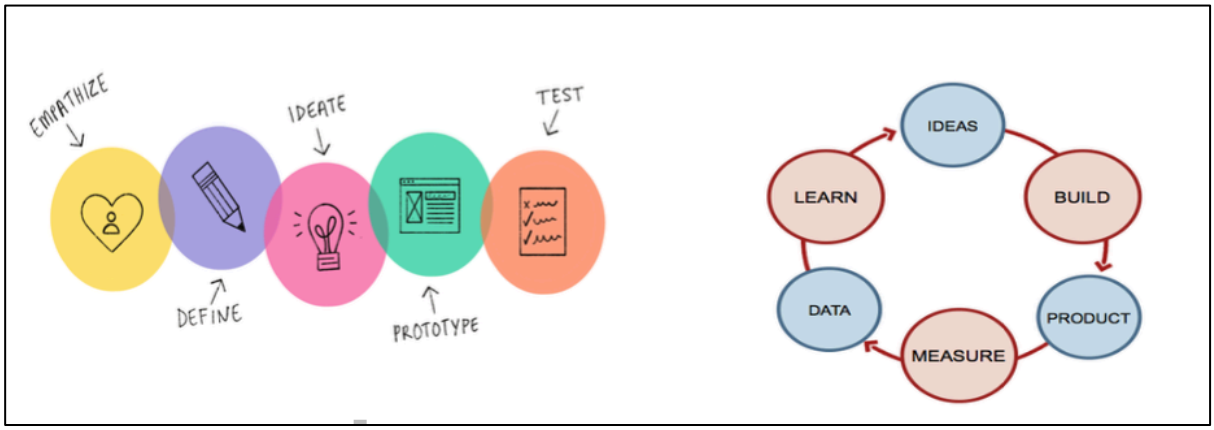


Figure 18. Design Thinking Cycle and Lean- Start-up Cycle (medium.com, 2020)

The design thinking (DT) method has been used to develop the prototype, requiring a short time of delivery, low cost, and decreased risks, but at the same time creating something that could be tried by potential users. According to the literature, "*fail fast, fail often is marketing rubbish"* (Kressel - Winarsky, 2016, p. 6). Concurring with a recent analysis directed by Forrester Consulting for IBM, teams implementing a design thinking method can decrease the time for progress and testing by as much as 33 % (Forrester Consulting, 2018)[63].

In the lean startup model, the creator pushes an MVP (Minimum Viable Product) through a test-and-learn cycle, while measuring metrics that assure a market fit of the product that is being created (Olsen, 2015).

The reason I decided to chose a (more oriented) design thinking approach is that using minimum viable products approaches and pivot, is more suited for software companies who have a low budget and pivoting the product until they find the right market fit (Kressel -

[63] Forrester Consulting, (2018), "The Total Economic Impact of IBM's Design Thinking Practice.", available at: https://www.ibm.com/ design/thinking/static/media/Enterprise-Design-Thinking- Report.8ab1e9e1.pdf

Winarsky, 2016, pp. 6-7). Whereas, in DT before the prototype, the founder (as in the Smartbag case) starts by sympathising with users, describing their most persistent issues, and, based on this information, propose different potential ideas. This attitude lowers the risks by investigating people's interest before the real product development. The Smartbag proposal already had a rough market direction because the need was clear to the founder, and the features were requested by the actors interacting with the catheter system. Contrary, within a lean startup process that would have required to build some features of the product and (then) find the customers afterward (Thoring - Mueller, 2012). In design thinking, the prototype is "unfinished," often less complete than MVP used by lean startup innovators. This is done to create flexibility that allows for transforming the product when interacting with the customer (Liedtka, 2018).

In practice, I used some low model build on the request of the users; for example, for the software developer, I used citations as below:

Assistant's citation*: "I would like to have an indicator, when the bag is full, such as the gas gauge of a car!"*

In this regard, I developed a drawing of the app, explained the functionalities, and gathered feedback (Kahn et al., 2013, pp. 8-9). (some of the illustrations used is in Appendix 4, 4.5).

Another example, for building the cover bag, a user expressed the following words:

Patient's citation: *"It would be nice to have something that camouflages the bag, so the liquid will not be noticeable," "It should not be cumbersome…"*

In conclusion, the flexible design thinking approached helped me to shape a fast prototype concept with the help of the people that will benefit from it (Kahn et al., 2013, p. 10) without going through many physical interactions. This type of market research must be used as an input to the design judgments and serve as a guide before pursuing the new product (Kahn et al., 2013, pp. 8-9).

4.2. Build the Concept

Differently, from the other proposed applications the prototype I suggest does not come into contact with the liquid (as the one integrating inside the tubes), the model includes a cover as requested both from the hospital and private patients, the entire system would be wholly external and integrational to the commercial urinary catheter system (bag). Moreover, the needs of mobility for the patient and the bag are satisfied by wheels. As a final prototype, but open

for modification, the data of the urine output will be sent to a mobile phone, which would collect and analyse the data.

The data will be managed and analysed remotely thought a Wi-Fi connection with the possibility to check the patient also from far away distances. The phone will act as a “central station” which in the case of the private customer would eventually be checked by relatives or assistants, and in the case of the hospital, by medical staff and nurses. Important to remind is the fact that the data is in the cloud and available wherever needed once collected by Smartbag, but from a user perspective, the phone will be the first point of connection to the device.

The support (hook) and cover part are combined with the electronic feature and are the skeleton for the entire structure. The purpose of the description done so far is also to use as much as possible cheaper material and design because of the actual product development.

4.3. Hardware in Use for the Prototype

The easiest way to build a prototype with electronics parts is to take an open source electronic circuit and start the experiments. The online availability of open source code and electronic boards is astonishing.

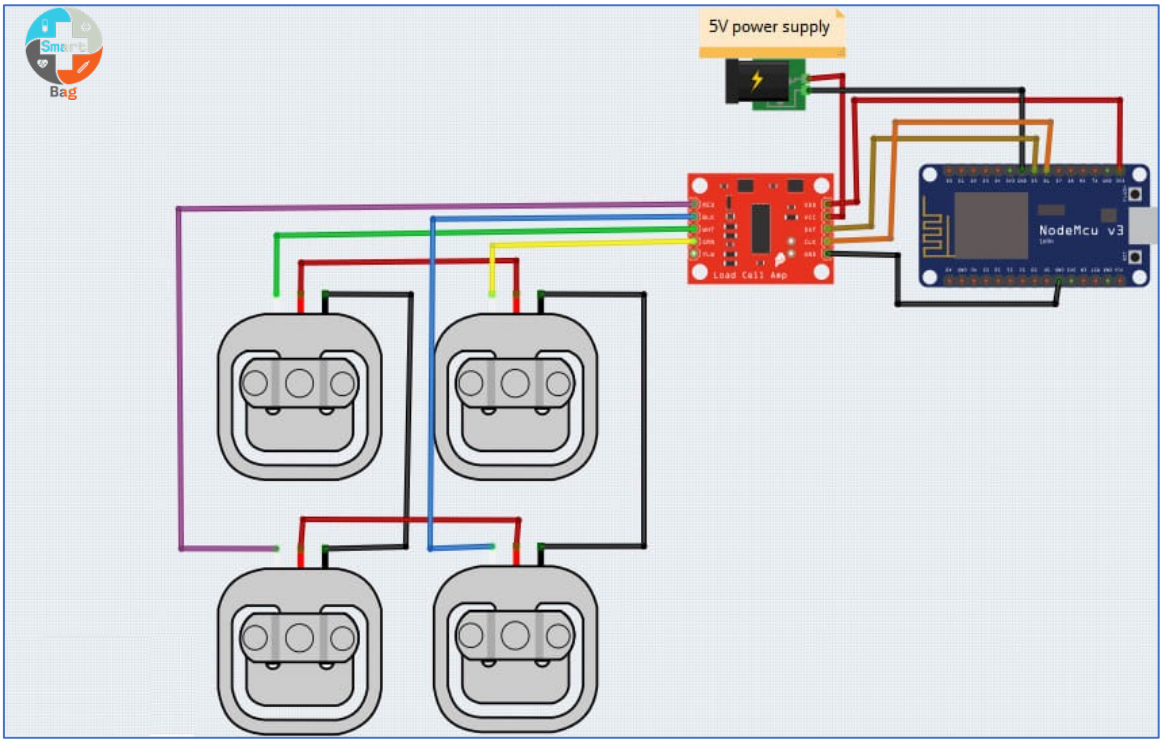


Figure 19. Scheme Electronics Parts (Own made).

The most common boards in use are the Arduinos. The choices for the Smartbag ideation have fallen into the Node MCU (same characteristics, but different brand). Because compared to the Arduinos boards it has the Wi-Fi integrated into the circuit itself and the cost is relatively low. This small circuit allow to have more space and wire a power supply without having high costs (6 times less than Arduinos, Amazon.com, Arduino, 2020)[64].

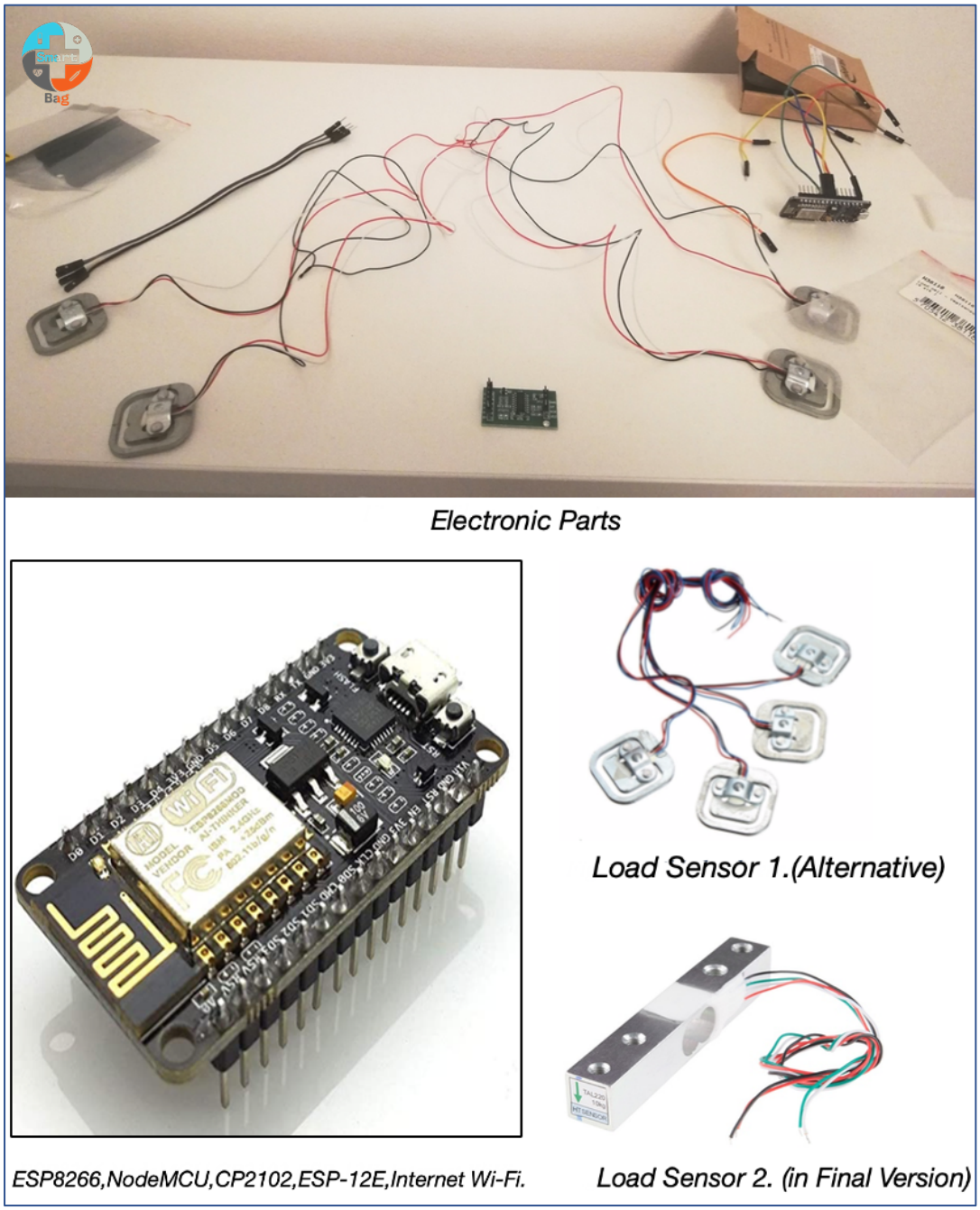


Figure 20. Components in Use (Top half, Own made, and bottom half, Amazon.com).

[64] Price of Arduino Wi-Fi components in Amazon.com, available at: https://www.amazon.com/Arduino-UNO-WiFi-REV2; Price of NodeMCU Wi-Fi components in Amazon.com, available at: https://www.amazon.com/HiLetgo-Internet-Development-Wireless-Micropython/

Regarding the sensors, as already discussed in the prototype review, there are many types of them, from optical to ultrasound, the weight sensor is therefore chosen because of the simplicity, precision, and fitting characteristics as an *external solution* of the Smartbag concept. There are mainly two types of weighing sensors that use the same scientific principle, which is the change of residence when weight is applied (Jost, 2018). I decided to experiment with both options but use the one with less possible sub-parts as in the picture to have a more centered weight sensor capacity in the structure. The other option is illustrated in the picture above. Therefore, the open-source electronics in use for the Smartbag prototype are:

Weight sensors, 50 kg Half-bridge

Load Cell, HX711 AD Module

Power Supply, Power bank

Chip as a Brain (for software application and WI-FI connection) Node MCU CP2102 ESP-12E

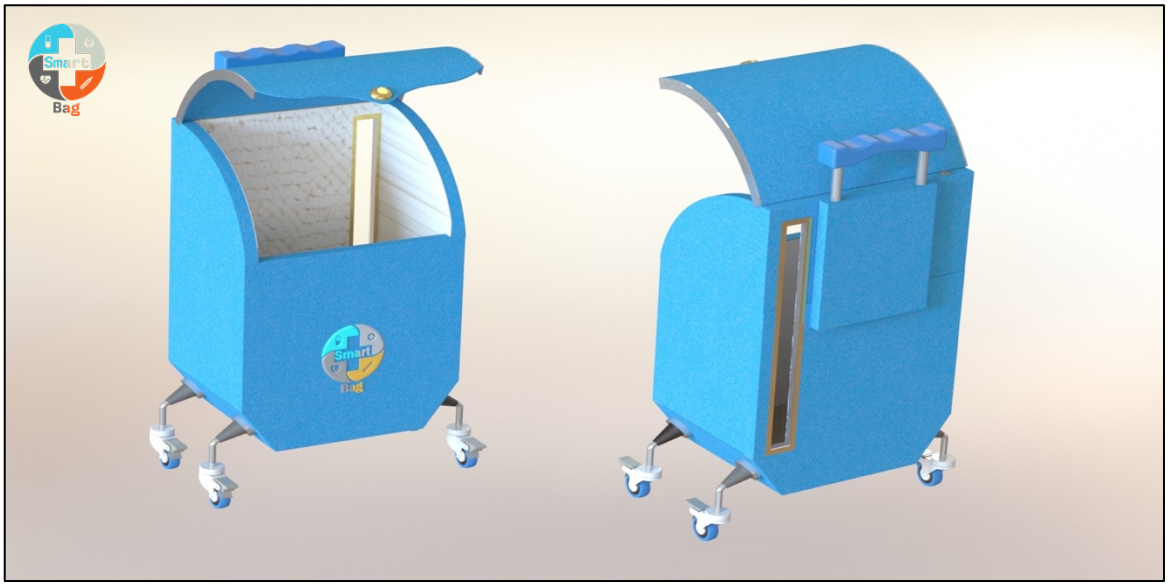


Figure 21. Smartbag External Semirigid (Virtual CAD, Prototype), (Own made).

The Smartbag cover is thought to be a semi-rigid structure in rigid fabric for being flexible at changes of the catheter bag that changes shape during the filling (at the beginning of the process the urinary bag is larger at the base). Moreover, it is ideal to have a waterproof material for cleaning it and safeguarding the electronic inside (leather in the concept). The transparent stripe

has the purpose to check the bag from an external view in case the Smartbag sensor system would fail[65].

Wheels and cover motivations are the product of careful considerations on the hygiene and movements of the users, comprehensively explained in the interview part in Appendix 1. To see the prototype stages and development see Appendix 4.

4.4. Electronic Shelter

The electronics parts for structural reason and protection are integrated into a wood structure, as in the picture below. The design should allow an easy power recharge with common cables for smartphone chargers (for example USB-A 2.0 han / MICRO-B han - 0.6 m).

Moreover, it permits the sensor and the electronics parts to be in the different layers for optimised functionality. In the picture in the right is shown the switch on-off and light for when the device is on. This shell is positioned at the base of the Smartbag structure, where on top will be placed in the urinary bag. This allows to put "weight" on the wood lid (connected with the sensors).

Figure 22. Wood Shell for the Electronics (placed inside the Smartbag), (Own made).

The real Smartbag product would eventually have a plastic or metal shell that would be in the same position as in the prototype's shell to strengthen the balance. The urinary bag would be positioned just on top of it. Appendix 4 (for prototype development).

[65] For a detail view of the prototype structure with the size look at Appendix 4.

4.5. Software Idea

As cited, in the previous chapter, the software developments depend on which environment the Smartbag products will be applied. This fact is due to different tasks and priorities related to management in-home care and hospitals. For the prototype developed for the private market, namely home care, usually of elderly people, an app was used with the simple aim to show and users of the status of the bag and alert when it is full. Moreover, the customer's experience brought me to add how many times per day, the bag has changed, and the daily quantity of liquid. The data kept would be analysed by relatives or nursing staff. This is done in general to monitor kidney issues and/or dehydration (see Medical Specification paragraph), which would serve to assign a precise treatment in case of problems.

For the prototype application, it was used as an open-source app called "Blynk" that would be connected with the electronics clarified above and send data to the cloud, in this case, was used IBM Watson IoT Service, which will send back the data to the phone. The app shows the weight during the day. Although simple and basic interface, it helped the users to become familiar with the Smartbag app concept that would be in the final product (see Appendix 4, 4.6 for pictures). I gave significant importance in making the user interface understandable and useful, which was in the top three in the house of quality for the Smartbag product. As Peter Diamandis says:

"The most important tell-tale factor is the development of a simple and elegant user interface, a gateway of effortless interaction…" (Diamandis - Kotler, 2016, p. 69).

4.6. Testing Smartbag

In line with the design thinking process, the last step before the Smartbag prototype is completed is the test stage. For this phase, the main supporting notion is the A/B testing.

To avoid decisions based on feelings or instincts, the A/B testing allows for a more reliable method of testing products and assumptions (Jenkins, 2014). Furthermore, transforming the ideas and analysing them in the form of tests, will avoid the dismission by managers and investors based only on presentations or blackboards. Making it easy to try the ideas through a test, it is also useful among teams in term of abstract communication, speaking about results and next steps rather than what could happen. Finally, according to the author Jenkins (2014), members involved in the project will get higher encouragement, watching their ideas in the real world. However, there are downsides in this kind of method, given that the tests could show

quick results, teams end up missing significant innovations, working on incremental progress (Jenkins, 2014). The method implied that two versions (A/B) of the product are tested, and the result shows which one performs better. The process starts with determining *what to test; secondly* is how to measure the performance (Gallo, 2017).

A further distinction is made regarding the players in the test phase. Indeed, alpha and beta tests, where the Beta test is conducted involving the users in their environment, while Alpha testing is done by the developer.

4.6.1 Smartbag A/B Test (Beta)

In accordance with the "House of quality" results (chapter 1), the features that most affect the customer perception and desirability are the Smartbag *structure materials* and *interface* with the product. The interface is intended in this case as the interaction of the Smartbag physical structure, software with the users, which is related to the parameter "easy to use."

- The hypothesis is that the Smartbag prototype is ergonomic enough to not create problems (heaviness or discomfort) during the user's mobility.
- The measurements are based on time of doing a certain task (walking, for example) with or without a certain feature, and if the user is willing to use the Smartbag product in that kind of condition again.

The test was conducted with two types of patients. The first type was a woman in a wheelchair, which, as a test's result, required the Smartbag to add a *hook* and refine the handle as "short." The hook will serve to move the wheelchair (by an assistant), the patient, and the Smartbag all together without handling too many objects while the short handle is required in general to lift Smartbag from the floor.

The second type of test was conducted with a walking patient, which as a result, required the Smartbag to add a *shoulder belt* in order to carry the system while walking, making Smartbag architecturally similar to the "Inspired Comfort" (in Aesthetic Product Review section). In both cases, the hook is useful to attach the Smartbag in the wheelchair or bed framework[66].

[66] It was interesting to find out that the Smartbag system was attached in the bed framework during the visits. The explanation was that in the perception of the users this would make the action more "hygienic". This was strange to me, because the wheels were supposed to prevent already any contact with the floor and the hook was supposed to be used for the wheelchair. As the job to be done theory claims, it is important to see how the users hire the products in certain circumstances, while the companies design them for other purposes (Christensen, 2016, p. 56 and p. 134).

It is the users' opinion that the Smartbag structure per se works fine. However, in the case of the patient in a wheelchair, the shoulder belt would get in the way going under the wheelchairs wheels and Smartbag system. Thus, based on these experiences, the ideal would be to have a *removable shoulder belt*, and the patient who needs it can just buy the *option*. My concern was that the Smartbag would be heavy for walking, but the architectural changes with the shoulder belt do not create complications of this kind to the performers tested.

Table 4. Example Question Beta Test

Parameters Check	Score (0-10):	Motivation:	Fix With:
Is the hole for the tube in the right position?	6	The tube should go out more from the centre, so it does not bend	I removed the lid (as in the pictures) and put the hole closer to the centre in the CAD.
How good is the size of Smartbag?	10	Very comfortable	
Is it easy to carry Smartbag?	7	Need to be attached somewhere	Shoulder belt and Hook
Do the wheels help to stabilise?	8	The dragging brings some instability	This is due to the components of the prototype.
Is the user's interface understandable?	9	It would need some colour for level distinctions.	The visual prototype has the colours requested.
How good is the Smartbag with the hook?	10		
Does the shoulder belt help?	10	(Depends on the kind of user).	

Notes: The questions in the table reflect the test conducted in the version of the working prototypes of Smartbag with some explanation on the functionality made by me while conducting the test. The first part of the lighter blue is before the modifications. The real product will use these insights.

Figure 23. Walk, Wheelchair Trials, Bottom View (Own made).

The software part was tested with the purpose of listening to the feedback from the users because of the development of the Smartbag commercial product. The testing app “Blynk” is not an app for users, but developers of IoT systems. Therefore, the features for the final product would have a different style and a more friendly interface. The test was conducted by explaining the functionality and proposing two different kinds of indicators for the liquid, one a simple bar, and second a circle indicator, which ended up being the one that is more similar to the gas gauge of car preferred by the users.

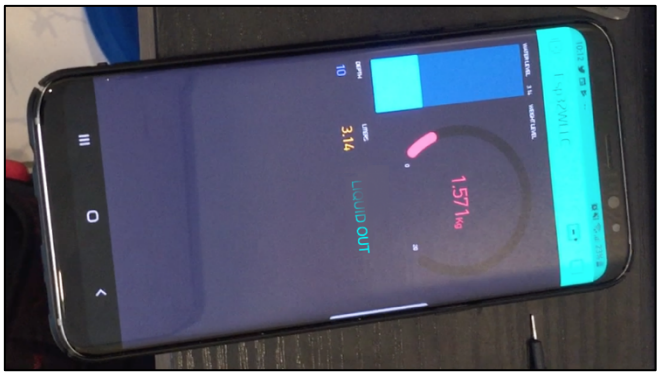


Figure 24. Test, Blynk App with Users, (Own made).

4.6.2. Smartbag Developer Test (Alpha)

The reason for alpha testing is simply to confirm the functionality expected by the Smartbag sensor system in delivering reliable data (liquid output) through a wi-fi network. The test, as stated in the Alpha test definition, was conducted *without* the inclusion of the users, given that it has just the objective to measure the quality of data of the prototype before delivering it to customers. For this reason, I used a simplified version of the Smartbag prototype, which has the same electronic components of the one that goes inside the Smartbag Beta test.

Figure 25. Alpha Trial (Own made).

4.6.3. Limitations of the Tests

The literature suggests that a small team of 3-4 people built up of an engineer, a designer, developer, and a business analyst (or product owner) is enough to conduct the test to have a broad skillset to analyse the results (Jenkins, 2014). As mentioned previously, the team is composed of only one member which may lack some skill. Moreover, from a statistical standpoint on the sample, the test should be repeated many times focusing on the same features to have a statistically significant result (Gallo, 2017). The software application interface (as in the visual prototype) has not been tested, given time constraints and cost of development. Even though the Smartbag project has been developed involving the users, and the features of the software (app)[67] are the ones requested by the eventual customers, the real interaction with the Smartbag app needs further attention.

[67] See Appendix 4 for the main mock-ups, paper and visual prototype of the App development.

4.7. Prototype Imperfections and Advantages

- The *cost* of material for the Smartbag prototype is relatively low, especially the electronics has a cost of around $10. While the major cost in proportion has been the wheels.
- Smartbag is depended on *Wi-Fi technology* (also Apple Smartwatch) so it needs to be connected to a router. This implies that without wi-fi connection the sensors cannot update the Smartbag App (instantaneously).

  Adding a *Bluetooth board* connected directly with a phone would make it less depended from a Wi-Fi network, while still needing to be connected to a network, which would be done through the phone.
- *Structure size,* the size was described as "perfect" fitting the environment of the patients.
- *Wheels size*, the wheels have to be small and light so when the bag is dragged the structure does not fall. In the experiments, the prototype had a heavier base (due to commercial availability of material used) than the bag at the beginning of the filling cycle. This fact made the prototype to be a little unstable (when hardly dragged).
- *Weight sensor*, (density of urine), the weight sensor was built into the Smartbag with the assumption that there is a linear relationship between weight and volume, namely called density (1000 g of urine = 1 litre). In reality, the pee density changes from person to person and even from day to day, due to temperature, elements in the urine, pressure etc. However, there is a small difference in the variation in general from a range of 1010g/L to 1020g/L (Flasar, 2008, p. 14)[68]. For example, in the extreme scenario, the weight would be 2.040g the sensor (in the constrains of instrument precision) would alert the user when it was 2000g few minutes before (The error could be up to 0.02%). This, in practical, should not cause any real problem, giving the advantage to have some time before reaching full capacity.

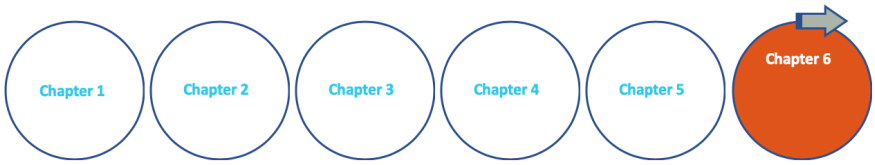
  However, one solution could be to get an average density (which is around 1.02 g/ml) and decrease the error in calculating the Volume (mass/density).Another solution of this not-perfect relation could be solved changing the type of sensor, which rather than measuring the weight would measure the volume through a pressure sensor positioned in the rigid sides of the structure.

[68] Urine had a higher specific weight than water (Engineering Toolbox, 2008, "Water, Specific Gravity", available at: https://www.engineeringtoolbox.com/water-temperature-specific-gravity-d_1179.html).

Sub-Conclusion

As seen at the beginning of the present chapter, the other prototypes did not focus on the customers, and probably, they were not seeking to build a commerical product to put in the healthcare environment, making overcomplicated designs with cool technologies, but that could not benefit the users. I created the Smartbag prototype that should overcome the complications due to legal and engineering issues of the previous attempts using the features that more benefit the users, combining support/cover bags and technology. With a business perspective and customer focus, I answered WQ.5, "*How is Smartbag concept transformed into a prototype?"*. However, it is important to remind that being a prototype, the legal requirement for a real Smartbag product could change some characteristics of the design[69]. Moreover, I believe that the lean start-up model can be utilized for a further test of the app interface.

[69] Some minor changes due to medical acceptance requirements could change, such as the type of fabric, type of frequency for wi-fi transmission, type of alarm, or structure to improve the usability or safety of the product (Church – Systems, 2018).



Chapter 6

Making the Business Plan

Introduction

To successfully deliver value to future customers, while sustaining the business through the Smartbag proposal, it is essential to implement a business plan. The present chapter will be the development of a business model, market strategy, and analysis for the resources needed to support the strategy. The chapter investigates WQ.6, "What is the initial business plan for Smartbag?". The literature in use is manly Tzuo and Weisert *(2018), with some reflection on crowdsourcing and crowdfunding in line with ExO's.*

The chapter is organized in the following sub-work questions:

1. *What is the business model?*
2. *What is the market strategy?*
3. *What resources are needed?*

The last examination in the design thinking method requires the economic viability of the project: Is there a viable business model for Smartbag for a price that customers are willing to pay for the job to be done? (Diderich, 2020, p. 177).

1. Smartbag Business Model

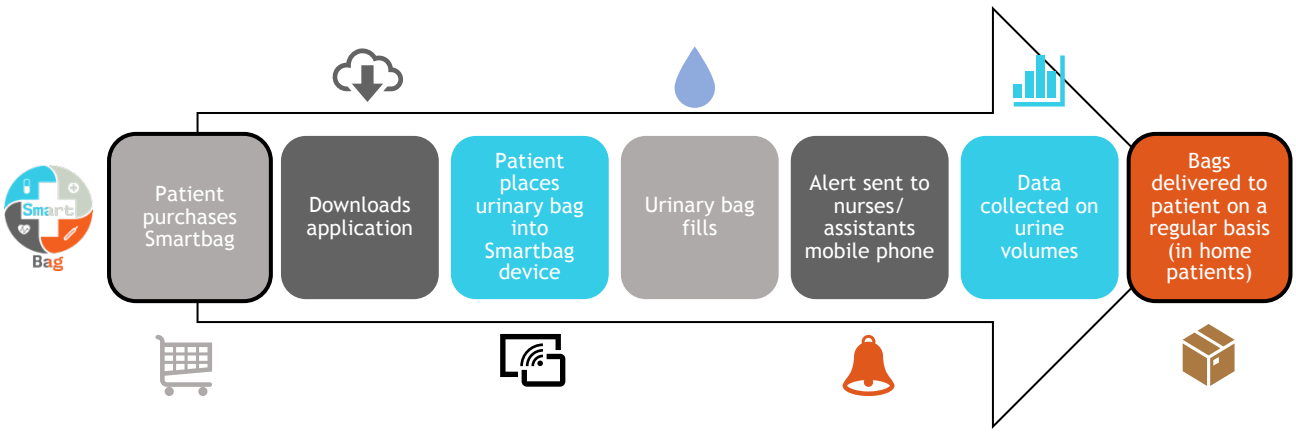
This section of the report is meant to investigate the *first* sub-work question, *"What is the business model?"*. The choice of the business model is based on financial advantages, on the Smartbag's users' conditions (to deliver the valuable benefits for people in general with limited mobility) and technological advantage that will benefit the eventual company in the long term. The possibility to implement a data-driven and powerful business model is enhanced by choice of technology in use in Smartbag. I have chosen to implement a subscription business model.

The design thinking approach for the development of the Smartbag prototype was customer value driven. To continue a strong and ongoing relationship with the users, the more suitable business model is the subscription one. In fact, (using data) it allows to have knowledge and understanding about the users.

"Today the overwhelming imperative of every consumer brand should be to know your customer. If you don't do that, you will fail, plain and simple" (Tzuo - Weisert, 2018, p. 44).

From a financial standpoint, the subscription business model is more predictable. The implication on the organization is that the first sale, moment of transaction is the start of a long-term relationship, not the end-line. The product development team advance frequently to meet subscribers' needs (Baxter, 2016). In practice, the Smartbag business model has been thought in two parts or two revenue streams.

1. Smartbag devices will be priced at $0 upfront and then $10 per month for six months, which includes access to the dedicated application (iOS and Android). The choice of the price is to stress the business model with a market entry price, that based on the interviews should be acceptable for the users. However, the price would be adjusted with future market learning once the product is available for sale.
2. The second part is another subscription-based model that will be offered to patients living in their homes, whereby they can receive a set number of bags per month delivered to their home. Through the data captured (Smartbag knows how many urinary bags the patient uses), the appropriate number of bags will be shipped to patients[70]. A monthly subscription of $25 ($20 bags' supply + $5 profit) has been assumed for this revenue stream for the financial projections. To have a better understanding of the dynamic the customer journey is set out below.



[70] So, they do not need to deal with direct purchases and supply of urinary bags.

1.1. Financial Projections and Market Size

Based on estimation on the study done by Sørbye et al. 2009, the prevalence of +65-year olds with a urinary catheter in Denmark is around 17, 700 individuals (National Board of Health, 2009)[71].

From the customers' experience done by me (ccustomer's experience section, chapter 4) the sum of the monthly subscription of $10 accounted in total at $60 should be acceptable, which means that in Denmark, the Total Addressable market is around *$1 million* (precisely 1, 020, 000, without counting the revenue from bags delivery). The financial projection, however, is flexible (tax rates and minor changes apply for different courtiers), and the numbers can be applied also in other markets as the U.S where the TAM is *$1.5 billion* ($60 x 25 million, without counting the revenue from bags delivery). However, the important concept to keep into account is not the TAM but the SOM (Serviceable Obtainable Market), portion that is possible to capture in the geographical area.
Based on the assumptions that *3, 500* Smartbag devices are assumed to be sold in the first year, increasing to *56, 000* in year five:

- Revenue is projected to increase from **$717.5K** in year one to **$19.4m** by year five as Smartbag builds brand awareness and penetrates the market.
- The device will be provided to patients at $0 upfront with 6 monthly payments of $10.
- Revenue will also be generated by offering patients a monthly subscription-based model for the supply of urinary bags where patients receive a set number of urinary bags per month, based on their needs. A monthly subscription price of $25 has been used for the projections.
- Net income is projected to increase from **($3K)** in year one to **$7.4m** in year five.
- Closing cash is projected to increase to **$8.2m** by the end of year five. No dividend payments have been assumed in the projections. (The organisation that will support these numbers and the relative figure are in Appendix 5).

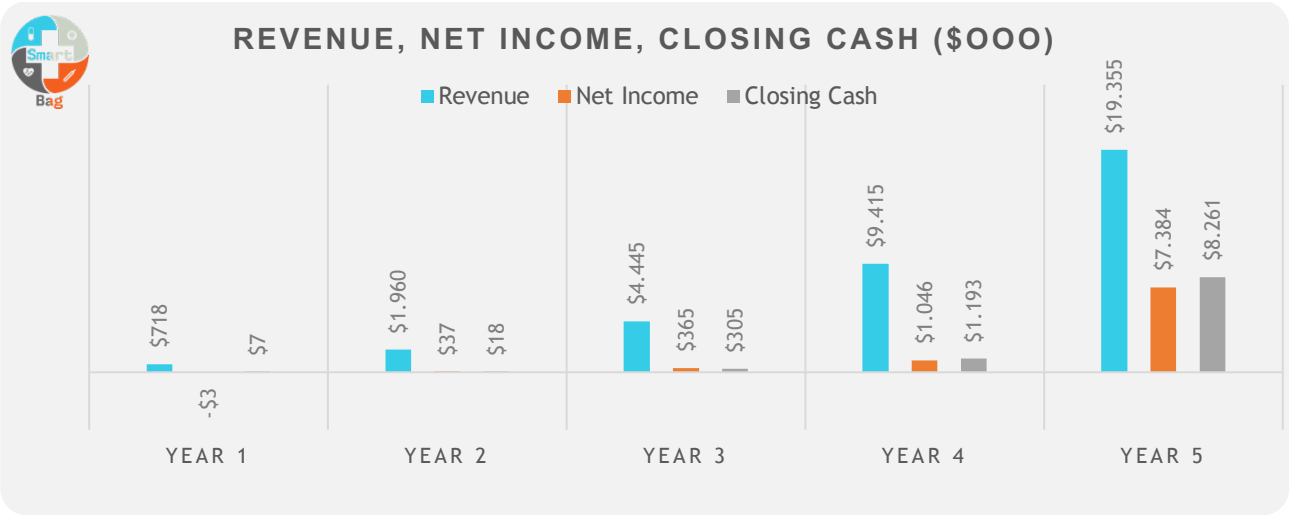
[71] It is very difficult to find out how many real patients use the urinary catheter system, the data taken in consideration is the least amount found to put the calculation in real as possible margin of safety. The limitation of the data was the age of the report (2009) and lack of data included by the authors themselves.

Table 5. Key Financial Assumption Used

Assumptions	Year 1	Year 2	Year 3	Year 4	Year 5
Sale price of device (per month for 6 months)	$10	$10	$10	$10	$10
Sale price of urinary bags (monthly package)	$25	$25	$25	$25	$25
Sales Volumes – Smartbag Device	3, 500	7, 000	14, 000	28, 000	56, 000
Sales Volumes – Urinary Bags	1, 750	5, 250	12, 250	26, 250	54, 250
Cost price of device	$25	$25	$25	$25	$25
Cost price of Urinary bags (monthly package)	$20	$20	$20	$20	$20
Marketing as a % of revenue	5%	5%	5%	5%	5%
Corporate Tax rate (21 %)	21%	21%	21%	21%	21%
Debtor Days	30	30	30	30	30
Creditor Days	30	30	30	30	30
Accounting fees / yr.	$5, 000	$5, 000	$5, 000	$5, 000	$5, 000
Office supplies / yr.	$2, 400	$2, 400	$2, 400	$2, 400	$2, 400
Website hosting / Development / yr.	$3, 000	$3, 000	$3, 000	$3, 000	$3, 000
Telephone / Internet / yr.	$3, 000	$3, 000	$3, 000	$3, 000	$3, 000
Legal Fees (FDA Yr. 1)	$5, 000	$2, 000	$2, 000	$2, 000	$2, 000
Data Storage / yr.	$3, 000	$3, 000	$3, 000	$3, 000	$3, 000

Notes: The assumption made in the table about the cost of production of a Smartbag of $25 may decrease during the years due to volume order increase or given the exponential technology trends. However, for safety reasons, I supposed it stable.

Table 6. Cash Projection



1.2. Comments

The subscription business model introduced above is an option of many, that can be changed in several ways. From charging $4 forever to letting the users pay upfront the cost of production while charging $2 for the time they use the Smartbag service. However, every option has to be tested in the market. Thus, the current choice is chosen to get the cost of goods sold as fast as possible and to spread the "burden" in 6 months while receiving a service for only $10 per month. In this way, the business model could be stress-tested using low-income revenue.
Regarding the overhead assumptions, I assumed that the marketing expense is set at 5% revenue, and every $1 million of revenue from user growth, one customer support, and sales (sales expenses) is added, increasing the salary expenses of $50 thousand per person. Moreover, using insights from ExO, it is possible to cut some of these expenses outsourcing the staff needed or hiring them part-time. However, for safety and financial understanding reasons, the staff has been assumed full-time hired. For the full information on the business, the explanation is in Appendix 5.

1.3. Limitation of the Model

The model does not take into account *directly* the logistic cost of the warehouse, delivery of goods from manufacturing to the company, and cost of shipment to the customers. However, given that these costs are variable and depend on contracts with third parties, I couldn't get precise information. Thus, I assumed them included in the cost of goods sold of $25. This

decision is taken because the cost of electronics is around $9 (based on the construction of the prototype), and the cost of the bag is around $10 (market prices of similar purses/handbags), which leaves $6 or %20 per unit of a margin of safety for expenses not accounted in the model. If this would result wrong, more than $20, 000 (800 Smartbag units) will be sought as an investment.

2. Market Strategy

The current part of the report is dedicated to giving a brief context and potential within the Smartbag subscription business model. Thus, it is addressed the *second* sub-work question, "*What is the market strategy?".* According to the literature, Tzuo and Weisert (2018), the adoption of a subscription business model also implies a shift from the traditional practice[72] of marketing strategy. Instead, data scientists and IT departments would take more control, creating ways for growth optimization, while implementing freemium models, building upgrade incentives, offering in-app purchases (Tzuo - Weisert, 2018, p. 206). The relationship one to one to the customers has emphasized thanks to the subscription business model. The shift denotes the changes in the perspective of the popular 4P's.

2.1. Place

The steps to follow in the subscription business model are as below:

- Establish subscriber identities.
- Delivery upgrades and innovations out regularly with an agile process as ongoing service.
- Permanently into the "beta mode", testing the features and validating through users.
- Educate eventual reseller and channel distributors to establish a permanent relationship as oppose to one-time sales. The steps to follow are in this order: adoption, renewal and possible upsell of the service.

The doctors and nurses/assistants are indicated as first "channels" for advising and sales of the Smartbag service. Thus, a partnership will be sought with these entities.

[72] For example, Salesforce, Netflix, Amazon Prime, or other successful subscription businesses don't spend money in traditional advertisements such as newspapers, Superbowl commercials, and so on.

2.2. Promotion

The brand is communicated through experience. Importance aspect of the success of the BM is the creation of social experiences and word of mouth. In line with the literature, Tzuo and Weisert (2018), storytelling are important in creating the experience and delivering the message through the promotion. The story is divided into three essential parts: the why, the who and the why.

- The first step for Smartbag is to justify promotions that make the Smartbag service relevant compare to the options.
- Secondly, it is important to communicate the usefulness, the purposes, benefits. In this face, real specific role-based advice, industry trends, and pertinent case studies can be delivered.
- Lastly, the promotion should express what the Smartbag service/product does in terms of qualities and mechanism.

2.3. Price

The strategy chosen for Smartbag is based on the value that Smartbag would deliver over time to the users. It is difficult to price a product such as the Smartbag. Most of the products in the market include only one aspect of the Smartbag, or the software application or only the physical object. To have a rough idea of applications' cost, the table below reports some significant information. Based on the potential users' conversations, and prices of other applications, the price of $10 (just for six months) that gives full access to the application and physical product should be an acceptable amount that would allow Smartbag to expand easily. Although there are other ways to get revenue, in the pricing and financial projection, these are not taken into account (eventual premium services, such as more accounts for using the Smartbag platform remotely, sale of data, ads inside the app). This is done because all models have to be tested in the market, and the premium and new feature services can be in the second phase in the pricing and packaging strategy.

Name	Price
My Fitness Pal (fitness app)[73]	$ 9.99 per month or $ 49.99 per year (Premium Service).
Noom (weight loss app)[74]	$ 59 per month + $ 20 per starter fee, $ 199 per year.
SleepCycle (help to wake and sleep well)[75]	Optional Premium subscription, that costs $ 29.99 per year.
Healow (match demand and supply, patients and doctors)[76]	Free for the patients (they get revenue from the e-management information for doctors).

3. Funding

The *third* sub-work question, "*What resources are needed?"* is critical for the understanding of the funds needed to start and run the Smartbag business based on the information and assumptions made. The need of *$20, 000* in crowdfunding is being sought to complete the development of the Smartbag device and launch the device. A crowdfunding campaign through the Indiegogo or Kickstarter platform will be pursued. After the crowdfunding campaign has been completed, and the initial crowdfunding order of Smartbag's manufactured, equity funding will be sought.

3.1. Reasons for Crowdfunding

Beyond the only purpose of raising capital, there are several benefits for crowdfunding, and every campaign should follow different steps, to reach the most desired of them. One of the

[73] My Fitness Pal, source available at: https://uk.pcmag.com/iphone-apps/5599/myfitnesspal

[74] Noom, source available at: https://uk.pcmag.com/personal-home/124165/noom

[75] SleepCycle, source available at: https://support.sleepcycle.com/hc/en-us/articles/115002692205-Terms-and-conditions-for-Premium-subscription

[76] Healow, source available at: https://xconomy.com/boston/2013/02/12/eclinicalworks-unveils-mobile-app-as-patients-go-to-site-for-healthcare/

benefits worth noticing as a positive collateral effect is the validation of the market for Smartbag and the real demand measurement during the mechanism of crowdfunding.

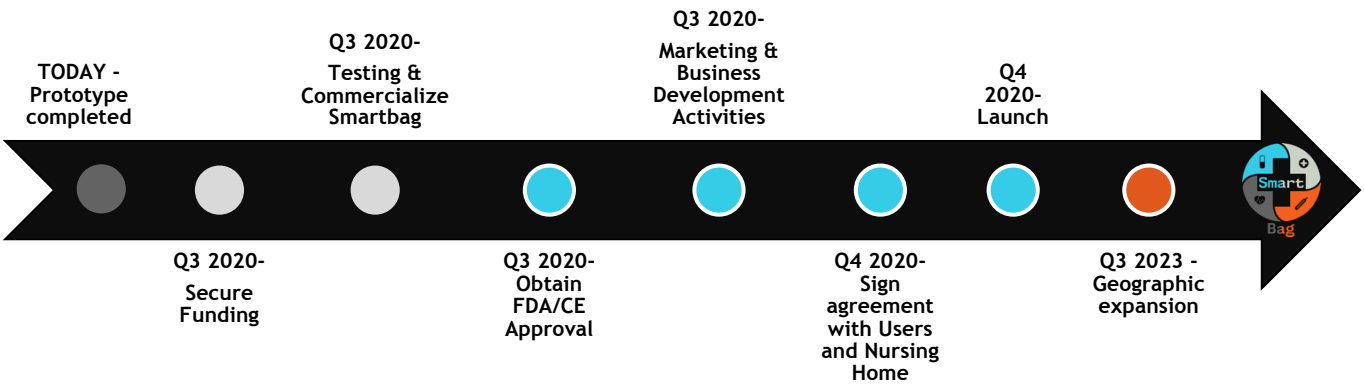
Putting Smartbag into this process will also help to validate the interests and wiliness toward the product. When starting a fundraising campaign, people engage in the idea presented, and they give feedback on the product. They may suggest new colours, new accessories and often even things that the team (developers) didn't think before. Moreover, when people help to back a product, they also release *data* that can be used by the Smartbag team, such as geographical information, price-sensitive that can help to improve the marketing strategy before Smartbag is in the real market. Customers, in a certain sense, are voting through their money and deciding what should be brought forwards in crowdfunding platforms. The downside is that going into the process of understanding what customers don't like, and then something should be changed (Diamandis - Kotler, 2016, p. 427).

Secondly, there are also venture capitalist that request to run a funding campaign to validate the market before making their investments, in this specific case, for example, it is possible to observe two advantages: a) the company may have a higher valuation from the beginning if the campaign goes well; b) having more reliability and then cash to grow from the beginning.

The crowdfunding process also allows entrepreneurs to build their customer community all over the world before the product is ready; usually, this is a difficult goal to achieve in the market. Analysing the cost per customer acquisition usually is expensive, whereas, in crowdfunding (if executed correctly), it's possible other than getting free advertisement, also getting promoted by the customer through their networks. Crowdfunding campaigns are also useful in terms of quickness, and there is no better way to make an idea happen fast and potentially gain a profit. If the campaign has some success at the beginning, the next fundraising may be a more road smoothed due to the initial success of the company in the first campaign (Diamandis - Kotler, 2016, pp. 372-375).

Sub-Conclusion

The last and final work question *WQ.6 "What is the initial business plan for Smartbag?"* has been addressed. The compressed information present in the current chapter is better explained, as mentioned in Appendix 5. Some of the information, such as legal fees for CE approval, has not been investigated. Thus, the FDA (legal clearance for medical devices in the U.S.) has been used in the assumptions. Finally, the model is pretty flexible and can be applied (with minor modifications) starting both from Denmark and expanding in Europe and vice versa for the U.S. The practical choice will depend on macroeconomic opportunities and my circumstances. Below are set the possible target milestone during the years for Smartbag.



Conclusion and Discussion

Introduction

In this final section, I close the report with a conclusion on the aspects related to the research and work questions that were described at the beginning of the process. I will discuss in brief what has been sufficiently addressed and what needs more time and investigation. Finally, I will add my learning with a reflection on the theories that I regard more important, concluding the report with future possibilities about the Smartbag project.

1. Research Process Conclusion

How to transform the Smartbag concept into an exponential technology prototype with design thinking for selected target customers? And on top of that, what is the initial business plan for Smartbag? (Research question).

At the beginning of the report in my vision, the scope was to prove if the Smartbag proposal could have opportunities as a business venture. The work has been organised in work and sub-work questions. Following the research methodology of Mathiassen (2017), the iteration and differences in the research design and research publication created a dynamic process that made every chapter to be adjusted in accordance with a logical and clear reading structure. The research question with the object of creating a real business was the guide for all the processes. Resulting from the research, the contribution that I wish to leave with this work are:

- The realisation that entrepreneurs can create a sustainable business model while creating innovation using disruptive technology in healthcare.
- A comprehensive guide to making successful innovation and solving patient's inefficiencies while developing in a relatively short time a prototype[77] with high market potential.
- From a medical standpoint, I created a simple tool that can be implemented for statistical correlations using patients' data. Smartbag would increase the reliability and quantity of information available for such studies.

[77] See Prototype Development Literature, chapter 5.

In this regard, supporting my statement, speaking about lack of data on urine output, the biographical material can be expressed and summarised as below:

"Inpatient hospital data collection is often depended on the nurses and other clinical staff to be completed thoroughly, and given how busy nurses and other clinical staff are, it's no wonder that many inpatients datasets have certain features, such as urinary intake and output or timestamps of medication administrations, inconsistently reported." (Kumar, 2018, p. 65).

More in specific, in relation to kidney and dehydration issues (expressed in the medical section, chapter 5) the medical literature expresses the following:

"Several limitations related to the urine output criteria also need to be noted. In setting outside of intensive care units, documentation of urine output is often unreliable, …urine output is often missing, even in critically ill patients limiting the diagnosing and staging of AKI[78] *entirely in blood creating concentration."* (Waikar et al., 2018, p. 19).

Moreover, while studying and collecting the data, I discovered that there is a need for companies and scholars to have a more accountable approach in counting the urinary bags consumption inside the hospitals, and as said, having reliable data on urine outputs (Smartbag would help in both cases). Additionally, there is a need in the Danish environment to know the real number of incontinent patients (the official reports used, stated the same problem). These data hopefully will be more available, adopting data-driven solutions as the Smartbag.

Regarding the practical process, I addressed all the work questions necessary to arrive at the final business plan for Smartbag. However, the choice of the market, investigated with WQ.3 (chapter 3), remains, as cited, an open result. Although the U.S market is larger, I would need to go into the same process (I went in Denmark) with the users in order to understand the circumstances of the patients using the urinary catheter. Hence, the business plan has been built, leading to the possibility of both Danish and U.S market entrance. In general, the financial viability seems to give Smartbag an opportunity in both markets. As stated, only the 0.2% (56, 000/25, 000, 000) of the U.S market would generate within five years a multimillion-dollar company with the possibility of further local, geographical and product expansion.

[78] AKI: Acute Kidney Injury.

2. Final Discussion

The Smartbag project has helped me to developed new knowledge. In particular, I believe the way of thinking from an entrepreneurial point of view establishing disruptive exponential organizations (ExO's) combined with the job to be done theory will benefit me in the future. As Christensen said: *"you can't build the future looking at old data, theory is the only help*[79]*"*. In the case of my investigation theories helped me to:

- Understand the why and to unveil the causality of the necessity with the job to be done, while using disruptive innovation theory to have an advantage in delivering the solution to the problem discovered.
- More practically, for example, the job to be done theory: discovery that before Smartbag people used to carry or drag around the urine bag and nobody for whatever reason solved this problem.
- That asking *"what if"* can bring the entrepreneur's imagination to address also other problem around the one researched. (For example, the urinary bag can be made of friendly material or the Smartbag could be a container that uses filters, so there is no need for plastic urinary bags).
- Design thinking and agile are useful methods for prototyping physical products, however, the lean startup model in making an MVP can help with the software development of the Smartbag platform.

The process report made me realize that in general, people don't have a broad vision as the ones that can have the entrepreneur. I always thought that other people could imagine things before real products. However, my experience showed that people have a narrow view of their own world. An example, the nurses work around the catheter system for all their lives, but they do not think to improve or make more efficient the systems, and before the visual prototype was difficult to make them understand the idea. Finally, the report, in relation to the Entrepreneurial Engineering program, has particularized aspects such as business development, innovation, entrepreneurial practices, agile methods, design thinking prototyping, an adaptation of marketing (subscription BM), and business model.

[79] Interview with Christensen Clayton by Labarre P., 2003, available at: https://www.fastcompany.com/47659/industrialized-revolution

3. Future of Smartbag 

There are many steps to follow to bring the Smartbag proposal in the marketplace. The most important ones are:

- Fund seeking
- Industrialization and manufacturing of the product
- Platform development
- Legal approval
- Partnerships with medical associations.
- Logistic model (shipment, warehouse costs, inventory time)

Regarding the product, I believe Smartbag could be integrated with Alexa or Siri to have more efficient communication with the user. Additionally, the physical design can be made by a professional designer. All of the above will be possible if the market and personal conditions will allow the development of a successful venture.

3.1. First Phase Sales Plan (How)

If the crowdfunding campaign is successful, around 1000 (20,000/25), Smartbag units will be manufactured for the first batch. The crowdfunding should bring around 500 customers, that backing the product would receive the first orders. However, the crowdfunding campaign requires time and money as well, and it has the implied uncertainty of not succeeding.
At this point, a realistic scenario (supposing the plan) without a crowdfund, would require the founder to personally deal with the sales of the product. In my view, there are two options that I would feel comfortable pursuing.

1. Directly sell few Smartbag products, from 10 to 50 units, to validate the market (using my resources). Subsequently, in line with the literature, Hoffman and Yeh (2018), using Blitzscaling.
   "Blitzscaling is a strategy and set of techniques for driving and managing extremely rapid growth that prioritizes speed over efficiency in an environment of uncertainty. Put another way. It's an accelerant that allows your company to grow at a furious pace that knocks the competition out of the water." (Hoffman – Yeh, 2018, p. 12).
   Find investors and invest a huge amount of money in taking as much as possible market share in the first three years at high speed while building the platform. This hypothesis

would make cash flow negative the Smartbag's income statement (to burn around $300,000 per yr in marketing expenses). The possibility of taking the market first (fist scaler advantage) in a short time should prevent other players from getting into the market before Smartbag has enough recourses to be self-sustainable. Once enough share of the market is taken, I will unleash the digital disruption of other innovative products inside and outside the Smartbag platform in order to grow the customer base within a flexible framework. The network effect (Hoffman – Yeh, 2018, p. 67) and data acquired should allow Smartbag future products to be tailored and repeat the cycle using both physical innovations to lock the customers[80] and disruptive digital innovation for faster growth.

2. The second hypothesis includes the use of digital disruption from the beginning, before the sales of Smartbag physical products. In this scenario, the platform built would gather and collect data, delivering a service linked to the urine output in a digital form. My hypothesis, based on customers' experience, is to connect water, drugs, drainage bags suppliers, and medical devices in a platform that advice products, treatments and creates a community around the incontinence and hydration topic. Once enough customers with incontinence care interest would be into the system, then, the Smartbag physical product will be sold. Also, in this case, a substantial amount of money to get a sustainable user base is necessary.

The (shy) 5% revenue expenses for marketing that makes the current business model less risky and to be profitable from the first year would be increased in both the cases described. These facts would increase the risk in the short term but allow for more growth and advantage in the longer term. Besides, the subscription business model should reduce the unpredictability of the revenue in all cases.

[80] Either the physical or digital product without the other are useless. The company using the healthcare platform that I have in mind would create unique products that also if copied (digitally and physically) can't benefit from the data collected and network effect created through the platform. Unless a competitor copies all the products at once and get all the data at once, this would be a competitive barrier for products as Smartbag that are inside the healthcare platform eco-system.

Sub-Conclusion

The current section of the thesis reported the advances made during the process and possible future scenarios for my product. I would like to stress the importance of working with the potential users of a new creation. In the case of Smartbag, many of the details, features, ideas, and insight would not have been possible if I did not observe and communicate with the people in their own life experience. The way of working while collecting advice and idea solutions from many and different people is fundamental to the creation of the best products. However, I think that to speed up the process of going to market, innovators should work (other than with users) since the beginning also with manufacturing. This would make prototype and product development in one phase, without potential changes in technology, materials, and processes.

APPENDIX

1. INTERVIEWS AND SURVEYS

The most relevant interviews are chosen and reported below, the information form important individuals involved in the value chain helped the developed of Smartbag.
In particular, below specialist of urology, hospital nurse, home catheter bag user, relative/assistant of a patient, hospice assistant, hospice catheter user.

1.2. Hospital Participants

The hospitals experience was characterised by different meeting with nursing staff and experts.

Interview A

Urology expert

In the department of Urology, I had a meeting with Susanne Vahr Lauridsen, Clinical Nurse Specialist, PhD, that does research on the field. First question I asked was how many catheters are in the hospitals, she interesting replied that already other companies like Bbrown, had asked the same questions. Unfortunately, they don't know because the departments are many and they do not count the patients with short catheter problems. Regarding the job of the Smartbag concept, she replied that is interesting and that *"improvement of the catheter bags Is very much needed"* , however for the hospital market in her opinion the need would be for people who had surgeries or are in really bad conditions, for the more usual situations there are already the standard nursing check-ups and there is not much a need to know the status of the liquid. Although she claimed to not be an expert in the private sector, she expresses the opinion that the idea would be helpful for people who are not completely independent because the other with urinary problems use different catheter systems with smaller bags that can be attached in the legs. She also added that right at this time she is studying the indwelling catheter problem in the U.S.A market where there are more studies and a bigger older population.

Interview B

Hospital Nurse

The interview was carried out with a Danish nurse from the Bisperbjerg Hospital, Copenhagen

As expressed in the various part of the report the nursing staff who deal more often in the changing catheter bags are the intensive primary units. During the experience I further validated that the process of changing the indwelling catheter systems is as described at the beginning of the report. They use a bag of 2 litres that will be emptied in specific machine at the end of the day. Moreover, she explained the complexity of the hospital environment, which changes from ward to ward. For example, considering the variables to put in a potential operation management system, they are different from the emergency ward to the urology ones bringing a challenge for integration of new systems. Also, in this case the number of total catheters was unknown.

1.3. Home Candidates

Interview C

Patient 

The specific patient is a woman around 80 years old, she can't walk and move without wheelchair. The assistant has to bring the catheter bag in one hand while pushing the wheelchair or put the bag on top of the patient's legs or ask her to hold it. This is not comfortable for the patient. She told that sometimes she has problem to communicate with her assistants. For example, if she is staying in the living room, while the assistant is cooking in another room, she sometimes feels abandoned and find difficulties in asking for help. In relation to the catheter she did know when they change it, but sometimes she has discomfort and irritations (related to the tube inside the body).

Interview D

Patient's relative 

The interview with a relative of the patient helped to understand the cycle of the catheter system from buying to displacing it. The specific person told me that she usually buys the catheter bags in the pharmacy every two weeks. Asking how she would eventually use the Smartbag product, she replied in the following way:

"

1. *If it alerts me when the bag is going to be full, I can substitute it in time, avoiding that explode.*
2. *If it memorises the flow during the day I can intervene with the right treatment, calling the doctor for diagnostic.*

3. *For aesthetic and hygienic reasons, given that is not pleasured to see the urine bag and I don't have to drag it if I have to move it, giving also a hygienic advantage."*

1.4. Hospice Participant

Interview E

Hospice assistant 

The environment explored in this interview was a nursing home care, where usually there are 9 to 10 patients assisted by a nurse and an assistant. The interview was with an assistant of the infrastructure. The problems stated with the home patient are similar if not more important in this case. But in this specific interview the candidate emphasises the importance of the catheter with the relative information:

"It is important in a dynamic environment to know which kind of catheter the patient is using, so the eventual app could have a patient profile, with age, cpr, and number of catheter so the process of changing it would be faster also in emergencies situations (i.e. collapse or faint). This is also useful because if the material of the new catheter would be an allergenic for the patient, knowing which kind is usually used would avoid this problem."

"It is also important to know and alert when the catheter was changed to avoid that it would compromise the patient hygiene".

1.5. Pharmacy

Interview F

Pharmacy's owner 

The interview with the pharmacy's owner was conducted in order to understand what the usual business cycle for the catheter bags is and in general medical devices like Smartbag. In general, medical devices (pressure measurement, oxygen machines etc) are sold by the sale people of the companies they represent. The owner according to Danish law have to keep mandatorily certain kind of product inside the shop. The choice of which one, based on the interviews is usually buying the inexpensive products with less bad reviews (they check online if they have reviews).

1.6. Reflections and Finding of the Interviews

Wheels motivation

At first glance can look odd to have the wheels in a structure like the "box" for the bag, but also for this there are reasons.

1.The main reason is *hygienic*, in fact, the bag is connected to the tube that goes inside the human body and touching the floor or other external surfaces can bring to bacteria grown and infection that affects the patients.

2. To understand the second reason, which is *stability*, it useful to imagine the context of elderly people in a bed or wheelchair, other than not touching the floor, the wheels will allow movements of the catheter bag when the individual is turning around.

3. The third motivation comes from another observation of the behaviour of patients, In fact, it has been seen that when they do *"longer movement"* for example a walk, both in a wheel chair or by feet, the bag is usually dragged, so the wheels would avoid also in not a stable position to not collect dust and dirtiness.

Cover motivation

As mentioned in the report, the cover will have aesthetic reason, that will cover the bag from the view of patient's' guest or during the normal activities of assisting.

1.7. Smartbag Questions Example

Inspired by "Disruptive Innovator's Model" question (Dyer et al., 2011, p. 87).

Smart Bag	**Question related to:**	
	Description of the territory	**Disruption of the territory**
Observing	*What is the main concern around the catheter system?*	*Why the urinary bag is dragged or transported by hands?*
	How it is monitored when the care giver is not close to the patients? What happens if not monitored?	*What if robots or AI could do the job of monitoring the system?*
	When and how many times the bag is changed during the day?	*Why is not carried or moved easily along with the patient?*

Networking 	*Who take care of the patient using the catheter system?*	*What if the urinary bag was hooked in a wheelchair or using a shoulder belt?*
Experimenting 	*What causes and solve the discomfort for the patient or the caregiver?*	*How might impact the users experience using wheels in a supportive design?*
	How the urinary output data are collected?	*What if the data collected is shared with anyone who needs instantaneously?*

1.8. Defining the Population Sample

The alternatives in the definition of a sample in quantitative research are many. An important first distinction is the difference between a complete sample and an unbiased sample. The complete sample method focused on a set of objects from a parent population that incorporates all such objects or elements that fulfil a set of defined selection conditions. For example, the sample of all Danish nurses working in Denmark would consist of a list of every nurse working in the country.

Whereas in the second option, called also representative sample, the objects are chosen from a complete sample of a bigger population, using a selection procedure that does not depend on the pre-defined properties of the elements. For example, indeed called representative because taking only a small percentage of the nursing population (let's say 10%) would be enough for the purposes of the research. For practical reasons, seems more concrete for the author to apply the second option and take only a small percentage of the population of nursing and assistants in the Danish healthcare system as a *representative model*. Besides, to take a sample where all the elements are independent and have a certain probability to be part of the model, it is possible to choose a *random sample*. Again, the random sample theory of probability allows choosing among sample models such as simple random samples, systematic samples, stratified random samples, and cluster random samples.

Whereas, in the systematic sample there is the need of a list of all the elements, and in the stratified random sampling usually there is a subpopulation to be analysed, within the population, for the aim of the present work, the most suitable methods are the random sample and the cluster random samples. The two seems to fit the research problem because the first

method accepts the sampling of a population from N elements, where each element has the same potential characteristics of the others and the researcher can choose a number n < N, however, given that the writer believes that both nurses and assistants can be considered as two different groups, with different mansions, the second option has been chosen for the part of the investigation. Namely, the cluster random sample where it is obvious the distinction between groups called clusters (in this case, doctors, nurses, patients, hospital staff). Thus, for nurses and assistants inside Danish hospitals, the *cluster method* seems more appropriate, while in the private market patients (and their assistant) have been categorized using the *simple random method*. Some of the citations and statements is displayed during the market research process.

1.9. Bar Chart Questions

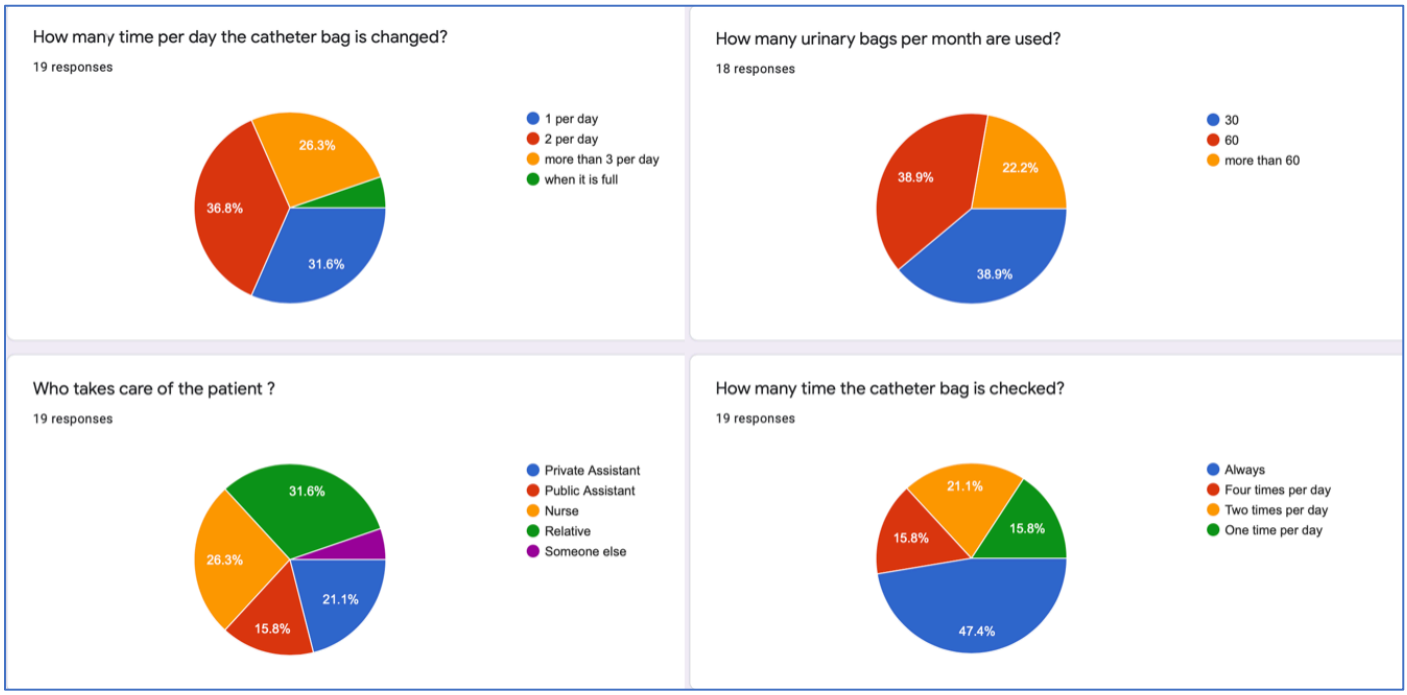


Figure 26. Qualitative Survey Results

Notes: Given the small number of individuals surveyed the results are meant to show patterns and relations in line with the qualitative study, rather than real data number. Such an example considering the individual responses, the nurses from the public sector check the patient less often than a relative, or the patients who have less need to use the catheters every day, use less bags.

1.10. Real-Win-Worth Questions and Scoring

Table 7. Real-Win-Worth Assessment

			Condition	0 (Uncertain?)	1	3	9
REAL	Market Attractivene		*What is the need or problem to solve?*	Unknown	Not well-defined	Identifiable problem to solve	Clear and validated by the market
			Who is the identifiable target customer?	Unknown market segment	Vague interest not validate by users	Well-defined customers interest	Well- defined urgency to buy the product
	Feasibility		*What is the solution that solve the problem?*	Not evident or no idea that addresses the need	Early idea exist that addresses the need	Potential alternatives identified	At least one clear solution has been identified
			Technologies and expertise to make?	New technology or invention required	Major development is required	Minor development is required (App and chip boards)	No development required
WIN	Product Advantage		*How Smartbag solution compete in design and features?*	Has many attributed inferior to competition required by users	It is equal to but in some aspect inferior to the competition	It is equal to but in some aspect exceed the competition	Clearly exceed competition with key customers' requirements
			To what extent Smartbag price meet users' expectations?	Price has not been validated	Price has been validated by internal sources (users experiences)	Price has been validated by at least one customer	Price has been validated by a significant portion of the market segment
	Competitiveness		*Does Smartbag team have the expertise, skills, resources to be successful?*	No full-time employees existing resources available for the project	Major resources additions are needed (See Appendix 5, 5.5)	Minor resources and skills are needed	Current employees and expertise meet the requirements
			Does the business model have potential?	No business model for go to market	Elements missing from the business model for existing market	Current business model has some potential	Current business model has lot of potential
WORTH	Strategic Fit		*To what extend Smartbag opportunity open doors for new businesses?*	Smartbag opportunity does not align with the vision of the team	Smartbag opportunity is partially aligned with strategic objectives	Smartbag business opportunity is closely aligned with strategic and long-term objectives	Smartbag business opportunity is a "must" to reach strategic objectives in view of the team
			What are the capital requirements?	Very Large (>$350k)	Large ($50-350k)	Moderate ($1, 5-50K) (A first round of $20k has been thought to start operation and validated the market).	Minor (<$1, 5k)
	Portability		*What is the range of revenue in 5 years?*	< $1m	$1-2m	$2-4m	>$4m (Following the assumptions of the BP the Revenue is 5 years is projected to be close to $20m).

			Does the team have enough confidence in the proposal?	Largely not validate (confidence <30%)	Validated (Confidence >30%)	Validated (Confidence >60%)	Validated (Confidence >90%) (With some minor *uncertainty* in the time of legal aspects and patent protection).

In order to assess the fundamental questions of the Design thinking method (Desirability, Viability and, Feasibility), the Table 6. has been composed. The literature in use for the theory is Day (2007) and model object of inspiration is available at: https://mgrush.com/blog/real-win-worth/

2. U.S AND DANISH HEALTHCARE OUTLOOK

2.1. U.S Market Trends

Looking at the healthcare trends can be coherent to take a glance at the PwC "Global Top Health Issues" (2020), where the central topics are related to the demographic shift, workforce transformation, pandemics, distribution of resources and consumer trustfulness.

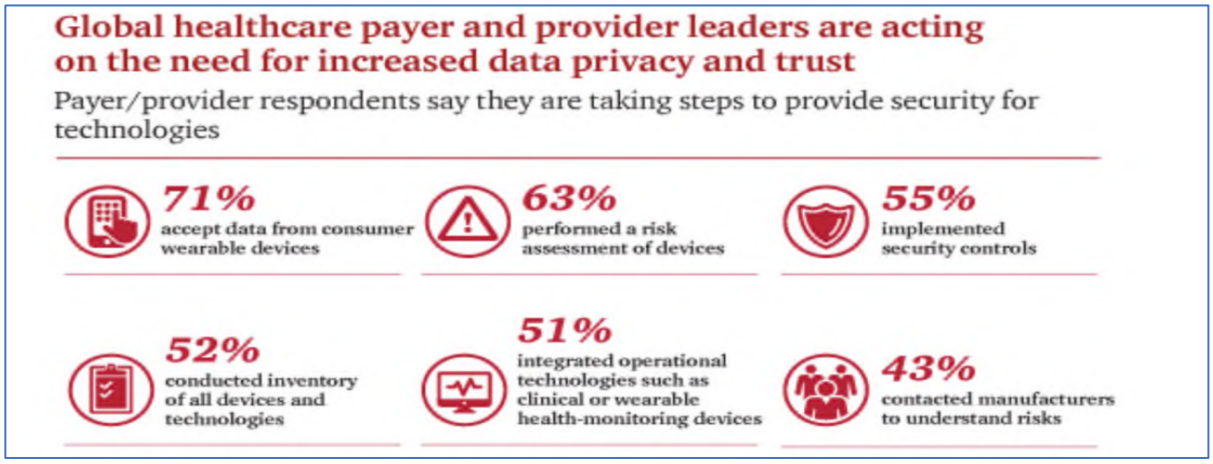


Figure 27. Global State of Information Security Survey, (PwC, 2018)

In the specific section "Human and Robots" of the same report, the topic of AI, data, and replacement of the workforce takes a central subject. According to the report, Industry managers desire to automate repetitive tasks on paperwork, scheduling, timesheet entry and accounting with AI-enabled tools, thus, employees will have more time to focus on jobs that can be done only by people. While 75% of the executive is trying to implement AI, the internet of things application and the customers are concern about trust and privacy issues (PwC, 2020).

2.2. U.S Market drivers

Deloitte (2020) insights, reported that more spending in-home healthcare infrastructure will occur due to the wills of managers to reduce costs and improve the efficiency of the healthcare businesses bringing also more money toward home health (Allen, 2020). Moreover, according to Ben Isgur, a leader at PwC Health Research Institute, the investments in the sector have more than tripled in the last ten years. In fact, despite a change to value-based care and uncertainty over the 2020 political events, the attention isn't fading, giving a growth opportunity (for similar devices to Smartbag) backed by private equity angry investors (PwC's Health Research Institute 2020)[81]. Even though in the previous section of the market trends was emphasized the slowing down spending in the short-term period of 2020, the estimation for Healthcare predictive analytics market share (in developed countries) is expected to exceed USD 5 billion by 2024 (Marketwatch, 2018).

2.3. U.S Market constrains

Gazing at the restrictions that can be foreseen soon, it is well known that it is usually difficult to enter the healthcare market with new products (Clarke, 2016). Moreover, there is a worldwide phenomenon regarding the availability of capital in healthcare spending which seems either diminishing or staying flat, Deloitte (2020) estimated a slowdown of 3.2 percent slowdown already in 2019 compares to a 5.2% spending in 2018. (Allen, 2020). Important for medical devices such as Smartbag is the analysis of additional competitors from outside the traditional healthcare sphere, involving many from the technology area that is pursuing to enter the healthcare market. (Bouwens - Krueger, 2018). Among them, Apple which updated its healthcare app, using the electrocardiogram (EKG) feature in the apple watch, while Alphabet helps Physicians taking note of information during a hospital appointment and connects home company Nest, to monitor patients in nursing homes (Chen, 2019). Yet according to Deloitte[82], connecting previous unrelated data sets and developing new business models that integrate the new ones, looks challenging.

[81] PwC (2020), "Global Top Health Issues, Defining the healthcare of the future", available at: https://www.pwc.com/gx/en/industries/healthcare/top-health-industry-issues.html

2.4. Denmark Healthcare Market Entry

Fortunately for Denmark, it was ranked by the World Bank at the 4th place in the world relative to the easiness of doing business (The World Bank, 2019)[83]. However, the same ranking put Denmark at the 45th place for starting a business. Moreover, according to The Economist, (2020), the national economic fundamentals are robust, supported by an active labour market and high capital expenditure. The National bank policy seems to follow the directives of the EU and the European Central Bank (The Economist, 2020). Forbes' 2018 assigned Denmark in the top 10 Best Countries for Business confirming it one of the most appealing countries for capital investment in the world, creating opportunities also for foreign companies to expand or launch their business (Forbes, 2018). Going into the healthcare topic, the U.S.A export.gov stated that the commercialization of medical devices in the category of Smartbag is usually done through the traditional distribution model, although health IT goods might involve a domestic presence or a strategic partnership with a local retailer (Export.gov, 2016).

2.6. Assessing Demand

In 2019, the total life-expectancy in Denmark has soared to 81.3 years for Danish citizens (Denmark Statistics, 2020) which is near the bottom in Europe. It can be relevant for Smartbag advancement to note that healthcare in Denmark is free, in general, Danish citizens are very unwilling to pay for healthcare treatment and medicines, subsequent in merely 14.7% of health expenses coming from private sources. Nonetheless, most individuals are worried about their well-being and are prepared to spend money on preventive measures involving healthful food, supplements, and sports subscriptions (The Ministry of Health, 2017).

2.7. Current Market Trends (Danish Healthcare System)

Generally speaking, Danish health and social services are financed by general taxes, nearly 84 % of healthcare spending is publicly funded (2015), the other 16% instead is financed by patients' co-payments. The total cost for health amount at 30% of the total public spending or around 10% of the GDP. Specifically, for the elderly, the public spending amounted to 2.8 %

[83] The World Bank (2019), "Ease of Doing Business rankings", available at: https://www.doingbusiness.org/en/rankings

of the GDP (2014). Public spending includes both hospitals and home nursing. In fact, services for elderlies in-home nursing and communities are provided by the municipalities free of charge. The service also allows citizens to stay in their own accommodation. Moreover, maybe relevant for the Smartbag project is the framework of ambitious domestic goals for the excellence of care, in fact, other than chief political priorities in the healthcare system to ensure that all levels of the system provide an excellent performance of quality, the Danish Healthcare Quality Programme presents among initiatives for improvements the "Systematic use of data that creates visibility of results" which fits the purpose of the Smartbag concept (The Ministry of Health, 2017). Denmark's health sector has 54 public health facilities with 107, 078 full-time employees (Export.gov, 2015).

2.8. Legal Policy on Medical Devices Europe, Denmark 

Being part of the EU, also Denmark divides the medical devices into four categories, based on the risk. Figure 28. Considering the Smartbag future products in the medical device's category seems reasonable to look at the main Danish legislation on medical devices. The entities for the responsibility and structure of the healthcare system are the Danish Ministry of Health and the Danish Medicines Agency, which among the other things supervises medical devices' availability and issues (Ørndrup - Federspiel, 2019).

The legal aspects instead are regulated manly by "the Danish Act on Medical Devices which implements the EU directives on medical devices, such as Directive 93/42/EEC concerning medical devices." (Consolidated Act no. 139 of 15 February 2016).

According to Danish law, the regulation of medical devices is categorized into three main sections:

1. Definition and purpose of Medical Devises
2. Manufacturing and Sale
3. Advertising

At this stage of the Smartbag project, it is even possible to give an idea in which specific place it would be positioned with legal aspects.

Regarding the definition, it can be placed in the category of *"Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap."*

The Manufacturing and Sale aspects seem more complicated, given that the law requires the only CE marked (Executive Order No. 1263 of 15 December 2008) with the exception for:
“

- *Custom-made devices.*
- *System and medical treatment packages.*
- *Devices for clinical investigation.”* (Ørndrup - Federspiel, 2019).”

Which the author hopes the Smartbag product will fall, to avoid legal complication processes.

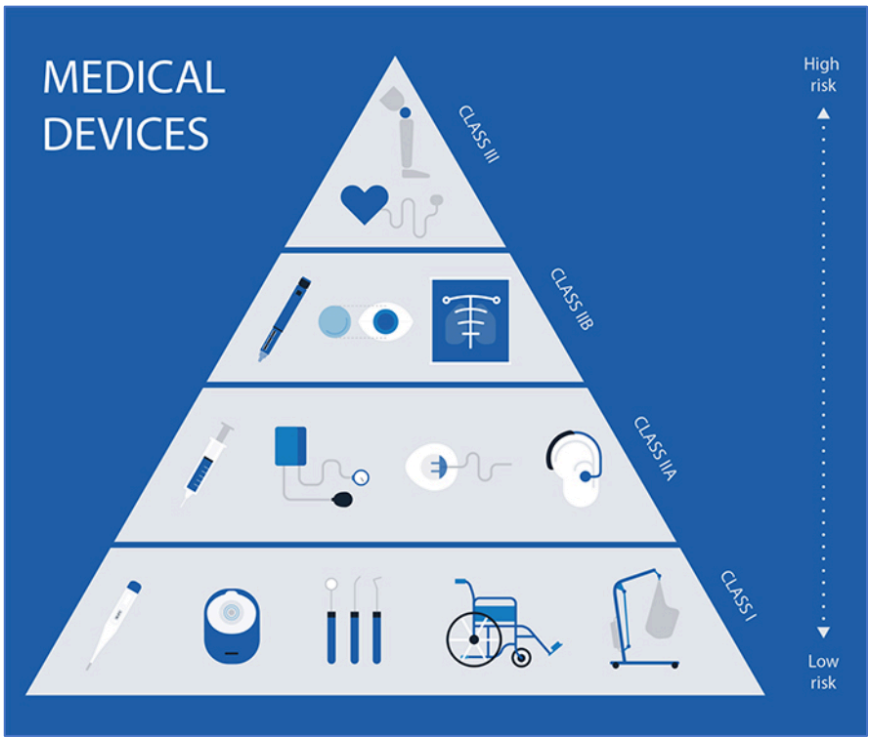


Figure 28. European Medical Device Categories (Ørndrup - Federspiel, 2019).

Also, the advertising side is tricky and quite regulated, aspects such as discounts, labels, information, etc. (Executive Order no. 1155 of 22 October 2014). Looks then, that a legal consular is necessary for the Smartbag venture to be considered in the development and in the phases of the business plan.

2.9. Reflection of the Section

The domestic view of the market would serve to have an understanding of the possible economic opportunities and restrictions that, after the study resulted in being under the global tendencies. In particular, trends toward home healthcare, difficulties in legal entry and growing aging population are also present in the Danish market. The hint that is possible to extract is the vast presence of public funds that goes into healthcare, compare to other countries where

there are more private solutions. This could bring to a strategy, where the B2G is a potential scenario. The exploration of the segmentation of the market is aimed to explore also this prospect.

3. COMPETITOR ANALYSIS

3.1. Porter's Framework for Competitor Analysis

To make the work easier and more reliable, I relied upon different theories, manly using Porter strategies (Porter, 1998, pp. 47-74) and Five Forces, (Porter, 2008, pp. 78-93).The importance of the present section gives a justification in the practical choices for a competitor's analysis and the following action plan in the subsequent parts of the report.

The need for a sophisticated competitor analysis is wrapped in the answer to the questions such as "Who should be picked to fight within the industry, and with what sequence of moves?" "What is the meaning of that competitor's strategic move and how seriously should we take it?" and "What areas should we avoid because the competitor's response will be emotional or desperate?"(Porter, 1998, pp. 47-74). The importance of the right description of the competition is clear and without doubt, but such understanding is often neglected in practice, and often managerial assumptions can become dangerous. Another practical difficulty is about the gathering of the data, given that the amount of information available for the current issue is hard to find without focus and handwork. The four components for a "healthy" diagnosis of the competition are the following:

- Assumptions
- Capabilities
- Future goals
- Current strategy

Analysing these elements will give at least an intuitive sense of the direction and the profile of the companies which need to be scrutinized. Furthermore, meaningful for the process is defining their strength and weakness in their strategy (the competitors). Broadly, the writer considered few questions useful in the definition of a framework for the Smartbag case. To compress the information Figure 3 shows what is the structure of the framework to use in Porter view.

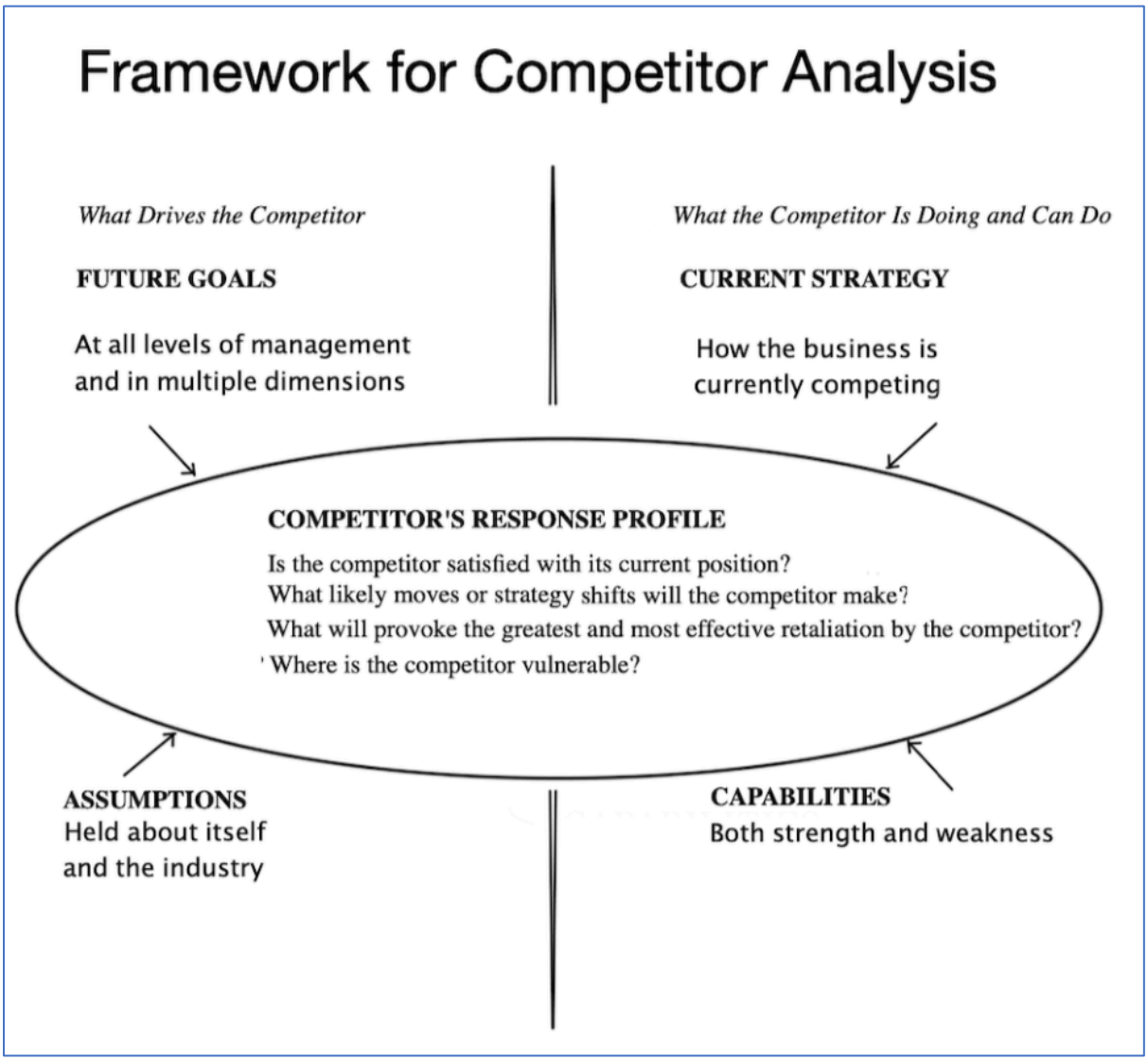


Figure 29. Framework Competitor Analysis (Modified of Porter, 1998, p. 49).

3.2. Danish Potential Competitors

For investigation purposes, of treats and opportunities a competitor analysis was shaped in the Danish environment. Although, the competition is global the author focused on the domestic market for constrains in time and place. Below are listed the most significant medical devises company in Denmark. In addition, a Porter's five forces analysis is added to understand the circumstances of the market.

The biggest companies[84] in this landscape of the medical devices and pharmaceutical are

1. Ambu, which mainly specializes in business areas such as anaesthesia, cardiology, and neurology producing goods for ventilation for artificial respiration, for ECG (electrocardiogram) tests and neurophysiological mappings. According to the company's webpage, the production is not in Denmark, where they are direct sellers but have only R&D departments (Ambu.com, 2020).
2. Bavarian Nordic, better known as a biotechnology company, while focusing in R&D production of active cancer immunotherapies and vaccines for infectious diseases. They state to that they are focused on bringing vaccines to market (BavarianNording.com, 2020).
3. Coloplast, the company manufactures and deliveries products to hospitals and institutions as well as wholesalers and retailers. The category of products ranges from ostomy, continence, wound, skin, and interventional urology (Coloplast.com, 2020).
4. *GN ReSound*, was acquired in 1999, but founder in 1943 from a Stanford medical professor in 1943. It is a supplier of hearing aids and accessories, represented in more than 100 countries, with headquarter in Bellerup, Denmark.
5. *H. Lundbeck*, is a Danish and world-wide pharmaceutical enterprise occupied in the R&D, manufacture, promotion, and selling of drugs for the treatment of illnesses in the central nervous system (CNS), among the diseases: Alzheimer's, Parkinson's, depression and schizophrenia
6. *Novo Nordisk* is a Danish global pharmacological business located in Bagsværd, Denmark, with production in 8 countries, offices in 5 (Novonordisk.com, 2020).

[84] For more information about the companies cited:

1. Ambu.com, 2020, available at: https://www.ambu.com/about/about-ambu/our-company
2. BavarianNording, 2020, available at: https://www.cdmo.bavarian-nordic.com
3. Coloplast.com, 2020, available at: https://www.coloplast.com/Global/1_Corporate_website/CP_CB_Company_Brochure_2019-20_PM09278.pdf
4. GN ReSound.com, 2020, available at: http://www.gnhearing.dk/da
5. H. Lundbeck.com, 2020, available at: https://www.lundbeck.com/global
6. Novonordisk.com, 2020, available at: https://www.novonordisk.com
7. Oticon.com, 2020, available at: https://www.oticon.com
8. Widex.com, 2020, available at: https://global.widex.com/en/about-widex

7. *Oticon*, leader in the hearing devise for aid, based in Copenhagen, Denmark. The company itself claims to be the most innovative company and second large manufacture of hearing aids (Oticon.com, 2020).

8. *Widex*, as the company previously cited, it is one of the largest manufacturers of hearing devices. With a market distribution in 100 countries and 4000 individuals employed (Widex.com, 2020).

3.3. Five Forces Analysis

3.3.1. Threat of New Entrants (Low)

For the B2B, as discussed previously, the market size in Denmark of the kind of application that Smartbag aims to propose is relatively small compared to other markets and products (Wound care, Hearings aids). Moreover, given the difficulties in the legal acceptance (CE mark)by Danish authorities of the products in the medical landscape, it is unlikely that the hospital segments would integrate such solution in the near future (1-3 years), and if it will happen is probably that the existing players with established contracts will develop such solutions. On the other hand, looking at the private market, the Smartbag solutions looks more compelling, because of the size, but also less complexity in product development and software system.

As will be explained in detail further on, in complexity of the hospital environment the Smartbag can be seen as part of a bigger system with many input data, that still don't have a infrastructure (as network, sensors), this makes the Smartbag proposal a software operational management problem and integration, which deal with many other issues. Whereas, in the private sector Smartbag could be a solution per-se and would be only another monitoring tool for elderly's well-being. In the second scenario a Smartbag patent could further protect the venture. Moreover, in case of selling it is important to have strong channel distributions to sell the product, the experiences with the pharmacies helped to shape this view. For these reasons this parameter has been considered *Low* from the author's view.

3.3.2. Threats of Substitution (Medium-Low)

As today, the process of changing and monitoring the catheter is still done manually both in hospitals and homes, the only substitutions that would possibly occurs are nursing and

assistants. There are not same products that do the same job of measuring the bag liquid and cover the pee bag in the same product. Although, there are alternatives for measuring the liquid with physical scale meters and cover or supports for the bag, the Smartbag product should be perceived as a worthy substitute. This part will be better explained in the choices for prototype development. The author considers the threat from other subsites *Medium-Low.*

3.3.3. Bargain Power of Customers (Low)

Established large businesses can take actions to moderate buyer power, for instance executing a loyalty plan. In general, buyer power is low if there are not many substitutes as in the case of Smartbag. Another factor worth considering is the customer's availability of information on similar products, (which don't exist yet in the market). Important also is the amount of order a singular customer would make, if the scenario is still the one in the private house or even nursing homes (bought by the relatives of the patient) the buying power for the last point and other above is considered low. Moreover, if the strategy to implement will consider the data aspect also used as obstacle to change product for a new one, because the older analysis and parameter would be in the Smartbag platform, this would lower the buying power even more.

3.3.4. Bargain Power of Suppliers (Medium-High)

Given that the Smartbag product is built from scratch without the use of existing parts (chapter 4) from the design to the choice of the material, it will all depend on the pieces in use. However, first consideration is possible on the singular components.

Regarding the electronic part, it is easy to find millions of open source and different architecture for the weighing liquid task, also if the job would be eventually done differently with cameras, infrared or other sensors, the supplier eventually would be easy to replace. For the structure component, the design described in the next chapter could become a problem if the choice of the supplier will be mistaken. More explicitly, given that the design is new and eventually some manufacture would accept to produce the design, would be the only one to produce such pieces, and that would become a problem if the design is not changed with existing parts already available in the market. Thus, for the information so far obtained (and based in a non-vertical business scenario) the author considers this aspect as *Medium-High* threat.

3.3.5. Competitive Rivalry (Medium-High)

As seen in the competitor analysis there is some international and already established business with a big advantage regarding supply chain and channel distribution. The aging population growth is seen as an opportunity also from other firms, this fact could bring some of the companies in the healthcare business to expand their products into different categories as Smartbag proposal, if it would be eventually become successful. In this case would be difficult to compete with such giants and a defensive strategy that take that into account will be developed in the next chapters' consideration above bring to estimate a Medium-high treat.

3.4 SWOT

STRENGTHS

- Scalable business model
- Strong value proposition, product is unique to the market
- Use of the latest technology
- Prototype completed
- Low cost management
- Attractive design
- Data analysis

OPPORTUNITIES

- Capitalize on first to market with device
- Growing prevalence of urinary incontinence (Market Growth)
- Expanding internationally
- Continued innovation through new technologies
- Patent protection possibilities

WEAKNESSES

- No brand awareness
- No customer base that might impact on profitability / cash flow in the early years
- Start-up with inherent risks of a new business / no operating history

- Lack of initial capital
- Team size/expertise
- Customer’s learning curve

THREATS

- Downturn in economy – COVID-19 impact
- New entrants that copy the device (Competitors)
- Key people dependency
- Supplier Dependency
- Industry regulations (potential changes)
- Technological changes

4. PROTOTYPE DEVELOPMENT 

4.0 Strategies Factors in Prototyping
1. Separating the work of prototyping in a single sub-part, of a set of sub-structures, or the entire structure. While impending the creation of a large system, it may be beneficial to break the job down into smaller subsystems. Thus, they can be progress with different optimal strategies.
2. Deciding on prototyping several concepts in parallel vs. prototyping individually. In order to receive critical feedbacks, it is possible to create different concepts of prototype at one and eventually chose the development the one who better fit the purpose.
3. Prototyping in an iterative way or a single prototype per concept. Using these considerations, the team could develop a prototype completely or adding certain requirements step by step in progression. This can be valuable when reducing the number of hypothetical designs to a final few.
4. Considering having virtual prototype or physical. It can be beneficial to develop the complex analysis on a virtual model (analytical, CAD, etc.) for mechanical and manufacturing reasons. However, the feedback from a physical development for user interaction are also important.
5. The process of prototyping can be outsourced, rapid prototyped or completed in house. Outsourcing can be beneficial in terms of expense and time because make available the team to focus on other aspects of the task and could offer access to resources that may not be available within the company. Rapid prototyping technologies let the team evaluate and produce in short times, however accessible materials are limited, which could end in a discordance with the final design requirements. Conclusively, the models can be finished in house, supposing the team have the proper resources and abilities. This alternative may be cheaper, but more time intensive.
6. Using scales of prototypes. When making a full-size model is not viable for cost or size (airplanes, ships) or is not possible to test the full-size equipment, a smaller version of it can be used.
7. Scale only some part of the prototype for functions testing

Some part of the prototype can scale (up or down) to be tested respecting some requirements at a time, to be capable to properly guarantee and assess the positive execution of requested qualities. This permit an easier testing and a final robust product but can create problems when to put together all the pieces.
8. Use similar or different components for prototyping than the final design. In general prototypes have the benefit of not having to meet all the ultimate design requirements at all steps, thus, the constituents in use can be different and used for the different purposes.
9. Use similar or different industrial and assembly techniques than the final design. The technologies of fast printing and rapid tooling allow teams in some case to decide if they want to use similar manufacturing and assembling types of the final product.
Source: Christie E.J., Jensen D., Buckley R.T., Menefee, D.A., Ziegler K., Wood. K., Crawford R. (2012), *"Prototyping strategies: Literature review and identification of critical variables"*

4.1. Prototype Structure Concept Process

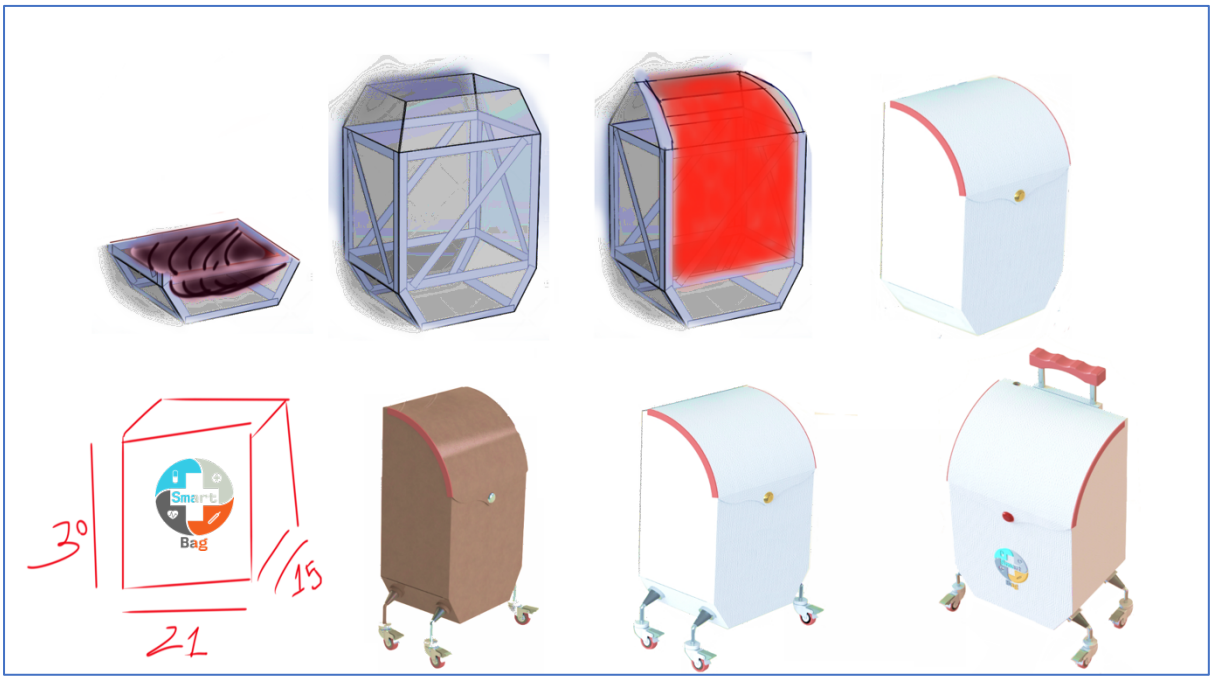


Figure 30. Smartbag, Prototype Structure Development (Own made).

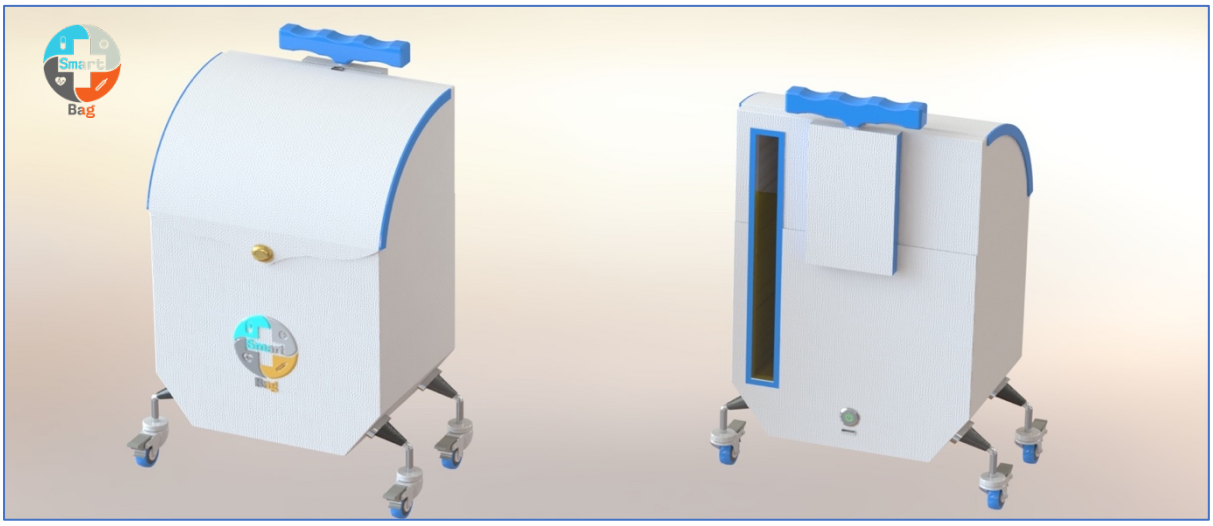


Figure 31. Smartbag, Digital Prototype (Own made).

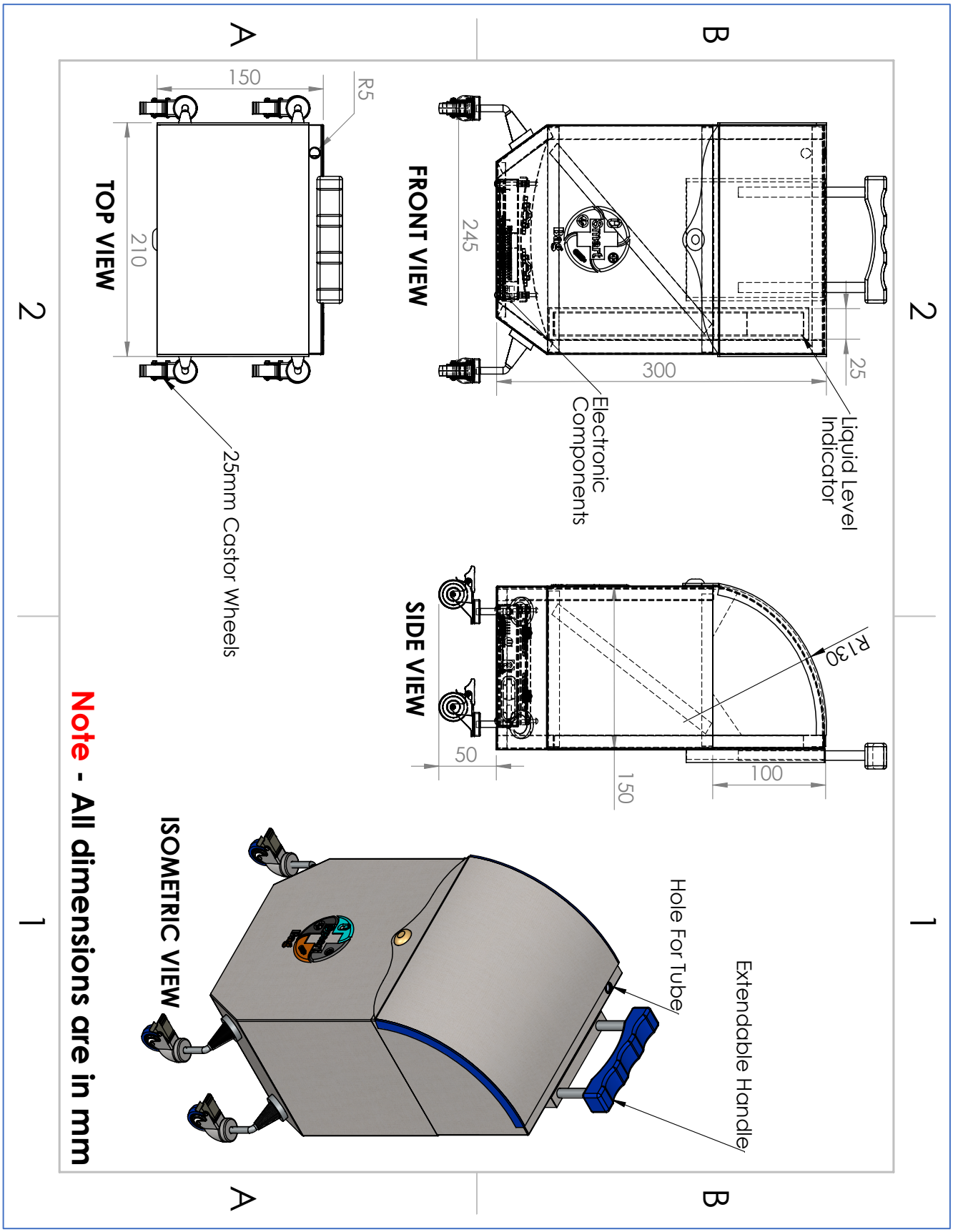


Figure 32. Smartbag, Structure, Visual Prototype (Own made).

4.2. Electronic Section of the Prototype

Figure 33. Electronics, Visual Prototype (Own made).

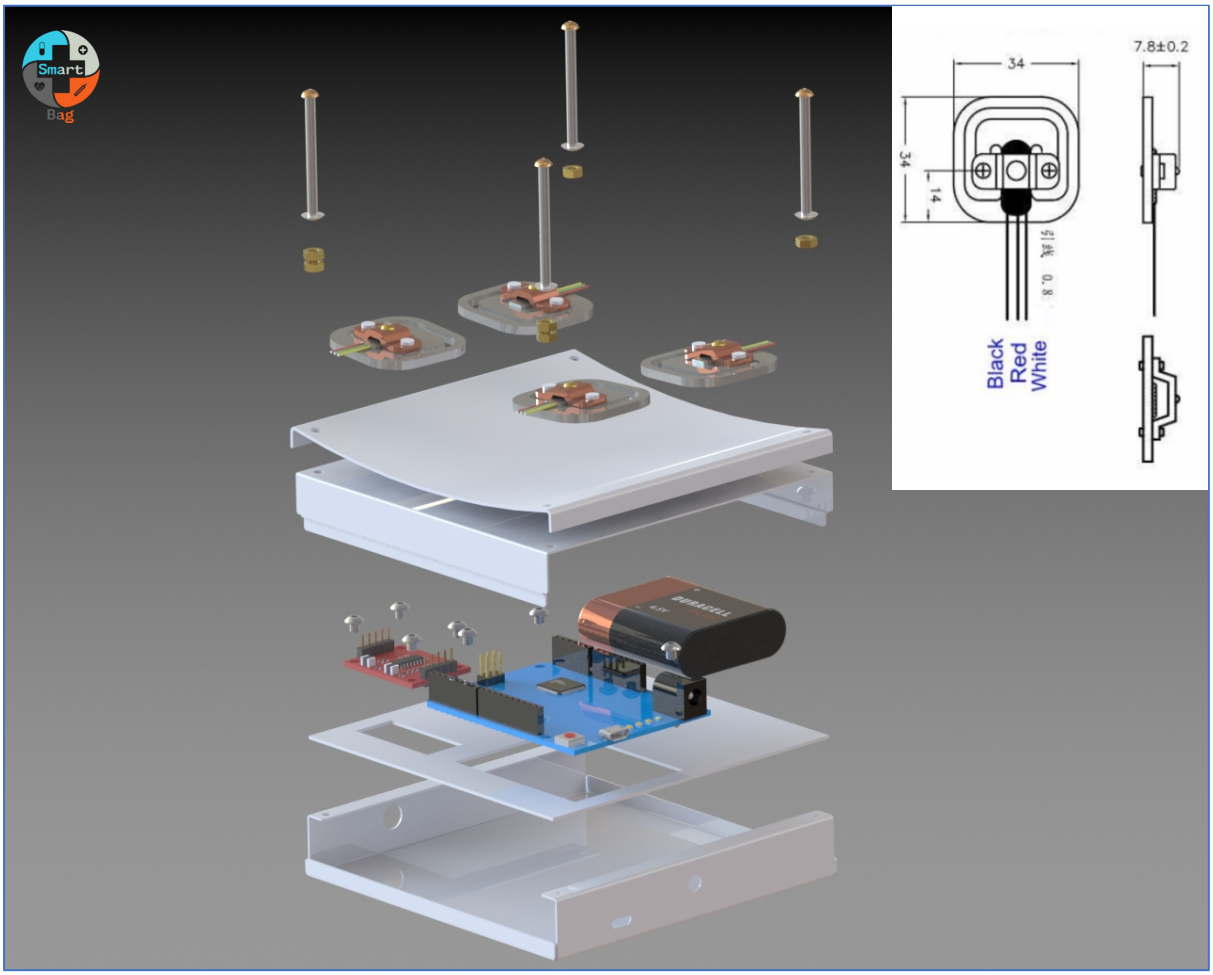


Figure 34. Electronic, Shell and Components (Own made).

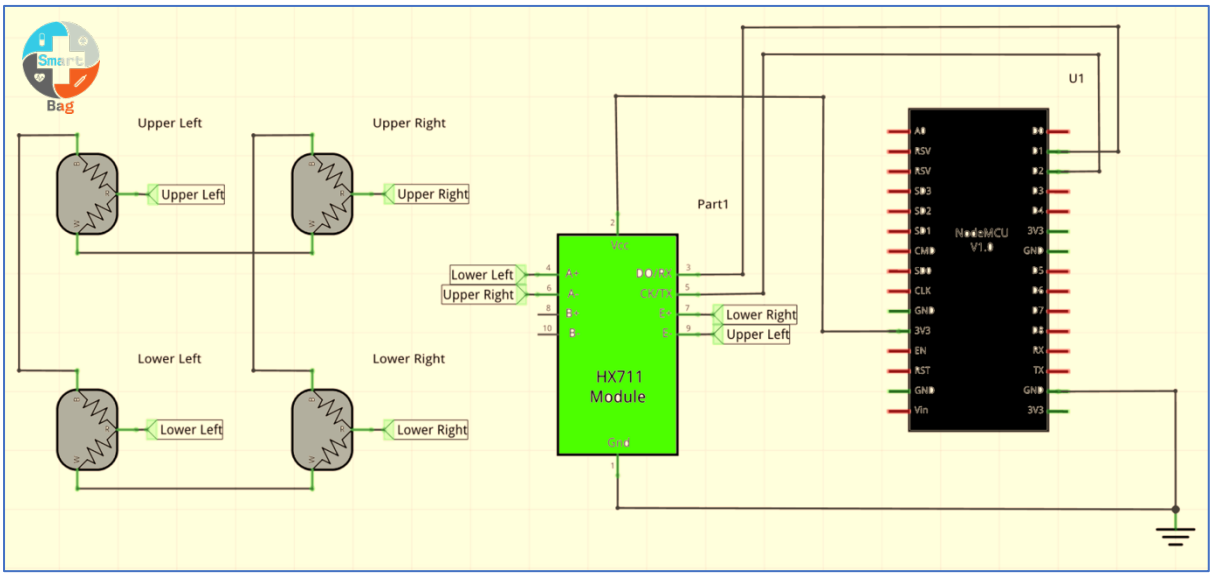


Figure 35. Electric Circuit of the Prototype (Own made).

4.3. Working Prototype (Actual Smartbag Prototype)

Figure 36. Smartbag, on Bed and Wheelchair (Own made).

4.4. Electronic Shell Working-Prototype

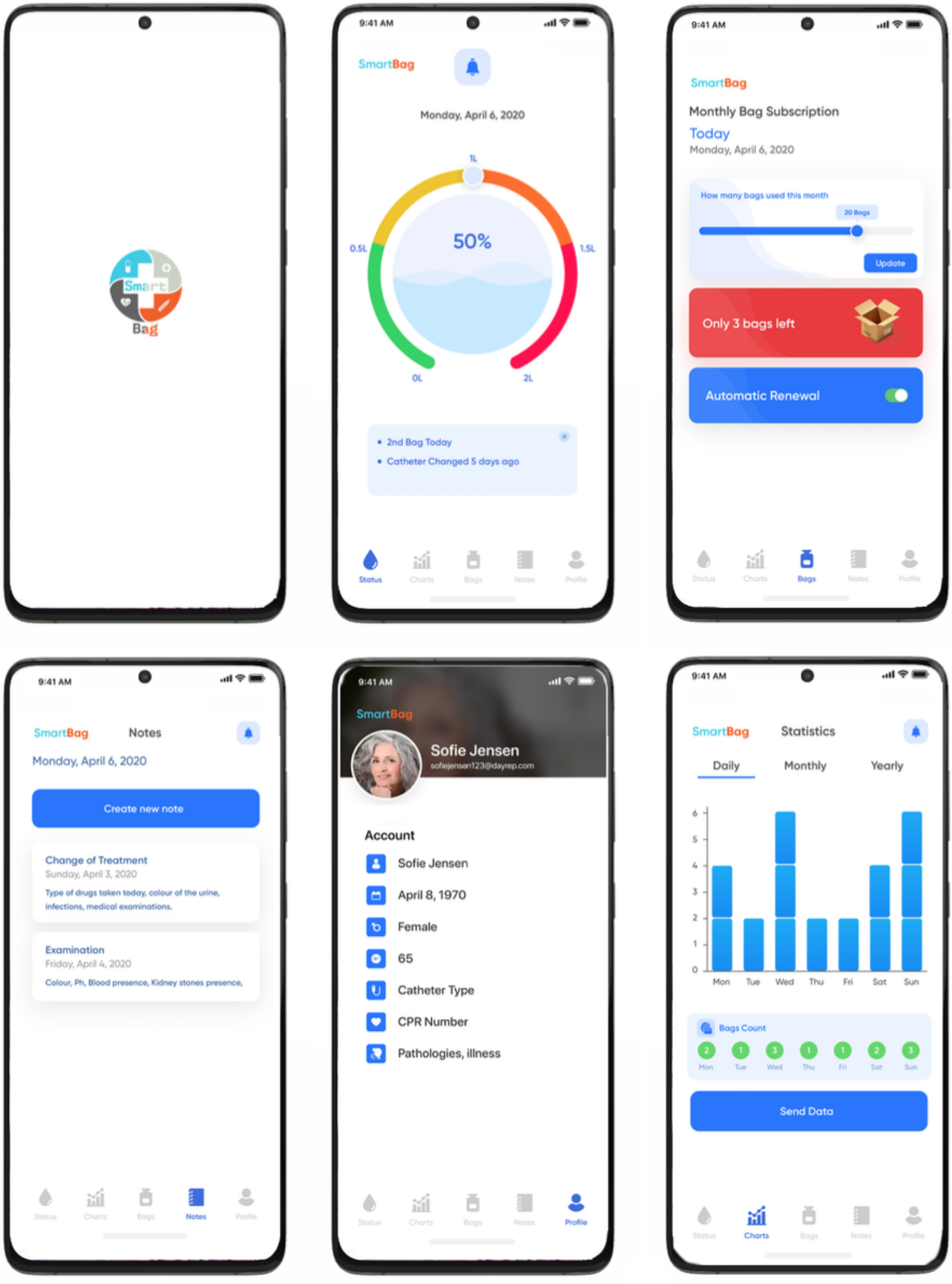
Figure 37 A. Phases, Wood Shell Building (Own made).

Figure 37 B. Smartbag Sensors, Smartbag Product, Smartbag Circuit (Own Made)

4.5. Smartbag User Interface (Paper-Prototype)

Figure 38t. Drawings, User Interface App (Own made).

4.6. Smartbag User Interface (Visual Prototype)



4.7. Results Test Urine Output

Date	Urine Output in ml
14/05/2020	1203
15/05/2020	1390
16/05/2020	1125
17/05/2020	1235
18/05/2020	1210
19/05/2020	1000
20/05/2020	995
21/05/2020	1210

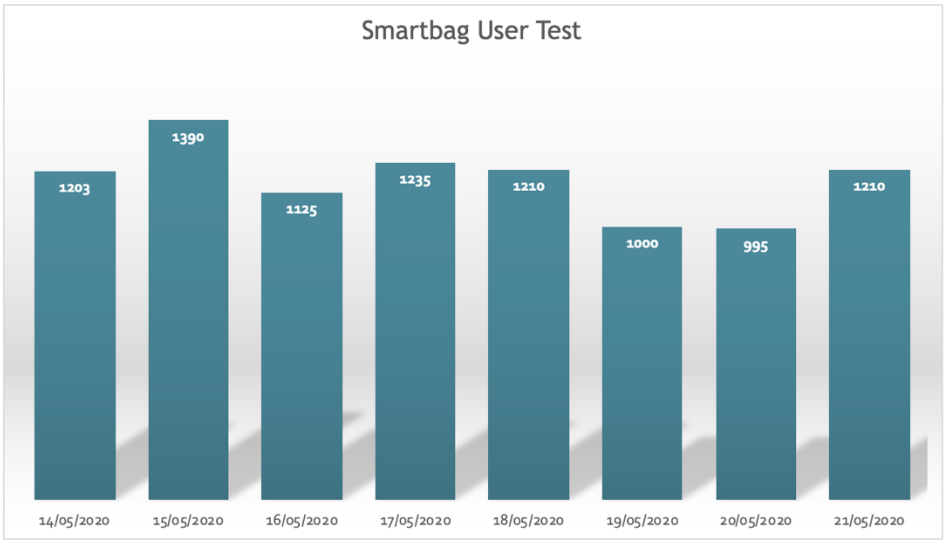


Table 1. Test Conducted Using the Working Prototype (Own made).

5. BUSINESS PLAN 

Introduction

Smartbag will operate through a *corporation* (this entity is not yet established). It will initially be 100% owned by the founder, Giovanni Amenta. The location of the business is initially located in *Europe*. Intellectual Property Smartbag has not registered any trademarks or patent at this stage. Regarding the regulatory elements Smartbag will fulfil and maintain all regulatory requirements to operate, including:

- All necessary tax registrations: Corporate tax, Employment taxes, Sales taxes
- Business & Licensing registrations
- FDA/CE approval for medical devices
- Data protection laws
- Privacy Laws
- Consumer laws
- Company Law

5.1. Financial Projection

The financial projections for Smartbag are outlined below. Key assumptions are described along the text in chapter 6.

Income Statement	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue	$717, 500	$1, 960, 000	$4, 445, 000	$9, 415, 000	$19, 355, 000
Revenue Growth Rate	na	173%	127%	112%	106%
Direct Costs	$507, 500	$1, 435, 000	$3, 290, 000	$7, 000, 000	$8, 120, 000
Gross Margin	$210, 000	$525, 000	$1, 155, 000	$2, 415, 000	$11, 235, 000
Gross Margin %	29%	27%	26%	26%	58%

Overheads	$213, 275	$478, 400	$692, 650	$1, 091, 150	$1, 888, 150
EBITDA	-$3, 275	$46, 600	$462, 350	$1, 323, 850	$9, 346, 850
EBITDA %	0%	2%	10%	14%	48%
Net Income	-$3, 275	$36, 814	$365, 257	$1, 045, 842	$7, 384, 012
Net Income %	0%	2%	8%	11%	38%
Net Cash Flow	$6, 734	$10, 948	$287, 551	$887, 965	$7, 068, 258
Closing Cash	$6, 734	$17, 681	$305, 232	$1, 193, 197	$8, 261, 455

5.2. Sales Projections

The table below sets out the sales projections by revenue stream for the first five years. Based on research by Markets & Markets, there were approximately 25 million patients in the United States suffering from urinary incontinence. Sales of 56, 000 units in year five would represent capturing approximately 0.2% of the market in the United States. It is assumed that 50% of the customers will subscribe to the urinary bags offer adding app year by year.

Revenue Stream	Year 1	Year 2	Year 3	Year 4	Year 5
Sales of Smartbag devices	3, 500	7, 000	14, 000	28, 000	56, 000
Urinary Bags – Monthly subscription	1, 750	5, 250	12, 250	26, 250	54, 250

5.3. Commentary and Analysis

Revenue is projected to increase from $717.5K in year one to $19.4m by year five. The Smartbag device will be provided to patients at $0 upfront with 6 monthly payments of $10. 3, 500 Smartbag devices are assumed to be sold in the first year, increasing to 56, 000 in year five. Revenue will also be generated through offering patients a monthly subscription-based

model for the supply of urinary bags where patients receive a set number of urinary bags per month, based on their needs.

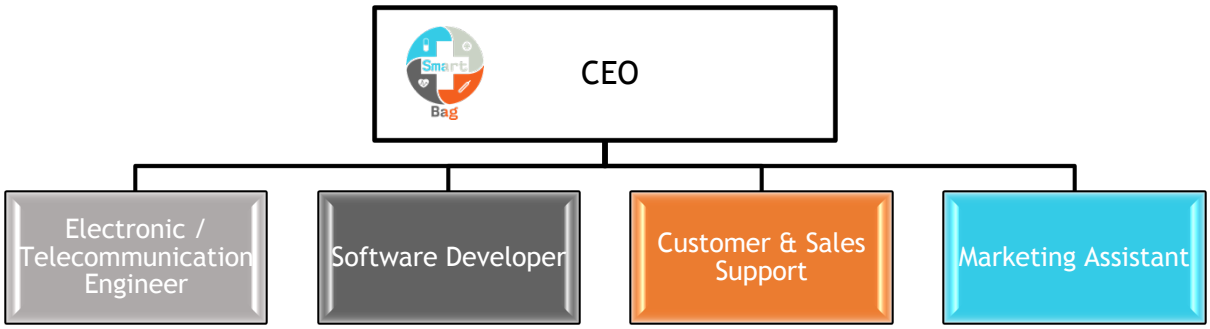
- A monthly subscription price of $25 ($300 pa) has been assumed for the projections, with the first two months provided to patients at cost of $20.Subscriptions to the monthly supply of urinary bags are projected to increase from 1, 750 in year one to 54, 250 by year five.
- It is assumed 50% of the patients who purchase a Smartbag device subscribe to the monthly delivery of urinary bags.
- Marketing costs are assumed to be 5% of revenue.
- Overhead costs include legal costs, salaries & wages (See Section 5.5 for the staffing profile), and other costs to operate the business.
- Net income is projected to increase from ($3K) in year one to $7.4m in year five.
- Closing cash is projected to be $8.3m at the end of year five.

5.4. Sensitivity Analysis Year 1

The following table sets out a sensitivity analysis for year one, which shows the impact to profitability should revenue be higher or lower than projected.

From:	-20%	-10%	Projected	+10%	+20%
Revenue	$574, 000	$645, 750	$717, 500	$789, 250	$861, 000
Net Income	-$146, 775	-$75, 025	-$3, 275	$ 68, 475	$140, 225

5.5. Staffing Profile and Team (expenses)



Team	Year 1	Year 2	Year 3	Year 4	Year 5
CEO	1	1	1	1	1
CEO	-	$50, 000	$80, 000	$80, 000	$80, 000
Electronic / Telecommunication Engineer	1	1	1	1	1
Electronic / Telecommunication Engineer	$42, 000	$84, 000	$84, 000	$84, 000	$84, 000
Software Developer	1	1	1	1	1
Software Developer	$42, 000	$84, 000	$84, 000	$84, 000	$84, 000
Marketing Assistant	1	1	1	1	1
Marketing Assistant	$42, 000	$84, 000	$84, 000	$84, 000	$84, 000
Sales & Customer Support Staff	1	1	2	4	10
Customer Support Staff	-	$60, 000	$60, 000	$60, 000	$60, 000

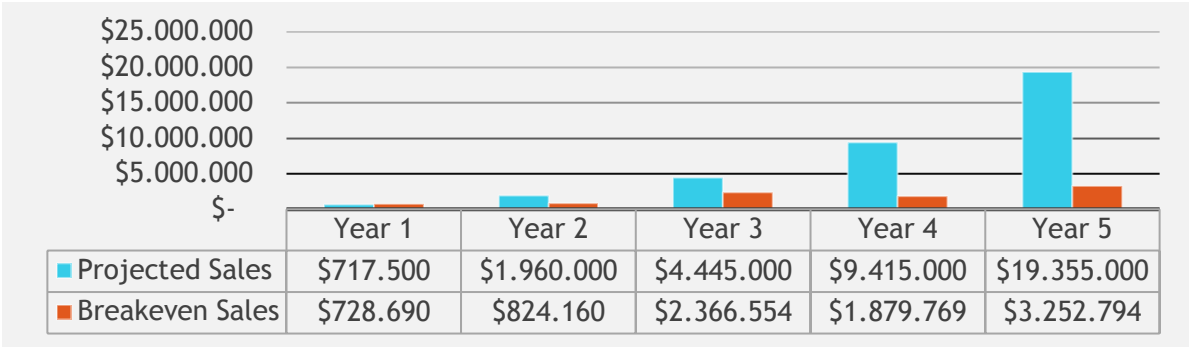
Founder - Giovanni Amenta

Giovanni is an engineer and entrepreneur engaged in using disruptive technologies to solve problems and improve people's lives. Giovanni started his studies at Polytechnic of Turin, Italy, with a degree in Civil Engineering. He enrolled and took courses out of interest in Physics of Complex Systems at the University of Turin. Among them, Quantum Mechanics, Mathematical

Physics, and Solid-State Physics. In 2018, Giovanni commenced the program in Entrepreneurial Engineering, Aalborg University, Denmark. In 2019, as an exchange student, he was part of the Global MBA program at Laval University, Canada, where he focused on financial accounting and information system technologies. Giovanni started minor projects before the Smartbag system, one of those regarding the sales of a statistical model to win the lottery (2017).

Breakeven Analysis

The breakeven sales point in year one is $729K compared to projected sales of $717.5K. The breakeven sales point increases to $3.3m in year five, compared to projected sales of $19.4m.



	Year 1	Year 2	Year 3	Year 4	Year 5
Projected Sales	$717.500	$1.960.000	$4.445.000	$9.415.000	$19.355.000
Breakeven Sales	$728.690	$824.160	$2.366.554	$1.879.769	$3.252.794

5.6. Projected Income Statement of 5 Years

	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue					
Smartbag Devices	210,000	420,000	840,000	1,680,000	3,360,000
Urinary Bags (Monthly Subscription)	507,500	1,540,000	3,605,000	7,735,000	15,995,000
Total Revenue	**$ 717,500**	**$ 1,960,000**	**$ 4,445,000**	**$ 9,415,000**	**$ 19,355,000**
Revenue Growth rate		***173%***	***127%***	***112%***	***106%***
Direct Costs					
Smartbag Devices	87,500	175,000	350,000	700,000	1,400,000
Urinary Bags (Monthly Subscription)	420,000	1,260,000	2,940,000	6,300,000	6,720,000
Total Direct Costs	**$ 507,500**	**$ 1,435,000**	**$ 3,290,000**	**$ 7,000,000**	**$ 8,120,000**
Total Gross Margin	**$ 210,000**	**$ 525,000**	**$ 1,155,000**	**$ 2,415,000**	**$ 11,235,000**
	29%	**27%**	**26%**	**26%**	**58%**
Overhead costs					
Marketing	35,875	98,000	222,250	470,750	967,750
Accounting fees	5,000	5,000	5,000	5,000	5,000
Data Storage (cloud)	3,000	3,000	3,000	3,000	3,000
Legal & licenses	5,000	2,000	2,000	2,000	2,000
Office supplies	2,400	2,400	2,400	2,400	2,400
Telephone & Internet	3,000	3,000	3,000	3,000	3,000
Wages	156,000	362,000	452,000	602,000	902,000
Website Development / Hosting	3,000	3,000	3,000	3,000	3,000
Total Overhead costs	**213,275**	**478,400**	**692,650**	**1,091,150**	**1,888,150**
EBITDA	**-$ 3,275**	**$ 46,600**	**$ 462,350**	**$ 1,323,850**	**$ 9,346,850**
EBITDA %	***0%***	***2%***	***10%***	***14%***	***48%***
Income Tax expense	-	9,786	97,094	278,009	1,962,839
Net Income	**-$ 3,275**	**$ 36,814**	**$ 365,257**	**$ 1,045,842**	**$ 7,384,012**
	0%	**2%**	**8%**	**11%**	**38%**

5.8. Projected Cash Flow Statement of 5 Years

	Year 1	Year 2	Year 3	Year 4	Year 5
Cash Flows From Operating Activities					
Net Income	-$ 3,275	$ 36,814	$ 365,257	$ 1,045,842	$ 7,384,012
Adjustments for:					
Accounts Receivable Decrease (Increase)	(27,521)	(47,658)	(95,315)	(190,630)	(381,260)
Accounts Payable Increase (Decrease)	17,529	21,791	17,610	32,753	65,507
Net Cash Generated (Used) in Operations	(13,266)	10,948	287,551	887,965	7,068,258
Cash Flows From Investing Activities					
Purchase of Fixed Assets	-	-	-	-	-
Net Cash (Used) in Investing Activities	-	-	-	-	-
Cash Flows From Financing Activities					
Funding received	20,000	-	-	-	-
Net Cash Flows From Financing Activities	20,000	-	-	-	-
Net Cash Flow					
Net Movement in Cash	6,734	10,948	287,551	887,965	7,068,258
Cash at Beginning of Period	-	6,734	17,681	305,232	1,193,197
Closing Cash Balance	**$ 6,734**	**$ 17,681**	**$ 305,232**	**$ 1,193,197**	**$ 8,261,455**

5.9. Projected Balance Sheet of 5 Years

	Year 1	Year 2	Year 3	Year 4	Year 5
ASSETS					
Current Assets					
Cash	6,734	17,681	305,232	1,193,197	8,261,455
Accounts Receivable	27,521	75,178	170,493	361,123	742,384
Total Current Assets	$ 34,254	$ 92,860	$ 475,726	$ 1,554,321	$ 9,003,839
Other Assets					
Other Assets	-	-	-	-	-
TOTAL ASSETS	**$ 34,254**	**$ 92,860**	**$ 475,726**	**$ 1,554,321**	**$ 9,003,839**
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current Liabilities					
Accounts Payable	17,529	39,321	56,930	89,684	155,190
Total Current Liabilities	17,529	39,321	56,930	89,684	155,190
TOTAL LIABILITIES	$ 17,529	$ 39,321	$ 56,930	$ 89,684	$ 155,190
Stockholders' Equity					
Funding received	20,000	20,000	20,000	20,000	20,000
Retained Earnings	(3,275)	33,539	398,796	1,444,637	8,828,649
Total Stockholders' Equity	$ 16,725	$ 53,539	$ 418,796	$ 1,464,637	$ 8,848,649
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 34,254**	**$ 92,860**	**$ 475,726**	**$ 1,554,321**	**$ 9,003,839**

Notes:

The accounts receivable balance is based on the assumption of receiving payments within 14 days of issuing an invoice (on average). The accounts payable balance is based on the assumption of paying bills within 30 days of receiving an invoice (on average).

5.10. Strategic Pillars

The strategic pillars of Smartbag are set out below.

BRAND AWARENESS & MARKET PENETRATION IN THE EUROPE

CAPITALIZE ON FIRST TO MARKET

PROFITABILITY & SUSTAINABILITY

GEOGRAPHIC EXPANSION

The Key Growth Objectives:

Strategic

- To build brand awareness and become the leading sensor device for urinary drainage bags globally
- To launch the service in the Denmark in 2020
- To commence geographic expansion into U.S in year three
- To build and execute an exit strategy by the end of year five
- To remain ahead of competitors in terms of product offering, customer service, and technological innovation

Financial

- To secure initial funding of $20K through a crowdfunding campaign
- To grow revenue to $19.4m by year five
- To generate a Net Income of $7.4m by year five
- To have cash reserves of $8.3m by the end of year five
- To commence dividend payments to shareholders in year three

Operational

- To consistently achieve excellence in customer service
- To build an engaged and high performing team
- To build or access the logistic infrastructure to deliver the product

5.11. Vision and Mission

Vision: To give people with urinary problems a solution for better help.
Mission: The future company will be committed to R&D, production and commercialization of innovative hardware and software applications to speed up the progress in helping patients and medical staff work more efficiently together while delivering excellent customer service.

5.12. Unique Selling Points and Business Model Canvass

The business model canvas is a tool to understand a business model in a concise, structured way. Thus, using this canvas will lead to insights about the clients Smartbag serve, the value propositions that are offered, the key partners, activities, and resources, and the revenue and cost structures of the business.

5.13. Marketing Strategy

The marketing objectives of Smartbag are:

- To implement and execute a successful *launch campaign.*
- Build *brand awareness* across the medical device market in the target market.
- Create an effective *digital marketing strategy* that harnesses social media platforms, email marketing, content marketing, affiliate marketing, influencer marketing, SEO, SEM, mobile advertising, and viral marketing tactics.
- Build *strong and clear branding* that creates a pull to the target audience - B2C focus
- To provide high quality marketing material that highlights Smartbag unique selling point for distribution through multiple channels.
- Establish a consistent, responsive *presence across social media* channels.
- Develop a content marketing strategy that engages the target audience *and builds trust* by becoming an authority in the industry.

5.14. Sales Strategy and Tactics

The sales channels that will be utilized by Smartbag are set out below:

CHANNEL INBOUND	DETAILS / FREQUENCY
CONTENT MARKETING - BLOGS, VIDEO, PAPERS	Three pieces of content pertaining to the medical devices market per month – focus on quality not quantity
SOCIAL MEDIA CAMPAIGNS	Facebook, Instagram, Twitter – develop a social media posting schedule
SEO	Ongoing
YOUTUBE	Explainer video
GOOGLE ADWORDS - PPC CAMPAIGNS	Undertake keyword research through a keyword tool Create campaigns on Google AdWords Create relevant content that includes keywords – the aim is to begin to show up organically in search results

PARTNERSHIP MARKETING	Create partnerships with Doctors, Hospitals / Nursing Homes to broaden marketing reach into these areas

CHANNEL OUTBOUND	DETAILS / FREQUENCY
EMAIL MARKETING	Email opt in pop up box on website (www.sumo.com) with an offer / discount for initial purchase
PUBLICATIONS AND WEBSITES	Identify suitable publications / websites that Seniors read / visit to promote the Smartbag device through
TRADE SHOWS / EXHIBITIONS	On an event basis
REPUTATION MARKETING	Word of mouth

To drive the execution of the sales tactics, Smartbag will:

Details / Frequency
Create a social media posting schedule
Set up google analytics
Include a call to action on web page
Create a newsletter sign up option box on website
Use a Social Media Management Platform – Buffer or Hootsuite

5.15. Execution Stages

Milestone	Status
Business name availability check	In progress
Business name registration	In progress
Registration of entity	In progress
Opening of bank Accounts	In progress

Application and obtaining Tax File registrations	In progress
Trademarking of business name	Not started
Purchase of insurance	Not started
Identifying and securing funding options	In progress
Writing of Business Plan and establishing strategic objectives	In progress
Application for business license and permit (where required)	Not applicable
Drafting of establishment contract documents (Shareholders agreement, Constitution)	Not started
Establishment of Corporate Governance Framework	Not started
Prepare Terms & Conditions, Refund Policy, Cookie Policy, and Privacy Policy	Not started
Logo design	Completed
Creating Official Website for the Company	In progress
Graphic Designs and printing of marketing / promotional materials	Not started
Complete development of prototype	Completed
Complete development / testing / commercialization of prototype	In progress
Secure agreement with nursing home to supply Smartbag device	Not started
Recruitment of staff	Not started
Creating awareness for the business both online and in the local market	In progress
Marketing launch activities	Not started
Official launch	Q4 2020

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Figure 13: source available at: https://www.amazon.co.uk/Ugo-Night-Bags-x10-Connection/dp/B07198CT78

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Figure 15: source available at: Sanguansri in http://eprints.bournemouth.ac.uk/

Figure 16: source available at: https://www.researchgate.net/figure/Urinfo-2000-device_fig1_318734595

Figure 17: source available at: Amazon.com

Figure 18: source available at: https://medium.com/@aldarawshehsara/design-thinking-b53b047df20f

Figure 27: source available at: https://www.pwc.com/gx/en/industries/healthcare/top-health-industry-issues.html

Figure 28: source available at: https://uk.practicallaw.thomsonreuters.com/w-015-3548?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1

"The future belongs to those who believe in the beauty of their dreams."

Eleanor Roosevelt

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