Characterization of Business Models in The Medical Devices Industry – the Case for Wearable Technologies

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ABSTRACT

The inclusion of wearable medical devices (WMD) in the daily operations of a medical institution is a complex multi-level process. Not only is the medical community frequently close-minded in what concerns the adoption of unconventional methodologies, but also the performance and design of WMD has to be flawless since, as it deals with human lives, patients’ security cannot be overlooked, and legal matters have to be approved.

The enthusiasm over WMD is quite recent. As so, there is little information covering the business strategies behind the commercialization of these products. This works aims to contribute to this very matter. It aims to understand what strategies are being utilized and how companies are benefiting from them. For this purpose, we’ll be using the Business Model Canvas proposed by Osterwalder and Pigneur [1]. As it condenses a wide range of information related to the way that a company conducts its businesses, it constitutes a suitable framework for analysis. To carry out this task, we conducted 5 case studies with executives from 5 different WMD companies, comprising a total of 8 interviews. By analysing these different companies, we compared distinct business models and realities.

The study revealed that all four companies who develop WMD share some common methodologies. The main findings were that they follow user-oriented methodologies in the product development phase; they have similar approaches in what concerns the order of key-activities to follow; although starting by establishing direct contact with potential customers, the next level of relationships depends on the customer’s archetype and buying cycle; and that reimbursement seemed to be a concern of those companies whose technologies have a preventive profile. Finally, besides the elaboration and analysis of the companies BMs, this work also includes challenges, game changing strategies, and expectations concerning the industry of WMD. Although forecasting a growing interest for wearable devices that track biosignals, the executives believe that such will not occur under the condition of medical devices.

Notwithstanding, more companies should be analysed. Not only from the perspective of developers (as to further validate the findings or find novel strategies), but also from the suppliers’ perspective (as to increase the sample of analysis and improve this part of the study).
Firstly, I would like to thank Prof. Catarina Maia for giving me the opportunity to work on a theme I proposed, and encouraging me to pursue this challenge. Without her willingness to teach and guide me through these unexplored subjects the completion of this work would not have been possible.

Secondly, I would also like to thank all the participants of this study. Their readiness to help and availability is highly recognized and appreciated.

Finally, I would like to thank my family and friends. Together, they remind me that every problem has a solution and that I will never walk alone. A special thanks goes to my mother, father, and brother for their endless support in every step that I make. After 5 years living away, I have learned that there is nothing like returning home. To my friends, I want to thank for the years of companionship, care and memories. You know that the less I cry the more I care for you.
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GLOSSARY

BM(s) - Business model(s)
BMC(s) - Business model canvas
CEO(s) - Chief executive officer(s)
COO(s) - Chief operations officer(s)
CSO - Chief Scientific Officer
DPN - Diabetic Peripheral Neuropathy
ECG - Electrocardiography
EEG - Electroencephalography
EMG - Electromyography
FDA - Food and Drug Administration
HCI - Human Computer Interaction
HR(s) - Human Resource(s)
ICT(s) - Information and communication technology(ies)
IDC - International Data Corporation
IP - Intellectual Property
IS(s) - Information system(s)
IT(s) - Information technology(ies)
KOL(s) - Key Opinion Leader(s)
M2M - Machine to machine
MEMS - Microelectromechanical systems
NbC - Number of changes
OEMs - Original Equipment Manufacturers
R&D - Research and development
SEM - Search Engine Marketing
sEMG - Surface Electromyography
SMEs - Small and Medium Enterprises
UK - United Kingdom
UPS - United Parcel Service
USA - United States of America
WD - Wearable devices
WMD(s) - Wearable medical device(s)
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1. **INTRODUCTION**

1.1 **Motivation**

Over the last few years, the use of WDs has become increasingly established in sports and fitness, which has lead to great market prospects for the upcoming years. Still, in the healthcare context, there is still space for the use of WD.

This integration of WMD (WD that constitute medical devices and have clinical evidence) in the healthcare system comes with associated advantages. These include the remote monitoring of patients who then become more autonomous and aware of their disease, costs reduction, and the elaboration of complete health profiles that help in the diagnosis process. Besides, because WMD have a wide range of applications, they cover both monitoring and treatment functionalities for different medical conditions. Despite of all the advantages and improvements inherent to them, these devices have still to overcome several obstacles that harm their development and acceptance, as is the case of a closed-minded medical community or patients, IP or certifications related legal complications, and, in the case of attaining reimbursement, assurance companies.

Given the potential of WMD it is appropriate to understand what is the best way to integrate them in the overall business landscape of a health institution, making the most of their inbuilt value propositions. Such process implies outlining specific needs and creating the value that addresses these needs. In addition, it is also essential to understand how it is possible to deliver value in an inclusive manner, so that not only the patient, the physician or the institution benefits from its use, but society as a whole. Furthermore, in order to be viable, companies must retain value. This leads to the concept of BM, a simple yet complete representation of building blocks through which a company creates, delivers and generates value.

As the application of WD to healthcare is an emerging market, simply identifying and promoting innovations is not enough. The documentation of successful or not BMs is of the utmost importance, since it allows for managers to understand whether and how the experience and lessons learned from other companies can be applied to their particular business and products.
1.2 Goals and Methodologies

This work focuses on studying and articulating the concepts of BM in emerging WMDs. Indeed, this particular type of medical devices is still not very explored given they are only now starting to gain relevance among the medical community. Particularly, it aims to diminish the gap of literature concerning their commercialization, and to collect substantial information capable of assisting researchers and professionals in understanding how WMDs are being commercialized worldwide.

Having the Business Model Canvas ontology [1] as reference for the way through which a company does business, we have developed an interview script to be used in interviews with collaborators of different companies in the WMD industry. This open answer script allowed the establishment of a thorough dialogue concerning the BM strategies applied by each company. With the obtained information, we were able follow a multiple case study approach, where 5 case studies were analysed. Following, the respective BM Canvas were filled and such strategies are then identified, compared and discussed. Finally, we also review some important challenges and expectations that may impact future BM relevant decisions. It is to note that from the 5 companies under analysis, one does not operate as a WMDs developer, but as a supplier of parts to integrate WMDs. Because the relation between suppliers and developers in crucial to any supply chain, the inclusion of this company in the study attempts to better understand the criteria and relationships behind the partnerships.

Accordingly, this work is divided in 8 main chapters. Firstly, an introduction with considerations about WMDs and BMs is made to contextualize the reader on these subjects. Then, the case study approach, as described by Yin [2], is detailed in the methodology section. Such is followed by the presentation of the results and subsequent discussion, conclusions, and future improvements.
2. Literature review

2.1 Wearable technology

The advances achieved in technological applications have allowed for wearable technology to evolve massively. In fact, the variety of wearable equipments is growing and their uses extend to a wide spectrum of industries. Currently, WD are mostly used in the sports and health areas. As this works intents to study WMD, we focus on WD that have clinical evidence and are compliant with local medical devices regulation.

The present section starts by overviewing what are wearable technologies, covering then the particular case of WMD. It continues by examining what led to their development, what circumstances pose as obstacles to their implementation in the healthcare system, and what factors can influence their commercial success or failure.

2.1.1 The case of wearable technologies

The history of wearable technology goes back to the use of watches. Primarily, these emerged as analog devices, evolving to digital ones in the early 70s. The digital era permitted the incorporation of other functions, as calculators, timers, altimeters, thermometers or even calendars, which allowed for the creation of small, light, portable, multi-function and unconnected devices. Such characteristics changed with both the development of the Internet and the progresses achieved in engineering. Ultimately, wearable technologies took the form of wristbands, smart watches, accessories, clothes or wearable equipments, capable of providing a great variety of services and doted of 24/7 connection features [3]. Wearable technologies can be defined [4] as...

... mobile electronic devices that can be unobtrusively embedded in the user’s outfit as part of the clothing or an accessory. (...) Unlike conventional mobile
systems, they can be operational and accessed without or with very little hindrance to user activity.

McCann and Bryson [5] propose a three category definition for wearable technologies. According to the authors, these can exist as wearable computers, wearable electronics or intelligent clothing. The proposed definitions are displayed in Table 2.1.

Table 2.1 - Categories of wearable devices

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wearable computers</td>
<td>(...) is a computing device assembled in a way which allows it to be worn or carried on the body while still having the user interface ready for use at all times. By constructing it to be body-worn, a wearable computer makes computing possible in situations where even a laptop would be too cumbersome to open up, boot up and interface. (...) It has both input and output and is capable of adjusting to multiple tasks.</td>
</tr>
<tr>
<td>Wearable electronics</td>
<td>(...) are simpler than full-scale wearable computers. (...) [contrary to wearable computers] wearable electronics are constructed with set tasks to fulfil one or more needs of a specific target group. (...) [they] differ from mobile devices by their appearance and by being fundamentally designed to be worn on the body. A true piece of wearable electronics is also required to be worn to function, i.e., conceptually linked to the wearer's body. Some (...) devices require the user interface to be present and available all the time meaning they are more obtrusive than devices with no input (such as the wrist unit and chest belt of a heart-rate monitor).</td>
</tr>
<tr>
<td>Intelligent clothing</td>
<td>(...) clothing is intelligent when it adds something traditionally unclothing-like to the garment, without taking away or compromising any traditional characteristics such as washability or wearability. Ideally (...) it offers a non-traditional garment function such as health monitoring, in addition to its traditional function as protecting the body. It could, for example collect data and either transfer it wirelessly and automatically to an external computing unit or process the data itself, and respond to the computed conclusions without any user interface.</td>
</tr>
</tbody>
</table>

Application wise, WDs can be roughly divided into three kinds: those that aim to measure parameters specific to a certain disease (for example, insulin and cardiac events monitors), those that can be worn during workouts (as is the case of bracelets developed by Nike or Jawbone) or continuously on a daily basis (as is the case of smart clothing). Accordingly, the purposes of wearable devices extend to a wide variety of fields, including sports, healthcare, entertainment, military, public sector, safety, lifestyle computing, communication and fashion [5, 6]. Figure 2.1 illustrates applications, functions and existing products for each sector benefiting from WD [7].

The core interest of introducing personal WDs in healthcare is the potential for continuous monitoring of crucial biological parameters. The possibility of remotely analyse the collected data for each patient reduces the need for personal appointments, which saves both time and money for doctors and patients [5]. The impact of WDs in the healthcare industry will be analysed subsequently.
2.1.2 The case of wearable medical devices

As mentioned, the progresses achieved in engineering boosted the potential for wearable devices. These reflect not only on the technological development itself, but also on the social consequences of such developments. A most relevant branch of the wearable devices universe is the one concerning medical applications. A WMD can be defined [8] as...

... a device that is autonomous, that is noninvasive, and that performs a specific medical function such as monitoring or support over a prolonged period of time. The term wearable implies that the support environment is either the human body or a piece of clothing.

Notwithstanding, the Food and Drug Administration defines [9] a medical device data system as a...
device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices: (i) The electronic transfer of medical device data; (ii) The electronic storage of medical device data; (iii) The electronic conversion of medical device data from one format to another format in accordance with a pre-set specification; or (iv) The electronic display of medical device data. [It] may include software, electronic or electrical hardware such as a physical communication medium (...), modems, interfaces, and a communication protocol.

The WMD market is categorized into two main segments: the wearable diagnostic medical devices and the wearable therapeutic medical devices [10]. Each decomposes into particular segments, depending on the product type or application. This is depicted below in Table 2.2.

<table>
<thead>
<tr>
<th>Segment</th>
<th>Divided by</th>
<th>Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wearable diagnostic medical devices</td>
<td>Product type</td>
<td>Vital signs monitors, fetal and obstetric devices, and neuromonitoring devices.</td>
</tr>
<tr>
<td>Wearable therapeutic medical devices</td>
<td>Product type</td>
<td>Pain management, glucose/insulin monitoring and respiratory therapy devices.</td>
</tr>
<tr>
<td></td>
<td>Application</td>
<td>Sports and fitness, remote patient monitoring and home healthcare.</td>
</tr>
</tbody>
</table>

WMDs have evolved a great deal through time. The miniaturization of the devices enables the delivery of clinical supervision beyond the healthcare facilities, into the home of patients and even to outdoor activities. This is only possible as that the companies that develop these devices aim to provide intelligent monitoring with real time feedback [8].

2.1.3 THE OPPORTUNITY FOR WEARABLE MEDICAL DEVICES

The present section explores the aspects that allowed the evolution of WMDs. The most relevant engineering developments for WMD [6, 11, 12] are:

- Sensors coupled to microelectronics, telecommunication and data analysis;
- Battery technology;
- Telemedicine;
- Smartphones, apps and cloud services; and consequent
- Communication platforms.

As sensors are key to physiological monitoring, their expansion to microscale flexible equipments is of major importance to health applications. In particular, the development of MEMS, micro sensors that can be batch fabricated, contributes to lower manufacturing costs. For example, if coupled with adequate textile materials, the result is a portable, wearable, and monitoring e-textile system. By itself, the microscale feature is advantageous since it reduces weight and dimension, hence contributing to wearability.

In terms of communication platforms, the smartphone has emerged as powerful tool. In fact, the smartphone market has grown significantly throughout the years, and is expected to grow even more by 2018. A press release by Gartner [13] reports that the sales of such devices to end users grew 20.3% in the third quarter of 2014, reaching to about 301 million units sold. Further, the report estimates that by 2018, 9 out of 10 phones will be smartphones. Indeed, the progression of smartphone technology and associated features, in particular, the development of apps and cloud services, has opened ways to a new concept of “staying connected” that conquered segments of all ages and backgrounds. People are now strongly responsive to technology and connectivity features, and are often waiting for the next breakthrough. As apps cover a wide range of interests and integrate the smartphone architecture, companies are capable of reaching their customers in direct ways through them. Accordingly, at the moment, apps are primarily included in engagement strategies and stand as the main channel for content and service exchange. A press by Gartner dated of January 2014 [14] projected apps to expand beyond smartphones or tablets, conquering devices ranging from home appliances to cars, reaching, inclusively, wearable devices. It is also expected that, by 2017, wearable devices will drive 50% of total app interactions, since they will sustain data exchange and provide technology with a user interface. It is safe to say that WMDs will depend on mobile apps to perform all sorts of input, output, configuration, content creation, consumption, and basic connectivity. It is hence understandable how the great prospects for these technologies can potentiate the development of WMDs. According to Brian Blau, research director at Gartner, the combination of WD and mobile apps is a positive one since...

... it is a way for manufactures to keep these devices small and efficient, therefore significantly reducing device costs in favour of using apps, which are more easily maintained and updated.

He further underlines the importance of the integration of apps into wearable devices with the example of a fitness-tracking device. He explains that...

... its onboard data will need to be uploaded into the cloud, processed, and then analyzed in reporting back.
The developments concerning smartphones, apps, and cloud services enable great data exchange services, while satisfying the current need for people to feel socially connected. Therefore, it comes with no surprise that current projections for their markets show great expansion prospects. Altogether, these technologies and the social networking demand serve as great platforms for the development of new products, inclusively mobile ones, as is the case of WMD.

Additionally, the modern health context contributed for the need for wearable devices. People are increasingly concerned about monitoring their vital signs not only during exercise, but also on a daily basis. Given the technological advances aforementioned, today it is possible to collect heartbeat, temperature and environmental factors from wristbands, patches, smart shirts or small sensors incorporated in accessories. Yet another study [15] predicts that customers concerned about their health will transmit the information recorded via wearable devices to their doctors upon appointments.

More than collecting fitness and sports data, it is believed that remote monitoring devices can contribute significantly to the medical healthcare landscape by providing continuous monitoring of vital signs or other biological data. Such functions allow doctors to continuously monitor their patients, while the patients are more aware and autonomous, taking appropriate actions when needed. The applications of wearable equipment in the medical landscape [7, 11, 12, 16, 17] include several areas, which translate into monetary savings for the healthcare industry:

- Vital signs monitoring (ECG, EEG and EMG);
- Safety monitoring;
- In vivo implants;
- Chronic disease monitoring;
- Home rehabilitation;
- Assessment of treatment efficacy;
- Early detection of disorders;
- Obesity control.

Indeed, WMDs are thought to play an important role in dealing with chronic diseases. Furthermore, they are also suitable for monitoring other conditions, as long as these can be prevented or addressed by repeatable and standardized protocols, or if they are non-intensive (that is, there is no need for human monitoring). Therefore, diabetes, emphysema, hypertension, congestive heart failure, chronic obstructive pulmonary disease, and fracture prevention are all medical conditions that can, somehow, be monitored using WMDs [12, 16, 18].

For the total duration of a doctor’s appointment, the physician collects data in search of abnormalities that can indicate how the body is functioning. Given their continuous monitoring capabilities, the inclusion of WMDs in the doctor’s normal workflow could provide information regarding a much wider timespan. Hence, WMDs are able to assist diagnostic with accurate and realistic health profiles, while alerting for particular abnormalities. Moreover,
the “home-monitoring” features of such devices can spare doctor visits by allowing patients to autonomously take the necessary preventive measures upon the alerts given. Ultimately, money and time is saved for every involved party.

Particularly, a study held in the United States of America in 2008 [19] revealed that the inclusion of home-care services in the healthcare system led to a decrease in hospital admissions by 1/5 and, consequently, to lower admission and treatment costs. Also, considering that in the United States of America alone about 86% of the health care budget is spent in the treatment of chronic diseases, the monetary benefit of including WMDs in the healthcare system cannot be discarded [20].

Gartner [21] reports that the impact of wearable health trackers and the expected growth of smartphones in developed countries will combine to form a good platform for the development of monitoring devices. In turn, these constitute a starting point in reducing treatment costs and increasing life expectancy. This study further adds that the use of these technologies can increase life expectancy by 0.5 years by 2020, and reduce the costs of treating diabetes.

Besides what was mentioned regarding technological advances, well-established segments, and the growing concern for health and well being, is the excessive patient affluence to hospitals, mostly for chronic diseases. Altogether, and considering the aforementioned reasons, these circumstances are creating the opportunity for medical wearable technologies.

2.1.4 Obstacles for wearable medical devices

Although varying in the overall market value of WD, different market research companies agree in the growing forecasts for such parameter [22, 23]. However, these forecasts are somewhat biased, since they analyse the overall wearable industry. For that reason, their studies include devices ranging from Google’s Google Glass and fitness monitoring equipment to actual WMDs. Nevertheless, these prospects are relevant, as they indicate a growing interest for wearable technologies, which, through time, is likely to positively influence the potential for WMDs. Statista.com [23] analysed the market value for wearable devices from 2010 to 2018. The chart displayed in Figure 2.2 forecasts that this market to reach about 12.6 billion dollars by 2018.

Analysing the particular case of WMDs, a market report from Transparency Market Research [10] states that the wearable medical devices market will reach 5.8 billion dollars in 2019, at a compound annual growth rate of 16.4% from 2013 to that year. It is worth noting that the market research company understands medical devices accordingly to what was described previously in Table 2.2.
In spite of the positive market forecasts, according to Gartner’s 2015 Hype Cycle for digital Business [24] displayed in Figure 2.3, technologies labeled as “Wearables” still need about 5 to 10 years to achieve a stable market position where expectations are shaped by the actual value of the technology, that is, until the plateau of productivity phase is achieved.

![Figure 2.3 - Gartner's 2015 Hype Cycle for digital business. The arrow points to technologies related to MWD. More particularly, wearables. Source: Gartner (August 2015) [24].](image)

However at the “peak of inflated expectations” phase, wearables are approaching the negative hype slope that leads to the “trough of disillusionment”. While the “peak of inflated expectations” refers to a period of unrealistic enthusiasm over the potential of the...
technology, the “trough of disillusionment” is the phase of disappointment when reality does not meet expectations. It is to note, however that in the 2014 Hype Cycle for Emerging Technologies the WMDs related technologies were “wearable user interfaces” (located in the peak of inflated expectations) and “mobile health monitoring” (located low in the trough of disillusionment). Further, it is also to note that one year later, wearables are still in the same position [25]. The appearance in 2015 of a general concept of “wearables” serves to show how wide and susceptible to change it is. Allied to it staying on the same cycle position, it may suggest that the branch of wearables that will prevail over others is yet to be settled.

In what concerns the integration of WMD in health organizations, McKinsey & Company [26] identified primarily two obstacles. The company finds that, until now, the integration of technology was focused mainly on processes and gave no attention to the actual customers needs, which contributed to the small adherence to the available products. Also, customers do not find quality in the existing options. The study further adds that patients do not desire for innovative features, killer apps, or a complex platform of service offerings. Instead, they want a simple, effective, and information accessible way to navigate through the health system, that provides real contact with professionals if doubts persist. Additionally, the inclusion of WMDs has other obstacles to overcome, both regarding development and implementation.

Unless the inherent benefits are indeed exceptional, the medical community commonly poses as a great obstacle to the introduction of any type of new methodologies. Physicians typically face such changes with reluctance, and most times counterbalance the upsides of the novel systems with the bureaucratic administrative work needed to obtain approvals, as well as with the issues associated to staff education and modification of current workflows.

Another important aspect is the ergonomic and wearability of the product, given that users must positively accept the design [6, 8]. It is important that they do not feel discriminated when using it, but also that the use of the equipment is both practical and user friendly as to ensure long-term adoption.

Adding to the obstacles already mentioned, there are technological and legal issues that issues have to be considered and exquisitely achieved, so as not to hamper the development and commercialization of the device [8]. These include:

- The usage of appropriate biomedical sensors;
- Outlining efficient processes of data handling and decision support;
- Incorporating flawless telecommunications between the user and the device;
- Autonomy and power consumption;
- Legal and ethical matters;
- Safety and reliability;
- Clinical validation plans;
- Risk analysis;
- Patient’s privacy and security.
Considering the obstacles and concerns associated to the development of a fully functional and acceptable WDM, it is important to understand what are the common risk factors associated to technology and WMD. Further, it is also fundamental to understand how business model design can contribute to overcome some of these issues, and aid in crossing the chasm that separates early adopters who seek for innovative technology, from mainstream adopters who further consider performance and convenience [17].

2.2 BUSINESS MODELS

This chapter provides an overview on business models. The concept of “business model” has been diversely defined over the years. We review it, alongside with technological evolution and associated market dynamics to better understand the need for including such models in the skeleton of an enterprise. Further, a brief description on what business models are is included, in order to contextualize why and in what context their use is advantageous for a company. In order to elucidate its designations, we also cover the different definitions and taxonomies, components, frameworks and ontologies, and, lastly, change models and BM innovation. Finally, the Business Model Canvas, a main tool for analysis, is introduced.

2.2.1 THE DEMAND FOR BUSINESS MODELS

Over the last few years, a body of literature, including works from Osterwalder [27] and McGrath [28], has been developed that states that technological change, industry clockspeed, complexity and uncertainty are the key characteristics of the modern business landscape.

Concerning technological change, it translates into the e-business boom upon the growth of the World Wide Web since the early 1990s. The high reliability on ICT by companies expanded the available business options. This originated a wide variety of approaches by which a company could achieve its strategic goals. Specifically, the incorporation of ICTs into business operations had implications on the way a network is organized (which is now cheaper and more accessible), on product portfolios (which are wider), on the ways customers are engaged (they are now more reachable given the emerging social media platforms), and also on new ways of obtaining revenue streams [27].

In spite of the current technological innovation and the competition inherent to it, the dynamics of an industry is specific to its economic and competitive reality. As such, the pace at which the industry evolves, i.e., the industry clockspeed, is a specific parameter of particular industry segments, and not a general one [27]. Practically speaking, this means
that the competitive advantage of a company highly relies on its capability of adapting to its industry's clockspeed.

Associated to clockspeed is complexity. It has been linked to capitalism [29] and to the high competition imposed by its goals for profit, which implies the pursuit for new products and services in order to expand to other markets/segments. The constant chase for innovation favours technological advancement and contributes to the acceleration of the industry clockspeed forcing other companies to keep up.

Together, the three mentioned characteristics contribute to unpredictable environments. With that being said, modern businesses are challenged with the need for business model understanding, characterization and innovation. In such uncertain conditions it is crucial that companies are flexible enough to adapt to market variations while maintaining their operational workflow in what regards distribution channels, supply chains, IT implementation, partnerships and revenue streams [27].

While every manager and entrepreneur has a clear view of its business, communicating such knowledge to others (e.g. staff, business members, investors) may not always occur easily. As so, the existence of a generic tool capable of facilitating communication within the different parties involved in a business is of most relevance. Further, if it also combines the core elements of the company's workflow, it enables the parties to have a clear understanding of what is involved in the processes of value creation [27]. Such tool is called a business model and it will be reviewed in detail throughout this work.

2.2.2 Diversity of Business Model Designations

Overall, BMs are a simple representation tool that gathers the business logic behind a specific company. That is, it mirrors the way a company organizes itself in order to deliver products or services (broadly designated as products) to customers, while creating value for itself [30]. As so, it outlines the needs of a specific customer segment as to facilitate the selection of features to integrate the product to deliver, it defines costs and profit streams as well as ways through which the product reaches the market [30]. Such organization is captured in a simple design that promotes an intuitive analysis and, hence, allows a good understanding of its content. Ultimately, it facilitates communication and content adjustment [27].

Although having the same core significance, not all authors are in agreement regarding the components that integrate a good BM, or even on its definition. Hence, BMs can be seen through different perspectives [27], namely:

- Taxonomies
- Definitions;
- Components;
- Frame-works and meta models; and
- Innovation and change models.

BM have been a subject of discussion in many diverse grounds, ranging from e-business, information systems, strategy, technology, management, and entrepreneurship. As such, different authors suggest different meanings for the expression, as they are biased by the purpose of their study [31, 32].

The term “business model” first appeared on an academic article written by Bellman and colleagues [33] in the late 50s. The expression was then used in the title and abstract of an article by Jones in 1960 [34], and, ever since, the term has gained popularity with the development of information systems, fuelled by the Internet expansion and consequent development of more complex and diverse ICTs. Furthermore, the processes of value creation also changed, which had repercussions in the way businesses were made. Value was no longer created by the manufacturing firm, but co-created by the stakeholders within the market [35]. Such progression amplified the complexity of BMs and hence, imposed the necessity of improving the existing ones.

This evolution reflects the greater importance of business models in the modern business landscape, and is correlated with the consequent increase in the number of studies on the subject. As a result, by 2011, at least 1,177 articles covering the concept of “business model” had been published since 1995 [32].

Osterwalder, Pigneur, and Tucci [36] resumed such diversity in designations by dividing literature into five distinct approaches. The first one defines and classifies BMs in taxonomies (that is, types); the following two are similar, but refer to different things (while one names what components a business model should address, the other describes such components as building blocks); a fourth methodology is characterized by a conceptualization of the components, which led to the development of BMs as meta-models in the form of reference models and ontologies; finally, BMs started to be applied in management and ISs applications, which demanded understanding and incorporating the notions of dynamicity and change.

For the purpose of this work, the literature review is centred on the definitions and principles by which to categorize BMs in taxonomies, suggestions of components that a BM should cover, analytical frameworks for complete meta-models portrayals, and on the emergent subject of BM innovation and change models.

2.2.3 TAXONOMIES AND DEFINITIONS

Considering BM analysis by means of taxonomies, Timmers [37] identified, in 1998, a different types of BMs at use in electronic commerce. According to the author, a BM is...

30
(1) an architecture for the product, service and information flows that includes a description of the various business actors and their roles; (2) a description of the potential benefits for the various business actors; and (3) a description of the sources of revenues.

In this definition, the BM fails in providing information regarding how the company’s mission will be accomplished. Furthermore, questions concerning commercial availability, competitive advantage, positioning and strategy are left unanswered. The taxonomic categorization held by the author is “based on value chain de-construction and re-construction”, which means that different architectures are categorized by identifying the elements of the value chain and the interaction patterns among them (Table 2.3).

In 2000, Linder and Cantrell [38] go further and differentiate between BMs components, real operating BMs and change models. Their categorization into taxonomies is based on what is the key profit making activity and where does it position itself on the price/value scale (Table 2.3). They state that...

... A business model is the organization’s core logic for creating value. (...) a good business model highlights the distinctive activities and approaches that enable the firm to (...) attract customers, employees, and investors, and to deliver products and services profitably”.

On the other hand, in 2004, Rappa [39] proposes a more general definition, admitting that within each industry the BM may change as function of the specific methods of doing business. Particularly, his approach to classify e-business models falls on the type of customer relationship at use (Table 2.3). Nevertheless, he states that...

... all BMs specify what a company does to create value, how it is situated among upstream and downstream partners in the value chain, and the type of arrangement it had with the customers to generate revenue.

Finally, Morris, Schindehutte and Allen [40] uncover three types of BMs, segmented based on a set of decision variables (Table 2.3). Each of them has its own list of components to include. The “economic model” is one that focuses on “the logic of profit generation” and, accordingly, answers questions regarding “revenue sources, pricing methodologies, cost structures, margins and expected volumes”. In turn, the “operational model” embodies the architectural configuration, dealing with matters of “internal processes and design of infrastructure that enables the firm to create value” such as “production or service delivery methods, administrative processes, resource flows, knowledge management, and logistical streams”. Finally, the “strategic model” ads considerations regarding competitive advantage
and sustainability and hence envisions the “overall direction in the firm’s market positioning, interactions across organizational boundaries, and growth opportunities (…) Decision elements include stakeholder identification, value creation, differentiation, vision, values, and networks and alliances”. Fittingly, they accept a BM as a…

... concise representation of how an interrelated set of decision variables in the areas of venture strategy, architecture, and economics are addressed to create sustainable competitive advantage in define markets.

Table 2.3 - Business model taxonomies divided by authors.

<table>
<thead>
<tr>
<th>Author(s), year</th>
<th>Domain of study</th>
<th>Division based on</th>
<th>Types</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timmers, 1998 [37]</td>
<td>Internet and E-commerce</td>
<td>Value chain de- construction and re-construction</td>
<td>E-shop; E-procurement; E-mail; E-auction; Trust services; Info brokerage; Value chain service provider; Virtual community; Collaboration platform; Third party marketplace; Value chain integrator.</td>
</tr>
<tr>
<td>Linder and Cantrell, 2000 [38]</td>
<td>Management</td>
<td>Key profit making activities</td>
<td>Price models; Convenience models; Commodity-Plus models; Experience models; Channel models; Intermediary models; Trust models; Innovation models.</td>
</tr>
<tr>
<td>Rappa, 2004 [39]</td>
<td>E-business</td>
<td>Customer relationship</td>
<td>Brokerage; Advertising; Information intermediary; Merchant; Manufacturer direct; Affiliate; Community; Subscription; Utility.</td>
</tr>
<tr>
<td>Morris, Schindehutte and Allen, 2005 [40]</td>
<td>Entrepreneurship and management</td>
<td>Decision variables</td>
<td>Economic; Operational; Strategic.</td>
</tr>
</tbody>
</table>

The authors that follow do not categorize BMs as taxonomies, but present definitions that sustain their studies on the matter. Accordingly, they do not divide BMs based on any criteria, nor do they present different types of models based on such division. For this reason, they were not included in the previous table.

In 2005, Osterwalder and Pigneur [36] advance the BM concept, proposing not only components but, in fact, a complete meta-model whose analysis will be made ahead. They define BM as a...

... conceptual tool that contains a set of elements and their relationships and allows expressing the business logic of a specific firm. It is a description of the value a company offers to one or several segments of customers and of the architecture of the firm and its network of partners for creating, marketing, and delivering this value and relationship capital, to generate profitable and sustainable revenue streams.
In a work from 2010, Teece [30] further adds that...

... a business model articulates the logic, the data, and other evidence that support a value proposition for the customer, and a viable structure of revenues and costs for the enterprise delivering that value.

The author also recognizes that successful BMs are commonly shared by competitors and establishes a link between them and competitive advantage. He states that the process of creating BMs pairs with the integration of a business strategy. In turn, such involves the creation of “isolating mechanisms” that inhibit reproduction by competitors or even disintermediation by customers.

In 2007, Zott, Amit and Massa [32] acknowledge that despite the many differences found, there are some emerging aspects in BMs. Accordingly, they recognize that...

... (1) there is widespread acknowledgment that the business model is a new unit of analysis that (…) is centred on a focal firm, but its boundaries are wider than those of the firm; (2) business models emphasize a system-level, holistic approach to explain how firms “do business”; (3) the activities of a focal firm and its partners play an important role in the various conceptualizations of business models that have been proposed; (4) business models seek to explain both value creation and value capture.

2.2.4 COMPONENTS, FRAMEWORKS AND ONTOLOGIES

The components that are believed to integrate a BM also differ greatly among scholars. In the literature, the components are also referred to as elements, building blocks, functions or attributes. Once put together, the components create a business model framework [40]. In turn, business model ontologies stand as a shared, formal and conceptualized representations of what BM should be for a given industry [41].

Although not referring specifically to BMs components in his work from 1998, Timmers [37], does consider the deconstruction of the value chain in the process of categorizing taxonomies. Such deconstruction considers both primary elements and supporting activities. In turn, in 2000, Mahadevan [42] reported a three dimensional framework for Internet BMs along side with factors to guide organizations in the choice of appropriate models. Details on both taxonomies are present in Table 2.4.

Linder and Cantrell developed in 2000 an operating business model that includes 7 components [38]. Their need to distinguish elements arose given the fact that people often say BM when indeed they refer to a specific part of it. The process of identifying the
operating BM, which, according to the aforementioned definition refers to the logic behind the process of creating value, must include only the components that crucially contribute to it.

Chesbrough and Rosenbloom [43] explored, in 2002, the BM by the functions it should perform. Besides the direct information residing on each component, altogether, as a whole BM, it allows the prediction of the financial capital and to define ways to improve the business.

Gordijn and Akkermans [44] created in 2003 the e3-value ontology for e-Business modelling. Their focus was to provide a better understanding of the hypothesis at hand, particularly, in what concerns the profit drivers. Such ontology is supported by a dual approach: it is based on a multi-actor network where the economic value creation, distribution and consumption is explored, as well as on “requirements engineering and underlying conceptual modelling techniques”, derived from IS.

Following what was said on the literature synthesis by Morris, Schindehutte and Allen [40], the authors advanced, in 2005, a framework for characterizing BMs. It is based on three decision-making levels (foundation, proprietary and rules) they believe to portrait the various managerial purposes of a model. The first defines the basic components and hence reflects the essence of a company. On the other hand, the proprietary level contributes to the creation of sustainable advantage by outlining unique combinations to each foundation element. This level of decision-making is where strategic deliberations are incorporated, the interactions between each element become more complex, more specific to each venture, and hence more difficult to replicate. Finally, the rules level sets guiding ideologies to be followed as to ensure that foundation and proprietary elements are reflected in continuous strategic actions. The authors exemplify how Intel has rules that condition the type of movies that Miramax makes or how Dell computer can turn inventory in 4 days or less.

Osterwalder and Pigneur started by listing the main components they understood should integrate a BM [27]. Only afterwards did they detailed and named each one of the building blocks that integrate the framework that sustains their ontology [1]. They introduce product, customer interface, infrastructure management and financial aspects as general components that, altogether, are subdivided into 9 building blocks. These form a thorough and complete framework, the Business Model Canvas, which will be analysed in more detail subsequently.

In line with the definition presented in the previous section, Amit and Zott [45] perceive a BM as a...

... Unifying unit of analysis that captures the value [by depicting] the design of transaction contents, structure and governance so as to create value through the exploitation of business opportunities. [It is a] system of interconnected and interdependent activities (...) conducted to satisfy the
perceived needs of the market, along with specification of which parties (...) conduct which activities, and how these activities are linked to each other.

That is, the authors include transaction content, structure and governance as the elements that integrate the e-business BMs. All revolving around the exchange of information, the first refers to the product to be exchanged and to the necessary resources; structure concerns the parties and relationships involved in the exchange, as well as the inherent sequence of events; finally, governance covers the flows of information and resources inherent to each party, as well as the legal form.

Finally, Johnson, Christensen and Kagermann [46] also proposed a framework for BMs in 2008. It is composed by four interdependent elements that, “taken together, create and deliver value”. The complete framework is build by decomposing each of the four elements into more specific ones. According to the authors, a successful BM covers the customer value proposition, the profit formula, key resources and key processes.

Displayed in Table 2.4 are the upper mentioned components, frameworks and ontologies, exposed as function of the author who explored them, the domain in which they studied BMs and the underlying decomposition approach/motivation. Still, it is worth noting that, despite the fact that BMs were studied in a specific domain, this does not restrict their use to that particular area.

Fittingly, the mentioned concepts of BMs enhance the coherence between its main elements. For this reason, they can serve as recipes, functioning as manuals. That is, a type of model known to deliver positive results for a particular type of product (or service) from a set of well defined elements can stand as a basic ground recipe to work with by other companies that want to follow the same business ethic. One of such examples is the standard BM of low cost airline companies [47, 48].

The mentioned approaches are all static. Overall, a BM describes the mechanisms by which the company creates an adequate value for a specific segment, structures a proper supply chain with the right distribution channels and partners, and combines all costs to generate and appropriate value, for a certain period of time. Inherent to this perspective is the thought that the described mechanisms are constant, which is a false premise.
### Table 2.4 - Business model components and ontologies

The subjects are displayed as function of the author, domain in which they studied BMs and what is the underlying decomposition approach/motivation that drove them.

<table>
<thead>
<tr>
<th>Author(s), year</th>
<th>Domain of study</th>
<th>Decomposing approach/ Motivation</th>
<th>Components (Ontology is specified if existing)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timmers, 1998 [37]</td>
<td>E-business</td>
<td>Deconstruction of the value chain</td>
<td>1. Primary elements: Inbound logistics; Operations; Outbound logistics; Marketing and sales; Service. 2. Supporting activities: Technology development; Procurement; Human resource management; Corporate infrastructure.</td>
</tr>
<tr>
<td>Mahadevan, 2000 [42]</td>
<td>Internet</td>
<td>Guidance in the choice of appropriate models</td>
<td>1. Value stream (where the value proposition for the partners and buyers is described); 2. Revenue stream (plan to generate revenue); 3. Logistical stream (related to designing the supply chain)</td>
</tr>
<tr>
<td>Chesbrough and Rosenbloom, 2002 [43]</td>
<td>Entrepreneurship</td>
<td>What functions should a BM perform</td>
<td>1. Articulate the value proposition (value to offer); 2. Identify a market segment (those to whom the offered value is useful to overcome a certain problem as well as mechanisms to generate revenue); 3. Structure the value chain (resources and processes involve in processes from creating to distributing the product and assets to support the company in the chain); 4. Estimate cost structure and profit potential; 5. Establish the value network (suppliers, customers, complementors and competitors); 6. Formulate the competitive strategy.</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Dimension</td>
<td>Description</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>--------------------------------------------</td>
<td>-----------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Morris, Schindehutte and Allen, 2005 [40]</td>
<td>Entrepreneurship and management</td>
<td>Decision making levels</td>
<td>1. Foundation level: How will the firm create value? For whom? What is the firm’s internal source of advantage? How will the firm position on the marketplace? How will it make money? What are the entrepreneur’s time, scope and size ambitions? 2. Proprietary level (strategic deliberations are covered) 3. Rules level (ideologies to be followed)</td>
</tr>
<tr>
<td>Johnson, Christensen and Kagermann, 2008 [46]</td>
<td>Reinventing BMs</td>
<td>Fulfilling a value proposition in a profitable way</td>
<td>1. Customer value proposition: Target customer; Job to be done; Offering 2. Profit formula: Revenue model; Cost structure; Margin model; Resource velocity 3. Key resources: People; Technology or products; Equipment; Information; Channels; Partnerships and alliances; Brand 4. Key processes: Processes; Rules and metrics; Norms</td>
</tr>
</tbody>
</table>
2.2.5 Change Models and Business Model Innovation

Indeed, assuming a static overview on any industry landscape is unrealistic. Despite the fundamental advantages inherent to BMs, for a company to prosper it is fundamental to expand views and perspectives. In fact, knowing what the customer needs are, developing an exceptional product-market fit and working a value chain to deliver that particular product to those particular customers loose relevance if those considerations were made for a reality that no longer exists. Therefore, both entrepreneurs and executives should have in mind possible future behaviours of customers and competitors, together with eventual cost fluctuations.

Realistically, hypothesis on the current market conditions are perfected as research either corroborates it or not, and a sustainable BM is only achieved by a series of gradual improvements that, ultimately, originate consistency and provide adaptability. Notwithstanding, companies must innovate to keep up with market fluctuations. Such transformational concept applied to BMs couples with important managerial questions and can, subsequently, assist in the process of BM innovation and change [30, 48].

Until recently, innovation implied investing in product development by combining internal research laboratories with great human resources. However, the costs associated to R&D or to the introduction of a new product in the market are massive and products have, currently, smaller life-periods. Such limitations have shaken the reliability companies can have on their products to generate profits before they become commoditized and, hence, companies started to spread innovation also towards BMs [49].

Through time, the notion of understanding a BM and identifying potential changing routes became an imperative and a new concept arose, the change models. These embody the alterations the BM at use must undergo when facing novel conditions so that new reforms are achieved, either by adjustment of its parts or by adopting an entirely new approach.

In 2000, Linder and Cantrell [38] identified technological innovation, law changes, development of competitor's strength, and swings in consumer needs as external pressures that may influence the profitability of an operating model and motivate enterprises to take action. Accordingly, for the authors...

... a change model is the core logic for how a firm will change over time to remain profitable in a dynamic environment.

According to the analysis made by the authors, a company can change business models by exploring an extensive variety of methodologies. Overall, these relate to improving value (product to service, service to solution or solution to experience) and/or price, redefining the channel concepts and value chain, changing the pricing mechanisms, improving value appropriation, and exploring new customer segments. After reviewing and interlinking
the detailed changing methods, their analysis pinpoints four categories of change models that induce less, more or total change in the core logic. Those models are “Realization models [which] maximize the returns from the existing operating logic; (...) Renewal models [used by] companies that (...) consistently and consciously revitalize their product and service platforms, brands, cost structures, and technology bases to counteract natural competitive forces; (...) Extension models [that] expand business to cover new grounds; and (...) Journey models [which] take a company to a new business model”.

Johnson and colleagues [46] disclosed in 2008 that the key to maintaining a prosperous business is knowing when their components need change. In turn, knowing so demands capability of recognizing opportunities that reflect a need to re-invent BMs. These can be the prospect of satisfying a discontent segment, re-inventing an existing technology, or introducing a job-to-be-done focus to an industry where such does not exist, as was the case of FedEx. The authors reinforce, however, that the decision to embark on innovation should not be pursued lightly. With effect, they suggest a set of questions that assess whether innovation and, consequently, change models are needed or not, based on whether the answers translate into novelty not only to the company itself, but also to the industry and market.

Teece [30], on the other hand, developed the concept of provisional business model in 2010. He understands it as a...

... model [that] must be evaluated against the current state of the business ecosystem, and against how it might evolve.

Further, just as Johnson and colleagues [46], Teece establishes a set of questions to be considered when applying such ecosystem evaluation. The fundamental ones concern the utility embedded in the product or service, how is it going to be used, by whom and at what prices, the market size, the delivery structure and costs, the partners, and the appropriation regimes. Besides these, the author also considers the existence of competitive offerings, technological evolution and the emergence of a dominant design.

In 2012, Amit and Zott [50] also studied BM innovation and the creation of value on innovation driven environments. They believe that innovation is nothing but a way of enhancing a company’s prospects, as it provides tools to resolve the trade-off between innovation costs and benefits. Inclusively, they add that such is accomplished by addressing how managers do business. Similarly to Johnson and colleagues [46], Amit and Zott admit that...

... an innovative business model can either create a new market or allow a company to create and exploit new opportunities in existing markets.
They specify three ways through which business model innovation can occur. Those act on each of the elements proposed by the authors to incorporate a BM. Accordingly, the referred ways are: (1) new activity system content (what innovative activities are included to satisfy noticed needs); (2) new activity system structure (how can activities be interrelated in different ways); and (3) new activity system governance (which stakeholder should perform each activity). The questions to apply before developing a new model also include determining what needs will be overcome with the new model design, how is value going to be created for each participant of the value chain, and what is the revenue model to use to accomplish value appropriation.

The case of digitally available information, and, more particularly, Dell, are examples of realities that demand business model innovation [50]. In the first, there is the case of book publishers (such as McGraw-Hill) versus digital books (available on, for example, Kindle or other portable devices) that forced publishers to keep up with customers needs and, hence, adapt the way by which they delivered value to the way customers obtained it. Concerning Dell, their BM innovation consisted on shifting the selling models. They replaced the traditional build-to-stock model by a novel customer-driven, build-to-order business model.

Indeed, the case of digitally available information serves as an example of how the value chain is influenced not only by the industry itself but also by others whose advances can dictate standards for new operating methodologies. Such has an even greater relevance if coupled to technological progress are shared customer segments. In the presented case, the consequences of the emergence of portable devices created the need for book reading in such equipment. Hence, publishers had now to satisfy customers who bought portable devices and so, their business model had to take into consideration this new way of delivering value. On the other hand, the example of Dell illustrates how BM innovation has the potential to revolutionize a particular industry.

Another example of how to approach BM innovation is through business cases, suggestion presented by van Putten and Schief in 2013 [51]. The authors see business cases as recommendations based on the analysis of benefits, costs and risks that, altogether, evaluate the proposed investment. Ultimately, they believe the adaptability of a company is improved by implementing merged or changed models, as well as by using business cases as notifications on when to apply change.

2.2.6 Evaluating Business Models

In fact, business models change and innovation seems to play an important role for the subsistence of a company. While studying BM change in early-stage university spin-offs, Costa [31] performed a quantitative and qualitative study on the frequency of change in BM
elements. It was verified that every spin-off changed its business model and that, overall, higher frequency of change was associated to lower performances.

The process of counting changes is a complex one. Nevertheless, the researchers who did it based their decisions in identical parameters. As effect, change was only considered to occur when a new type of item (e.g. a customer segment or a key activity) was included or deleted, but not replaced. Conclusively, six propositions were established, that relate six different parameters to higher or lower frequency of changes \[31\]. These are that 1) lower/higher commitment of the founding team is commonly associated to lower/higher NbC; 2) Higher/lower market, managerial and entrepreneurial knowledge is related to lower/higher NbC; 3) The higher/lower the uncertainty upon a determined BM component, the higher/lower the NbC; 4) High/low performances in early-stage spin-offs are linked to less/more NbC; 5) Spin-offs with better performances are faster in what concerns dialoguing with stakeholders to perform iterative testing; and 6) Earlier BM testing results in higher customer stability which reduces the NbC.

Although concerning early-stage spin-offs, these parameters are present in every company. Therefore, they affect them, the respective BM components, and, hence, contribute to BM change.

Considering the reviewed definitions, it is evident an evolution in the “business model” concept. At first, they presented somewhat of a static character. They were defined concerning the roles and relations between each involved stakeholder as well as the sources of revenue. Afterwards, authors expanded their considerations and considered that BMs should provide extensive overviews of the entire value chain and some did, inclusively, proposed complete frameworks and ontologies for managers to stand by. The next step marked by whatever deviations economy and technology endured. These set the new grounds on which companies have to operate to remain profitable.

If anything, the mentioned approaches show the variety of ways through which a company can seek to define logical means to produce, deliver and profit from value propositions. Regardless, BMs have a wide range of applications, as will be discussed next.

2.2.7 APPLICATIONS OF BUSINESS MODELS

Notwithstanding the various designations that can outline what BMs are, their applications are wide, useful and recognized by different authors.

As they capture the business concept in a clear way, they are strong communication and sharing tools. Further, the schematic character of the Business Model Canvas (a graphical way to depict a company’s BM) facilitates the understanding of complex systems because it
only enhances the main features and how they relate to one another. A company is a large organization of professionals with divergent backgrounds and roles. For example, while the business experts define the route and lay objectives and goals, engineers and ICT designers are responsible for transforming the given concept into tangible goods. Thus, the existence of dialog tools such as the BMs can translate into substantial advantages [27, 36].

Another use of the BMs is that of an analysis tool, approach held by structured observation and comparison of different models [36, 47]. As mentioned, the modern business landscape has a strong evolitional caratter, which requires companies to have great adaptability profiles in order for them to remain profitable regardless of the imposed pressures. The task of identifying which measures are blocking the necessary growth and determining the ones that are suitable alternative solutions is facilitated if one has already a well-structured and functional BM, that can be easily benchmarked. Further to assessing new business concepts based on a deficient BM, it is also possible to raise new hypotheses by comparing the weakened BM to those of successful companies.

Following the analysis purpose, BMs also pair with management roles. If the analysis of existing BMs coupled to market reality allows insight on what changes need to be done, they also assist in managing such improvements by facilitating the design, planning and integration of such changes under [36]. In particular, when a company undergoes the adoption or adjustment of BMs, they can use a specific type of model, representative of the pathways through which a firm will reform with time. Those models are the aforementioned change models presented by Linder and Cantrell [38]. Additionally, and subsequent to serving as a communication tool to efficiently transmit the business logic, BMs add to management functions by enriching discussion and decision-making.

Furthermore, BMs are also believed to promote innovation [36]. Given the modular character of BMs, a manager can easily hypothesize on what operations to hold given specific future contexts and further determine what changes need to be done to form a functional model. Assuming specific industry’s realities and building the respective BM can, thus, lead to a broad BM portfolio. Such implies an in-depth understanding on possible industry paths and, consequently, contributes to a company’s capability of adaptation to change.

Finally, patenting either the complete BM or only its components can increase the value of a company by empowering its legal strength and decreasing the ease with which new companies can enter the market. Further, if the methodologies behind a new model are innovative enough to change the economic profile of an industry and if they are difficult to mimic, the BM itself can pose as a competitive advantage. Particularly, Amazon’s “one click” ordering system is an example of BM patenting [36, 52].

Overall, BMs are flexible and iterative representations that sustain a company by enabling dialogue between different parties, by backing the management team through analysis and postulations, by promoting adaptability to withstand changes, by encouraging innovation, and by increasing a company’s value through the enhancement of its unique value propositions.
BMs alone are insufficient to create a business [52]. In fact, representing the organizational and financial architecture that allows a company to act on a certain market segment, deliver a specific product, and achieve profitability and sustainability is a task that demands knowledge other than knowing what information goes into each BM component.

As previously mentioned, BMs are a great communication tool between the different parties of a company. Accordingly, its content must cover the central information regarding each party, reason why in the skeleton of a company, BMs serve as a conceptual link between business strategy, business organization and ICT [27, 30]. Figure 2.4 represents such association.

The concept of strategy is variable. Overall, strategy comprehends the means through which a company achieves their proposed goals [27]. Hence, it covers market segmentation, understanding each segment’s archetype and value proposition, setting customer relations, defining how value is delivered and, ideally, setting up mechanisms capable of preventing imitation by competitors. With that being said, BMs encompass a company’s vision, market positioning, goals, and ways to achieve them [27, 30].

Another element enclosed in the BM is business organization. This covers the material form of a company that allows BMs to be implemented, i.e., departments, units, processes, and workflows. BMs influence business organization since modifications on its content may require organizational adjustments to assure proper alignment on key structures, as supply chain and partnerships [27].
Finally, ICT is the last of the three elements that BMs enclose. The relevance of this element has increased with the evolution of both technology and the Internet. By adopting management information systems, such as Enterprise Resource Planning or Customer Relationship Management software, companies are able to explore new ways of reaching and maintaining customer relationships. With this in mind, the variety of available ICTs allows for some of them to be more suitable and hence advantageous to particular types of BMs [27].

Technological change, competitors, and legal and social environments have an impact on customer demand. Hence, these external factors also assist in defining the strategy to pursue, as understanding such variables grants a clear and realistic view of the current (and prospective) market(s). Thus, the BM is central to a company, and it defines the specific business architecture that best suits all the variables.

Therefore, BMs stand as the relation between business strategy, business organization and ICT, which, in turn, are dependent on external factors that impose the needs and pains to deal with. Hence, because BMs condense all this relevant strategic information, they portrait the basic operations set up, playing a core position in a company’s design.

2.2.8 The Selected Framework: Business Model Canvas

The business model ontology to follow is the one proposed by Osterwalder and Pigneur [1]. As mentioned, this framework is composed by nine building blocks, which are specified in Table 2.5. The nine building blocks can be put together to form a useful tool, the Business Model Canvas (Figure 2.5).

This particular framework was selected given the familiarity with the way it is structured and also because it is a popular model among executives. Further, we believe that the framework successfully conjugates the essential information concerning the organization of an enterprise.
<table>
<thead>
<tr>
<th>Building block</th>
<th>Description as proposed by the authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer Segments</td>
<td>... defines the different groups of people or organizations an enterprise aims to reach and serve. (…) A company may group [customers] into distinct segments with common needs, common behaviours or other attributes.</td>
</tr>
<tr>
<td>Value Proposition</td>
<td>... describes the bundle of products and services that create value for a specific Customer Segment. (…) It solves a customer problem or satisfies a customer need [as it] caters the requirements of a specific Customer Segment. (…) [It] is an aggregation (…) of the benefits that a company offers customers.</td>
</tr>
<tr>
<td>Channels</td>
<td>... describes how a company communicates with and reaches its Customer Segments to deliver a Value Proposition. (…) Communication, distribution, and sales Channels comprise a company’s interface with customers. Channels are the customers touch points that play an important role in the customer experience.</td>
</tr>
<tr>
<td>Customer Relationships</td>
<td>... describes the types of relationships a company establishes with specific Customer Segments. (…) Relationships can range from personal to automated [and] may be driven by the following motivations: customer acquisition, customer retention and boosting sales.</td>
</tr>
<tr>
<td>Revenue Streams</td>
<td>... represent the cash a company generates from each Customer Segment. (…) [It is the] value each Customer Segment [is] truly willing to pay. (…) Each revenue stream may have different pricing mechanisms, such as fixed list prices, bargaining, auctioning, market dependent, volume dependent, or yield management.</td>
</tr>
<tr>
<td>Key Resources</td>
<td>... describes the most important assets required to make a business model work. (…) These resources allow an enterprise to create and offer a Value Proposition, reach markets, maintain relationships with Customer Segments and earn revenues. (…) [They] can be physical, financial, intellectual or human.</td>
</tr>
<tr>
<td>Key Activities</td>
<td>... describes the most important things a company must do to make its business work [that is,] the most important actions a company must take to operate successfully. [They] are required to create and offer a Value Proposition, reach markets, maintain Customer Relationships, and earn revenues.</td>
</tr>
<tr>
<td>Key Partnerships</td>
<td>... describes the network of suppliers and partners that make the business model work. (…) Companies create alliances to optimize their business models, reduce risks, or acquire resources. [There are] four different types of partnerships: strategic alliances between non-competitors; coopetition: strategic partnerships between competitors; joint ventures to develop new businesses; buyer-supplier relationships to assure reliable supplies.</td>
</tr>
<tr>
<td>Cost Structure</td>
<td>... describes all costs incurred to operate a business model. (…) Creating and delivering value, maintaining Customer Relationships, and generating revenue all incur costs. Such costs can be calculated relatively easily after defining Key Resources, Key Activities, and Key Partnerships.</td>
</tr>
</tbody>
</table>
2.3 Market studies on wearable medical devices

As WMD are an emerging market when compared to other segments of the WD industry, there is not a lot of information regarding the commercialization of WMDs or about BMs applied to this particular type of WDs. Such fact hampered the execution of a literature review on this specific matter. Still, information on WMD related matters was found in market studies conducted by different companies. These include negative impact factors on technology, the digitalization of the healthcare industry, home care technologies, and, finally, the emergence of the health care market.

Given that WMD are somewhat related to all of them, some important conclusions retrieved from those studies are subsequently reviewed.

2.3.1 Negative-impact factors on technology

The processes between identifying an unexpected problem and capturing value from the created solution are hard and time-consuming, and, frequently, companies cannot accomplish what they set out to achieve. Such can occur due to the fact that the value proposition was not properly evaluated, because the product or service is being delivered to
the wrong segment or because during the R&D phase, the product either becomes obsolete or other companies were faster in solving the problem.

Gartner Corporation [53] proposed four principles that negatively affect technological progress and advancement expectations. As stated by the research company those are that...

...[1] Technologies progress in bursts or sacades (...) rather then a smooth and even path; [2] The four predictable obstacles to progress are lack of performance, infrastructure/ecosystem, user acceptance or return on investment; [3] Technology silos continuously expand and periodically merge with other fields; [4] Public amazement at a new technology never survives mainstream adoption.

These explain the current position of wearable user interfaces and mobile health monitoring in the Hype Cycle presented previously in Figure 2.3, as well as the time prospects of 5 to 10 years until mainstream adoption. Table 2.6 details how the aforementioned principles can negatively impact technology.

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology progresses in bursts</td>
<td>It harms technological development by the associated dependence on other technologies. It concerns the fact that parallel technological advances and commercial factors may favour the development of the technology in question, and lead to a development burst.</td>
</tr>
<tr>
<td>There are four predictable barriers to progress</td>
<td>Performance: Until every aspect of performance, functionalities and design are not flawlessly achieved the acceptance of such devices is harmed. Infrastructure/ecosystem: Some technologies require integration with other technological platforms, as well as with other companies to ensure performance and the functioning of the supply chain, respectively. Such adds complications as it increases the number of stakeholders and the technological features inherent to the product. User acceptance: Novel products, especially if optional, must possess exceptional benefits that appeal user’s curiosity to a point where their interest evolves to experimenting. To achieve usability and social acceptance, it is not only important to have exquisite individual and corporate value propositions, but also to have great customer relationships strategies that potentiate value delivery. Return on investment: It poses as an obstacle given that companies have difficulty in achieving value appropriation.</td>
</tr>
<tr>
<td>Technologies expand and merge</td>
<td>It can be a problem given that from a single concept various techniques, applications and management requirements can emerge that are not at the same stage of development. Further, the inclusion with technologies not commonly associated with ITs can also occur.</td>
</tr>
<tr>
<td>The “awe factor”</td>
<td>This principle can shackle technological progress since it covers the expectations developers have on the “plateau of productivity phase”. In particular, if the uniqueness of the product has either a trendy outlook or if it rapidly becomes mainstream the “awe factor” is more likely to have a negative impact.</td>
</tr>
</tbody>
</table>
2.3.2 Digitalization of the Healthcare Industry

McKinsey & Company suggest three guidelines to take into account when proceeding with healthcare digitalization [26]: (1) One is to realize that as patients are getting more used to health ISs and to digital service provision, healthcare organizations can begin to offer more complex services such as integrated-care apps and mobile health records. The consulting firm inclusively compares the path healthcare organizations should pursue to the one followed by Facebook and Google, in the sense that they should gain their patient’s interest with simpler services and slowly add new ones that capture the patient’s attention, while contributing to building value; (2) Another consideration involves the primary understanding of what is the job to be done and what is the best way to accomplish it. Such involves talking to customers to delineate what features they really need, studying competition and self-evaluating the tools the organization already possesses; (3) Finally, following the clarification of the job to be done, is segmenting the company’s own basic services in what concerns the required investment, patient demand and created value. This also covers evaluating if the novel service ultimately improves a healthcare feature significantly. Additionally, the report reinforces the importance of knowing who the customers are and what they look for in digital services. The study revealed that while younger crowds are more open to social media channels, older ones prefer the traditional websites and e-mail. The same research company also explored the particular case of home care technologies [12] by identifying three success categories they believe should sustain the BM of those products. These are: (1) Financial (alignment between payers and providers, and remunerative factors); (2) Effectiveness (concerns the features to include in the job to be done); and (3) Accessibility (usability and repeatability). Table 2.7 overviews such factors in more detail.

<table>
<thead>
<tr>
<th>Category of success factors</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial</td>
<td>Alignment between payers and providers: It aims to assure economic success by promoting cooperation between payers and providers. Such is due to the fact that a home treated patient generates less revenue for the health institution. Success can be achieved by implementing new reimbursement models that promote market development without discarding the delivery of services that positively impact the patient’s life quality. Examples are capitated models by patient per year, direct payments for the use of the technology, or adapting bundled reimbursements where institutions are reimbursed as function of the expected costs. Remunerative factors: It concerns the return of investment of home care technologies, which should be clear and beneficial to users.</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Promote positive impacts: Home care technologies should positively alter the course of the disease progression or treatment. Possesses actionable features: They must not only alert to abnormal events, but also allow for action to be taken through a device, nurse or the patient itself.</td>
</tr>
</tbody>
</table>
Good performance: They must be rapid and reliable, and also to comprise a closed feedback loop that registers the patient’s activity (from achieved goals to performed treatments) as to permit evaluation and improvement of the technology’s value.

Yet another report on the emerging market in health care innovation by McKinsey&Company [16] studied the business strategies of 30 companies. Their analyses focused on identifying common approaches in the respective business models. The report states that innovators have found novel but efficient ways to deliver care at lower costs while favouring access and quality, which are desirable features for WMDs. The uncovered common strategies were (1) closeness to patients, (2) usage of existing technology to reinvent delivery; (3) specifically train the workforce for a certain skill; (4) standardization of operating procedures; (5) borrowing someone else’s assets; and (6) create novel revenue streams. Table 2.8 summarizes the mentioned business model features.

Table 2.8 - McKinsey&Company findings in strategic common grounds in healthcare innovation business models

<table>
<thead>
<tr>
<th>Features</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closeness to customers</td>
<td>Explores the behavioural patterns of patients and moves the delivery of care closer to their homes. By doing so it permits reducing the distribution costs and improving the adherence to clinical protocols since information products and services are standardized.</td>
</tr>
<tr>
<td>Usage of existing technology to reinvent delivery</td>
<td>This methodology repurposes already existing technology platforms (mobile-phones and call centers, among others) to extend health care access, increase the standardization of care and improve labour productivity. The integration of such platforms in WMD can lead to reduced emergency-room acceptances or to remote care delivery in the case of chronic diseases.</td>
</tr>
<tr>
<td>Specifically train the workforce for a certain skill</td>
<td>This practise has to do with attributing special capabilities to specific workers. Innovators use it to link skills and training requirements and consequently lower labour costs and overcoming labour constrains.</td>
</tr>
<tr>
<td>Standardization of operating procedures</td>
<td>Successful innovators have used this strategy to minimize waste, improve the exploitation of both labour and assets, raise the quality of care and ease the transmission of knowledge.</td>
</tr>
<tr>
<td>Borrowing someone else’s assets</td>
<td>Taking advantage of established supply chains (including institutions, infrastructures and networks) allows the reduction of capital investments and operating costs.</td>
</tr>
<tr>
<td>Create novel revenue streams</td>
<td>Finally, the report states that health care innovators often create novel revenue streams by expanding their activities to other sectors. This allows for additional value appropriation and subsidization of costs. Besides, health innovations can be promoted by other industry sectors.</td>
</tr>
</tbody>
</table>

Considering what was said on factors capable of posing as obstacles to technology commercialization, there are some preventive judgments that can counteract, or at least decrease, the chances of failure. Overall, these include [26, 53]:
- Accompanying technological innovations and market forecasts;
- Searching for customer needs that are yet to be solved;
- Only invest in pioneering situations or unique applications;
- Realistically assess if the product or service improves the overall product delivery landscape;
- Reflecting on whether the benefit and maturity of a technology/product balances the associated risk, and, if not, understand why. Further, given the expansion of technology and its applications, analyse the maturity of each individual intervenient
- Seizing advantageous or novel value propositions to innovate the process of doing business and, possibly, change the industry;
- Building a solid value proposition. Consequently, clearly understand what is the job to be done, what is being made by competitors, and what are the technological innovations forecasts;
- Including a well defined experimenting phase in the process for innovation;
- When working with novel technologies it is advisable to extend the study further than to the product or the vendor, as the recipe for success is not a fixed one. Also, studying different approaches is a great source of knowledge and can contribute with a wide variety of lessons learned;
- Thinking outside the box and consider non-IT activities;
- Adopt a familiarization approach to build value, that is, gain customer’s interest and curiosity and gradually introduce new services/features;
- When working with medical services, seek to standardize protocols;

As effect, the core of the problem is not only what and how to invent but also how to implement it. Indeed, in healthcare there are several characteristics that must be provided in an interdependent manner, namely cost effectives, quality and accessibility [16].


The healthcare industry is a complex market. Not only is the medical community frequently close-minded in what concerns the adoption of unconventional methodologies, but also the performance and design of WMD has to be flawless, since it deals with human lives.

Including WMD in the daily operations of a medical institution is a multi-level process that is deeply related to the concepts addressed in the analysis of Figure 2.4. The functioning architecture of the healthcare system involves a great amount of stakeholders with distinct interests. For example, while patients look for efficient and cheap treatments, investors seek income. Accordingly, there are a lot of aspects that must be carefully detailed as to provide solutions that please all involved parties and promote financial stability.
3. METHODOLOGY

Although there is an important amount of information on wearable technologies, it does not cover the specific segment of medical devices. Therefore, the motivation behind this work was to gather missing information capable of enlighten researchers and professionals about business model characteristics applied to the particular case of wearable medical devices.

This chapter describes the implemented research methodology to address the mentioned gap of information. In particular, the research methodology aims to:

- Identify companies that commercialize wearable medical devices;
- Elaborate an interview protocol whose questions focus not only on business model characteristics, but also, and within possible, on the evolution of the company;
- Establish contact with the company executives as to conduct interviews with them;
- Analyse the collected information and cross-reference it with the BM framework at use, the Business Model Canvas;
- Compare and analyse the created BMs and strategies behind them;
- Discuss such strategies and compile final remarks.

3.1 RESEARCH DESIGN

According to Yin [2], a case study is...

... an empirical inquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident [and] relies on multiple sources of evidence.

Further, as a comprehensive research strategy, a case study deals with situations where there are more variables of interest than data points, and relies on several sources of
information. Therefore, a case study requires for a triangulation of the collected data, backed by previously obtained theoretical knowledge.

Overall, this work consists of both an exploratory and explanatory case study [2]: exploratory as it explores what strategies are applied, and explanatory as it also seeks to cover how and why the chosen strategies prevail over others.

There are mainly two essential criteria behind using the case study methodology. One is that the questions behind the subject intend to explain why or how does a certain circumstance occur. The other criteria is that the questions require an in-depth description of some social phenomenon. In particular, the need for case study research arises from the desire to understand a complex social situation. It allows researchers to stay focused on a specific matter, while retaining a realistic and distinctive perspective about it.

A single case design study is only suitable when it represents [2]...

... (i) a critical test of existing theory, (ii) a rare or unique circumstance, or (iii) a representative or typical case or when the case serves a (iv) revelatory or (v) longitudinal purpose”.

Such methodology was not suitable for the study at hands. In fact, the companies under analysis failed to represent a unique circumstance given their different stages of complexity, their years of existence, and also their political and financial realities. Thus, a multiple case approach was followed. If each case is seen as a unique experiment that stands as an individual analytic unit, multiple cases are discrete experiments that serve as reproductions, contrasts, and extensions to the emerging theory [54].

Although arduous because it requires more resources, a multiple case enables acquiring comparable information. Hence, it makes it possible to find common patterns and facilitates theory building. As such, multiple case studies are often considered to be more precise and trustworthy than others [2, 55].

Indeed, there are advantages in utilizing a multiple case approach [55]. One is that it enables the identification of a certain occurrence as idiosyncratic to a particular case or frequent throughout cases. Further, relationships are more credibly established because propositions can be supported by empirical evidence from different sources. Consequentially, it is possible to set an appropriate level of abstraction, to enhance results exploration, and to build reliable theories. All in all, the results determined by this methodology are considered to be more precise and trustworthy.

The unique strength of case studies is their capacity to deal with a wide variety of data sources, as opposed to what happens in a traditional historical study. Thus, information can be assembled from interviews, archival data, surveys, ethnographies, and observations [2, 54, 55]. Given that several sources of information were used, such as interviews, papers, and online information, once again, choosing a case study approach seemed adequate. The usage of interviews with open-ended questions as the main source of data enable gathering
more detailed, reliable and honest perspectives on the matter. Notwithstanding, although efficient in what concerns collecting rich and empirical information, interviewees are susceptible of producing biased results given their sensibility and personal bond to the topic [55]. Such can be downgraded if the case study uses a reasonable number of informants, and if these can bring different perspectives to the table. Perspective diversity can result from different hierarchical levels, functional areas, groups, and geographies.

With that in mind, the choice of requisites followed some pre-established guidelines. These intended to restrict the selection of cases while providing for some diversity. It is to note that companies were selected as function of their products. Considering a wearable medical device [8] as...

... a device that is autonomous, that is noninvasive, and that performs a specific medical function such as monitoring or support over a prolonged period of time [and] that the support environment is either the human body or a piece of clothing,

and that the Food and Drug Administration defines [9] a medical device data system as...

... a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices: (i) The electronic transfer of medical device data; (ii) The electronic storage of medical device data; (iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or (iv) The electronic display of medical device data. [It] may include software, electronic or electrical hardware such as a physical communication medium (...), modems, interfaces, and a communication protocol,

the following considerations were obeyed:

(i) The product has to fit the description of a wearable medical device;
(ii) The product has to be classified as a Class I, II, or III medical device;
(iii) The product has to be on the market

Notwithstanding, it is to note that one company was included in the analysis despite not following the requisites. This company sells manufacture and supplier activities to WMDs companies. Accordingly, the decision to include it in the study was based on the fact that it integrates the value chain of the WMDs industry and could, for that reason, bring interesting insights regarding how partnerships are established, and how relationships are held.

With that in mind, the unit of analysis in this study is the business model behind each selected medical device.
Finally, information was handled aiming to avoid influencing the results by any external factors and leaping to conclusions, as these commonly lead to premature or even false conclusions. Hence, data was analyzed as suggested by Eisenhardt [54]. Based on the collected information, similarities and differences within the different business models were uncovered as to try to find common features and categories. Such methodology was conciliated by another suggested by the same author [54], where similarities and differences can be found by juxtaposing the cases under study as to induce a more detailed oriented comparison.

### 3.2 Data Collection

The process of searching for companies with products that fit the aforementioned criteria resulted in a collection of 32 companies and, given that some had more than one medical device on the market, 42 products.

The order by which the companies were contacted was not random. Three of them were Portuguese and so, contacting them was not a problem. Hence, the international companies to be contacted first were chosen based on their products being similar in function, design, or utilization procedures. Such was made as to try to restrain the analysis to a particular type of product. However, when all contacts were established, that was not possible, reason why a multiple case study approach was followed.

Ultimately, from the 32 companies identified initially, only 14 were considered to be suitable for the study at hands. The reasons for dismissing companies were based on the products not following the criteria aforementioned. In what concerns the first and second criteria, either no information was found or products were not considered medical devices but well-being and fitness products.

Accordingly, all 14 companies were contacted, 12 via e-mail and 2, the Portuguese ones, personally. In the absence of response, two more e-mails were sent. From this group of 12 companies, 7 companies responded. In turn, 4 found the interview protocol to require sensible and confidential information and did not agree to collaborate. With the other 3 companies, Skype meetings were arranged. In what concerns the 2 companies contacted personally, face-to-face meetings were held. Hence, a total of 5 companies contributed to this study and a total number of 8 interviews were conducted.

The guidelines behind the interview protocol were established based on literature descriptive of the business model framework at use, the Business Model Canvas proposed by Osterwalder and Pigneur [1, 36, 56]. The questions were made in the hopes of retrieving information capable of reflecting the descriptions presented in Table 2.5, back in Chapter 2.2.8. The final interview protocol is a document composed by 19 questions, being that 15 of
them are intended to characterize the 9 building blocks that compose the framework, and the other 4 are more general, personal questions that focus on personal experiences and future perspectives. The integral interview protocol follows in the Appendices, on Chapter 8.1. Besides the interview protocol, a consent form for study participation was elaborated. Such document is also present in the Appendices, on Chapter 8.2. The consent form was given to the participants before starting the personal interviews. In the case of Skype interviews, the participants would be asked to state their agreement with the recording, transcription, and utilization of the information.

Data was collected by recording interviews, and, to facilitate content analysis, tape transcriptions were performed. For each company, the answers were cross-referenced with each building block, and the BM was assembled. Then, as BMs were completed, information was compared between companies as so search for strategies, thoughts, experiences, or other information that could lead to conclusive results. Further, the results were also cross-referenced with literature as to provide a more meaningful and thorough investigation.

Table 3.1 displays an overview of the companies and their products, how they were contacted, and what position does the interviewee have on the company. Company C is the one that was exceptionally included in the study.

<table>
<thead>
<tr>
<th>Company</th>
<th>Product</th>
<th>Means of contact</th>
<th>Number of interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>ECG monitoring t-shirt</td>
<td>Personally</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skype</td>
<td>2</td>
</tr>
<tr>
<td>P</td>
<td>Muscular monitoring body sensors and wearable hub</td>
<td>Personally</td>
<td>1</td>
</tr>
<tr>
<td>O</td>
<td>Pressure sensing shoe insoles</td>
<td>Skype</td>
<td>1</td>
</tr>
<tr>
<td>T</td>
<td>Motion body sensors</td>
<td>Skype</td>
<td>2</td>
</tr>
<tr>
<td>C</td>
<td>Components to include in WMDs</td>
<td>Skype</td>
<td>1</td>
</tr>
</tbody>
</table>

It is to note that the contextualization of the companies under study was made with information from the respective websites. However, such references were not included as to preserve their confidentiality.
4. RESULTS

This chapter contains the results obtained from the conducted interviews. Ultimately, 5 companies were analysed. For each company, a brief introduction on the company was written to contextualize the case at study. The information retrieved from the interview was used to build the respective BM.

4.1 COMPANY B

Company B is a Portuguese biotechnology company. This privately held company was founded in 2006 and employs a total 8 workers. The company started as a spin-off of the Institute of Electronic and Telematic Engineering of University of Aveiro. It specializes in developing and commercializing biomedical solutions for medical diagnostic applications.

When it was set up, Company B started to develop products to be used in the context of hospital admissions. However, once the company evolved and the decision to go to market was made, a market study revealed that there was no opportunity for those types of products. The company then shifted its strategy to what it does now, medical devices intended for cardiological ambulatory uses. Their portfolio includes two versions of Product B to be utilized in medical settings, and a third SDK version intended to provide developers with a software development kit. Particularly, one of the medical versions of Product B uses one ECG sensor to continuously record biosignals during cardio training or cardiac rehabilitation exercises for up to 5 days. In turn, the other uses a 5 leads Holter System\(^1\) [57] to record up to 72 hours of continuous signals for cardiac screening in patient with arrhythmias.

Interviewee B performs COO functions since 2010.

\(^1\)A Holter system is continuously records ECG signals in ambulatory conditions for a certain period of time [57].
4.1.1 Business Model Characterization

Product B is a wearable t-shirt containing multiple sensors. It is designed to monitor cardiac signals in an ambulatory context, with the quality and reliability of hospital equipment. As it is discrete and comfortable, it allows the user to maintain a normal lifestyle without feeling the anxiety of a medical exam. Such is important as anxiety in a clinical setting is responsible for erroneous results that lead to misdiagnosis. Furthermore, the battery life allows long term monitoring and hence, more reliable results. Also, the product is supplemented by an high-performance software that presents graphics, statistical data, and easy to read reports.

Company B focus on the cardiology market, which includes pediatric, adult, and rehabilitation cardiology. Their most important customers are private health institutions. On a national level these are mainly represented by private hospitals with capital to buy these sorts of products. In foreign markets, the financial difference between public and private hospitals weakens, but the most relevant clients are still private institutions, which, besides hospitals, also include clinics.

The strategies to customer acquisition differ depending if customers are on domestic or on international markets. In the first case, the company schedules meetings with health institutions and personal contact is established. In contrast, in international markets, local distributors assure customer acquisition. Therefore, purchases can be made by either direct channels (where contacts are made available on the website or on personal meetings), or by contacting distributors, respectively. The strategies for maintaining customers are also very traditional. The company maintains regular contact, provides customer support, and sends regular e-mails.

As the components are outsourced, the company’s key partners are the suppliers who provide them with such parts. Once the company specifies the textile and electronic designs, each partner manufactures the equivalent t-shirt and electronic components. Further, the company also relies on one assembling partner, process that is also not conducted in-house. Ultimately, in what concerns the selling chain, Company B only deals with the packaging of the different parts of Product B (that are supplied by the aforementioned partners), and with the ordering and delivering processes.

In what concerns its current key activities, the company is focused on the commercialization of Product B, as well as on the development of new products. Above all, Company B is a development company and hence, its R&D activities are never discarded. Understandably, human resources are crucial for the company, since they assure both key activities.

Regarding the cost structure of the company, it is hard to define whether Company B is more cost or value driven. In spite of the strong value proposition they offer, the company had to adjust their costs not only to the reality of its segments, but also to their competitors.
Regardless, the most important costs of the business model are those of staff and production. Finally, Product B contributes to the company’s revenue is by asset sales.

Figure 4.1 displays the described BM.

4.2 Company P

Company P was founded in 2007. Headquartered in Portugal, it currently employs 15 workers. This privately held company works in the manufacturing of electronic products. By combining wearable body sensors, wireless connectivity communications, and software applications, it aims to develop novel biosignal monitoring platforms for physiotherapists and researchers.

The interviewee of Company P has been in the company since 2007. He was one of the founders of the company, and performs both President and CSO functions.

While doing his PhD, P became aware of a technological need regarding the monitoring of the human body. Not only were the existing tools too limited and expensive, but also conducting ECG measurements was quite an impractical procedure. For instance, as the equipment had wires someone had to hold them while the test subject run from one place to another. Determined to improve and ease the way physiotherapy and research on biosignals was done, P grew his individual research project to a start-up, which was initiated in Lisbon’s Instituto Superior Técnico.

Company P has a portfolio of five distinct products:
- One is a wearable body-sensing platform that tracks biosignals for biomedical, HCI and sports researchers;
- Another is directed for professionals who provide computer access to people with motor impairments;
- A third one performs ergonomic risk evaluations in the area of injury prevention;
- The fourth is a toolkit intended for the creation of projects with physiological sensors;
- And the last one, that uses wearable body sensors to provide biofeedback of EMG signals for rehabilitation purposes.

The BM analysis focuses only on the later, Product P, which is on the market since 2011. The 4-year interval since the establishment of the company allowed achieving organizational stability before producing medical devices. During this time, the company focused on the development and commercialization of products destined to other applications. In fact, the one intended for investigation was the first to be introduced to market. Hence, by waiting, the company was able to acquire experience and reach a position where investing in medical devices was a safe move. Further, the fact that the company
matured over the years made it a good candidate for receiving funding. In particular, in early 2013, the company received venture capital that allowed for development and marketing studies necessary to the development of Product P. Consequently, it was possible to take Product P to a suitable growth market.

Product P is made up of:
- 1 wearable wireless belt clip: enabling the monitoring of 4 muscles simultaneously. This component is responsible for collecting and digitizing the signals from the sensors, and transmitting them via Bluetooth to the tablet, in real time.
- 25 reusable disposable detection sensors: these body sensors include 4 sEMG sensors that record muscular activity, the respiration belt designed to measure abdominal or thoracic respiratory cycles, and an urinary incontinence vaginal probe;
- 1 tablet with embedded biofeedback software.

Altogether, they provide muscular feedback in real time, guide patients towards performing the correct movements, help the physiotherapist to define goals, and report and track progress.

4.2.1 BUSINESS MODEL CHARACTERIZATION

Product P is an efficient and effective high performance wireless EMG biofeedback system to be used by physiotherapists in the context of both rehabilitation and prevention. By itself, the device monitors muscular activity with top of the line noise reduction filters while providing real-time feedback, guidance towards the execution of the correct movements, and reporting the patient’s progress. The results achieved by the device are proven to be faster and more lasting than existing ones, playing an important role in preventing reoccurrences.

Although being directed towards the specific segment of physiotherapy clinics, the benefits of the value proposition extend to patients. The mentioned applications are useful for physiotherapists as they can perform objective assessments of muscular activity and perform more accurate treatments. As far as the patients go, the device provides a more comfortable and efficient way of assessing their condition. It eases the learning of the correct physiotherapy movements, accelerating recovery and reducing pain. In particular, Product P’s most important customers are Dutch physiotherapy clinics.

Regarding customer relationships, Company P uses distributors with background on medical devices in order to leverage their contact network. By using this indirect channel of distribution, the company is not only able to acquire customers, but also to provide personal assistance concerning both product education and post-purchase support.

Accordingly, distributors are the most important of key partners. Besides them, two
suppliers are also worth mentioning as key partners: one is responsible for constructing both the printed circuit boards and enclosures, and the other for the assembling of the different parts. It is to note, however, that the production of the parts is based on designs that are elaborated in-house.

The company currently focuses on improving and updating the product, as well as on marketing, and reinforcing clinical evidences (studies which are being conducted). The concern for this later subject has to do with the hope of attaining reimbursement. By enlarging the test population, the company hopes to prove the increased efficacy of its product as opposed to other methods, and hence to have a strong enough of an argument to motivate its adoption has a standard treatment methodology.

In what concerns crucial aspects to their current operations, P identifies human resources, since these assure the previous key activities. In particular, given the strong presence in the Dutch market, the company has a permanent worker in the Netherlands and others that frequently travel to that country. Thus, its cost structure’s most important costs cover their work force and marketing operations, as well as the costs of component acquisition. Finally, Product P contributes to the profitability of the company by its sales to customers.

The described BM is displayed in Figure 4.2.

4.3 Company O

Company O was founded in 2010 by a surgical resident. It is headquartered in Canada and employs, currently, 12 employees. While doing her residency, she was frequently addressing patients with diabetic related foot complications, such as tissue damage, infection, ulceration, and amputation. Because all derive from DPN, which biologically is the loss of feeling and sensory feedback in the feet, the founder realized that the solution to such problem could be developing plantar sensory replacement systems. Hence, Company O develops sensor-based wearable technologies that allow self-monitoring and prevention of chronic health-related conditions.

The portfolio of Company O includes one plantar replacement system, Product O. Although this is the only commercialized product, other products are under development.

The final package of Product O includes the shoe pod, a hub to place in the front of the shoe, a smartwatch, a USB charging cable, a smartwatch charging cable, an AC adapter and an instructions guide. The technology behind Product O uses pressure sensor-embedded shoe insoles to determine the force being exerted on the bottom of the feet. When prejudicial foot pressures are detected, such information is wirelessly transmitted to the smartwatch as a notification system. The user can then modify its movements and prevent
diabetic related complications. The system is also able to track and store data over time, which is useful to study the progress of the medical conditions.

Although starting as a marketing associate in 2013, the respective interviewee is currently the marketing and inside sales manager of the company.

4.3.1 BUSINESS MODEL CHARACTERIZATION

Product O is on the market since December 2014. Although Company O was officially founded in 2010, it was only in 2011 that the founder started working full-time in it.

As the product replaces the loss of sensation under foot, it prevents the occurrence of diabetic related complications that can lead, in most extreme cases, to amputations. The value proposition focuses on performance and convenience to both doctors and patients. By accessing the stored data, doctors have a more realistic understanding of the patient’s medical condition and can, therefore, advise them in more specific ways. Also, by using this type of preventive product, doctors reduce the number of possible complications. Such is financially beneficial for health institutions and even the government, which saves by not having to finance the treatments that were averted. Also, from the patients’ point of view, they avoid pain, the stress of having to attend hospitals, the associated treatment costs, and can even avoid amputations.

Although patients are the end users, the customer segments also include doctors whose patients suffer from the mentioned condition. Patients can order Product O via the e-commerce platform or via authorized resellers (which are the wound care and pediatrics neuropathy centers). Accordingly, the sales channels include both direct (the e-commerce platform) and indirect approaches (the aforementioned resellers, in which the order is made via the doctor). In either case, the company uses UPS services to deliver its products to its customers. Currently, the operations of the company are limited to North America. Nevertheless, the company plans to establish a distribution network in North America, as well as to internationally expand their market of operations to Europe.

In order to attract new customers, the company relies on KOL as well as on the presence in trade shows and conferences. The company also invests in SEM and social media platforms, namely Twitter and Facebook. In order to keep customers, the company has a designated department responsible for customer care. Besides, customers receive routine e-news letters and the company engages its customers by displaying their performance through time on a platform. Such aims to stimulate patients as they observe their overall improvement.

As mentioned before, opinion leaders constitute a key partner. Besides them, Company O also relies on supply partners who ensure the delivery of components who are then assembled in house.
As Product O has been on the market for a short period of time, the company’s key activities cover areas besides R&D and product testing. The company also focuses on market assessment, exploring and exploiting different marketing channels and setting up sales. The most important costs are hardware and customer acquisition. Thus, human, marketing, and financial resources are crucial for the company.

Finally, Company O revenues derive mostly from the sales of Product O. However, the company is also financed by non-diluting sources of revenue, such as government grants and awards.

The described BM is displayed in Figure 4.3.

4.4 COMPANY T

Company T was founded in 2011 and its headquarters are located in the UK. This privately held company operates in the medical devices industry, and houses about 10 workers. It specializes in wearable devices, product design and development, software development, and consulting. Particularly, it aims not only to provide world class consultancy work for technology companies, but also to develop and market wearable motion technology devices and software with sports and medical recovery applications.

The interviewed worker was one of the founders of the company, being CEO ever since. Before starting this company, he worked for many years in motion analysis, coupling sensors to the very first smartphones. Additionally, he also worked in the gaming industry. Then, having one relative affected by poliomyelitis and being T involved in elite sports, he felt the need for better ways of sensing the body. Once he got aware of such need, he adapted the existing gaming system technology to motion analysis. Having obtained quite excellent results in terms of helping people in sports and physio, T and his team decided to develop a professional version, creating Product T. It is now in the market for 1 year and 9 months.

Product T is now part of the company’s portfolio, alongside with different software modules that go with it. These are adapted to the final application of the product, which can be directed to either sports or physiotherapy applications. Product T is a wearable wireless sensor to be placed at the site of interest. When sold, it is paired with the respective software module. Hence, while Product T collects motion information, the software allows the interpretation, analysis and visualization of such data with live animated feedback and graphics.

In more detail, Product T is a combination of high performance, small, light, wireless sensors carefully designed to ensure the alignment with the skeletal mass. Unlike other

---

2 Disease caused by infection that can lead to muscular paralysis
products, it wirelessly transmits the collected data to computers, tablets and Windows-based tablets. Ultimately, Product T allows the measurement of the direction, rotation, speed, acceleration, force, power, and endurance of the body, while performing accurate diagnosis and rehabilitation therapies. The product can track the movement of the head/neck, upper or lower extremities.

4.4.1 BUSINESS MODEL CHARACTERIZATION

The value proposition focuses on performing real-time, accurate and repeatable body measurements in a more easy, practical, and cost-effective way. Combined with the physiotherapy software module, it allows the visualization of the collected data, providing the clinician with live feedback of the patient’s motion. Such translates into accurate data about the patient’s motion patterns. Therefore, the physiotherapist can perform exact diagnosis and apply suitable treatments, while comparing the patient’s progress against historical data. Also, by using Product T, the use of traditional methods like goniometers and inclinometers, which are less accurate, are dispensed.

As Product T, the wearable wireless sensor, is sold along side with the software module, the main customers are physiotherapists (regardless of the final application being intended for orthopaedics or sports), sports scientists, and elite athletes/teams/coaches. Nevertheless, physiotherapy applications represent the biggest percentage of customers and hence, it is the segment that most contributes to revenue.

The company acquired its initial clients by going “door-on-door” and talking directly with potential customers. Such strategy was applied to both the health and sports segments. Having conquered a loyal customer base, the customer relationships strategies also include digital marketing. The presence in trade shows around the world, and the current distributors network is attracting new customers, which are drawn to the company’s website. Also, current customers are kept engaged by recurrent e-mail campaigns, as well as Twitter and Facebook activity.

To get the product to its customers, the company uses direct and indirect channels. The direct ones include the e-commerce website, and a sales force distribution channel created by the own company. In turn, the indirect channels are established by sales through OEMs and local distributors. While the first covers orthopaedics and health physiotherapy applications, the later covers the remaining segments. Therefore, some of the company’s most valuable partners are its distributors and the OEMs partners.

Regarding key activities, the main focus of Company T is customer relationship marketing and R&D. This later activity in still present given that, although Product T is already on the market for 1 year and 9 months, the company is constantly getting customer
feedback, aiming to manufacture improved versions of Product T or even products with new applications. Accordingly, the company requires mainly HRs specialized in marketing and business development, while also detaining IP assets. In what concerns research and development, given that the team is specialized in sensors and has a strong technological background, the company does not have to buy these types of resources or activities. In line with what was mentioned, the current most important costs support marketing engagement.

Displayed in Figure 4.4 is the described BM.

4.5 Company C

Company C is the exception that was included in the study. It does not produce wearable medical devices, but supplies the components that integrate them. That is, it positions itself as the manufacturer partner who develops and produces solutions. This privately held company specializes in the mass-production of e-Textile biometric sensors to be applied to sports electronics, medical products, and home healthcare. Founded in 2001 in Finland, it currently employs 40 workers in that country and about 350 employees in its Chinese e-Textile manufacturing installations. The interviewee of Company C works as a marketing manager since December 2011.

Company C was firstly approached since it was thought to be a developer of WMD. Having realized that such was not the case, the inclusion of Company C in this work was backed by an interest in understanding how WMD companies are connected to their suppliers in the supply chain.

The company is as a white label supplier of sensor components, therefore, it does not have a portfolio of products commercialized under the company’s brand. It is involved in the wearable technology industry since 1998. By the late 90s, Nokia’s international impact on the telecommunications industry boosted the interest for mobile and information technology. With that in mind, a Finish textile manufacturer partnered with two universities to develop a prototype of a wearable technology. Consequently, from 1998 to 2000 a functional prototype of the first heart rate sensing t-shirt was achieved, accomplishment that set the wheals in motion for Company C.

4.5.1 Business Model Characterization

The value proposition of Company C is highly focused on solving the problem of discomfort, since they came to learn that people are more open to embrace new technology
depending on the experienced comfort level. Further, the company also offers highly customized mass production services, which is the center of their BM.

The company’s customer relationship strategies are very meticulous. The company makes use of market intelligence to find customers that fulfill specific requirements, the most important of which being the ability to order large amounts of sensors. If a customer of interest is found, then personal contact follows. Further, the company extends the face-to-face approach to presence in trade shows and conferences. Also, the current reputation of the company is by itself attractive for companies looking for mass production services. In fact, customers themselves sometimes approach Company C.

The company focuses its commercial efforts on sports wear, sports electronics and medical instruments. Acting as a manufacturer, it relies on a direct sales model, without resorting to third parties as distributors.

Given the present structure of its business, the conducted activities are very user-oriented. The company has a large network of suppliers and a wide understanding on how to license technology. Such allows it to manufacture a wide range of solutions that meet the particular requirements of each client. Accordingly, the key activities focus on product development and manufacturing. For the same reasons, suppliers are considered to be the key partners.

In what concerns the key resources, C highlighted the importance of the employees. Although the machines in use are not highly complex, the know-how and expertise behind the manipulation of such equipment to achieve mass production the way it has is the real value of the company. Accordingly, the most important costs are those that cover materials and labor.

Finally, revenue streams are assured by the mass production services the company has to offer. Also, it is to note that contrarily to most companies under analysis, Company C was financed by government grants that promote technological innovation. Such is directly related to the fact the Finish government highly supports technology and its development.

The described BM is displayed in Figure 4.5.
<table>
<thead>
<tr>
<th><strong>Key Partners</strong></th>
<th><strong>Key Activities</strong></th>
<th><strong>Value Proposition</strong></th>
<th><strong>Customer Relationships</strong></th>
<th><strong>Customers Segments</strong></th>
</tr>
</thead>
</table>
| Suppliers of:  | Sales and commercialization | Product B is a wearable t-shirt that seeks comfort and performance, designed to monitor cardiac signals in the ambulatory context. A t-shirt, a recording and data emission device, and the analysis software compose the medical device. Unlike other products, it is the only Holter System with an embedded accelerometer. | Acquire  
- Nationally: schedule visits to health institutions, face-to-face meetings.  
- Internationally: through distributors  
Keep:  
Constant contact (personal, e-mail, phone, customer support) | Cardiac niche (pediatric, adult, and rehabilitation). In particular,  
- Nationally: private hospitals  
- Internationally: private clinics and hospitals |
| - Textile (t-shirt)  
- Electronic components | Development of new products | | |
| Assembling partner | | | |

<table>
<thead>
<tr>
<th><strong>Key Resources</strong></th>
<th><strong>Channels</strong></th>
<th><strong>Cost Structure</strong></th>
<th><strong>Revenue Streams</strong></th>
</tr>
</thead>
</table>
| Human resources that assure both key activities | Nationally:  
Direct by postal services  
Internationally:  
Indirect by distributors | The most important costs are those of human resources and production costs | Asset sales |

Figure 4.1 - Business model of Product B
<table>
<thead>
<tr>
<th><strong>Key Partners</strong></th>
<th><strong>Key Activities</strong></th>
<th><strong>Value Proposition</strong></th>
<th><strong>Customer Relationships</strong></th>
<th><strong>Customers Segments</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Distributors</td>
<td>Improving the product</td>
<td>Product P is a wireless EMG biofeedback system designed for physiotherapists in the context of prevention and rehabilitation that allows monitoring of muscle activity. A wireless belt clip, body sensors, and a tablet with embedded software compose the final package. Unlike other products, it has great extraction capability and is backed by strong clinical evidence.</td>
<td>Acquisition and post purchase support is held by the distributors</td>
<td>Physiotherapy clinics (most important customers are in the Dutch market)</td>
</tr>
<tr>
<td>Suppliers of parts</td>
<td>Marketing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assembling partners</td>
<td>Reinforcing clinical evidences aiming for reimbursement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Key Resources</strong></td>
<td>Human resources (that cover the above key activities)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intellectual property</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cost Structure</strong></td>
<td>The most important costs are those that cover the work force, the marketing operations, and component acquisition.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Revenue Streams</strong></td>
<td>Asset sales</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 4.2 - Business model of Product P
| **Key Partners** | KOL  
Suppliers of components |
|------------------|--------------------------|
| **Key Activities** | R&D  
Product testing  
Market assessment  
Setting up sales  
Marketing channels |
| **Value Proposition** | Product O is a pressure sensor-embedded shoe insole designed for medical patients that have lost sensation under the foot. It was developed in the context of the prevention of diabetic related complications. |
| **Customer Relationships** | Attract:  
KOL  
Trade shows and conferences  
Online marketing (Facebook, Twitter, Google campaigns)  
Keep:  
Customer care  
E-news letters  
Send performance feedback updates |
| **Customers Segments** | Patients with foot sensory loss  
Doctors of the above mentioned patients |
| **Cost Structure** | The most important costs are those of hardware and customer acquisition |
| **Key Resources** | Human resources  
Intellectual property |
| **Channels** | Direct:  
E-commerce platform and UPS  
Indirect:  
Authorized resellers (wound care and pediatrin neuropathy centers) and UPS |
| **Customer Segments** | Customer care  
E-news letters  
Send performance feedback updates |
| **Revenue Streams** | Product O sales  
Non-diluting sources of revenue from government grants and awards |

Figure 4.3 - Business model of Product O
<table>
<thead>
<tr>
<th><strong>Key Partners</strong></th>
<th>Distributors</th>
<th>Orthopaedic OEM partners</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key Activities</strong></td>
<td>Customer relationship marketing</td>
<td>R&amp;D</td>
</tr>
<tr>
<td><strong>Key Resources</strong></td>
<td>Human resources specialized in marketing and business development</td>
<td>Intellectual property</td>
</tr>
<tr>
<td><strong>Value Proposition</strong></td>
<td>Product T is a wireless wearable sensor designed to perform real-time, accurate and repeatable motion related measurements. Combined with the physiotherapy software module, allows the visualization of the collected data, providing the clinician live feedback of the patient’s motion. Compared to other products it can either use only one sensor, be cheaper, or more reliable.</td>
<td></td>
</tr>
<tr>
<td><strong>Customer Relationships</strong></td>
<td>Personal contact</td>
<td>E-mail campaigns</td>
</tr>
<tr>
<td><strong>Channels</strong></td>
<td>Direct: E-commerce platform and sales force distribution channel</td>
<td>Indirect: For health: Partnerships with OEMs</td>
</tr>
<tr>
<td><strong>Customers Segments</strong></td>
<td>In health: Orthopaedic implant manufacturers</td>
<td>Orthopaedic surgeons</td>
</tr>
<tr>
<td></td>
<td>In sports:</td>
<td></td>
</tr>
</tbody>
</table>

**Cost Structure**
The most important costs are those of marketing engagement

**Revenue Streams**
Sales of the set composed by Product T and software modules (mainly the physiotherapy one).

*Figure 4.4 - Business model of Product T*
<table>
<thead>
<tr>
<th><strong>Key Partners</strong></th>
<th>Customers</th>
<th>Suppliers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key Activities</strong></td>
<td>Product development</td>
<td>Manufacturing</td>
</tr>
<tr>
<td><strong>Value Proposition</strong></td>
<td>Develop and manufacture biometric sensor electronics to integrate in wearable technologies. The products are designed for both sports and medical applications. Unlike other companies, the company strives for comfort and allows mass-production of highly customized solutions.</td>
<td></td>
</tr>
<tr>
<td><strong>Customer Relationships</strong></td>
<td>Market intelligence</td>
<td>Trade shows and conferences</td>
</tr>
<tr>
<td><strong>Channels</strong></td>
<td>Direct sales</td>
<td></td>
</tr>
<tr>
<td><strong>Customers Segments</strong></td>
<td>Sports wear, sports electronics, and medical instruments companies who are in need for mass manufacturing of their products.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Key Resources</strong></th>
<th>Human resources</th>
</tr>
</thead>
</table>

**Cost Structure**  
The most important costs are those of materials and labor

**Revenue Streams**  
Profit is generated by the mass production services (the price is fixed, although more variable for medical components)

Figure 4.5 - Business model of Product C
5. DISCUSSION

This chapter aims at discussing the obtained results. The different blocks of the BMC are discussed throughout the subchapters, alongside with relevant considerations important for the understanding of the companies’ BM. It is worth noting that, since Company C is not a medical device producer, but a manufacturer of parts to be included in them, it is analysed separately.

5.1 VALUE PROPOSITION AND CO-CREATION

As stated, the definition of value proposition adopted for this work was [1] ...

... describes the bundle of products and services that create value for a specific Customer Segment. (…) It solves a customer problem or satisfies a customer need [as it] caters the requirements of a specific Customer Segment. (…) [It] is an aggregation (...) of the benefits that a company offers customers.

From the collected data, we can see that all companies started by identifying scenarios with room to improve. Table 5.1 summarizes what inspired each company to pursue the development of the respective WMD.

It is noticeable that Companies P, O, and T knew the specific segment to which they would deliver novel products and services. This is mostly due to the founders of these companies. Since they already had experience in the respective medical area, they knew from the start the specific market in which they would operate, as well as the overall concept of the value proposition. Contrarily, Company B was founded from a university spin off with great technological insights, but with no real understanding of the needs in the WMDs industry. So, while the other companies identified a real problem in a specific segment from the start, Company B only realized the need for a device like Product B while defining the go to market strategy of another product (which was actually abandoned given the lack of commercial potential). Therefore, while Company B reflects a case of
“technology push” activities - finding a possible commercial application for a technology, all the others reflect more “technology pull” behaviors - identifying a problem and addressing it through technological development.

Table 5.1 - Motivations that inspired the development of WMDs

<table>
<thead>
<tr>
<th>Company</th>
<th>Motivation</th>
<th>Technology transfer activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company B</td>
<td>Will to produce wearable medical devices</td>
<td>Technology push</td>
</tr>
<tr>
<td>Company P</td>
<td>Dissatisfaction towards existing products</td>
<td>Technology pull</td>
</tr>
<tr>
<td>Company O</td>
<td>Inexistence of solutions to address the problem</td>
<td>Technology pull</td>
</tr>
<tr>
<td>Company T</td>
<td>Dissatisfaction towards existing products</td>
<td>Technology pull</td>
</tr>
</tbody>
</table>

Regardless of being motivated by more or less specific reasons, once realizing the market need, the concept of the value proposition remained constant in all companies. In line with the aforementioned definition this means that although changing the inherent features in concordance to the received market feedback, companies remained true to the nature of the products and services to offer.

Further, iterating between prototypes based on feedback from professionals and end-users was also common to all of them. By considering the product’s context of use and adapting its features accordingly, companies were able to achieve very user-oriented products. Indeed, all products under analysis share common characteristics. These are:

- Usability, as they seek comfort;
- Specificity, as their features are adjusted to the work needs of the end-user;
- Utility, as they address real problems or necessities; and
- Credibility, as they have proven efficiency.

These common value proposition characteristics are in line with the market studies that were analyzed previously in Chapter 2.3. Indeed, companies worried about understanding the specifics of the job to be done and on accomplishing it in ways that significantly solve a particular problem. Hence, the products’ barriers to commercialization and marker success are diminished, since they outstand in performance, are well integrated with the professional routines of the institution, and they are well accepted by the end users.

The strategy to include customers in the value creation process is referred to as value co-creation [58, 59]. By itself, the firm is responsible for designing, developing, manufacturing, delivering, and executing back and front office processes. Nevertheless, before a commercially viable product is created, companies produce test models to be used by customers. This enables the company to explore the potential value they have created, as to attain real commercial value [58].

The fact that companies followed value co-creation methodologies was evident in their initial key activities, which were focused on R&D and product development. Further, value co-creation can be associated to a user oriented product development methodology,
where customers try and evaluate the products. This approach combines human factors and ergonomics engineering with product design [60]. There are essentially three aspects that characterize it [60]:

- One is that the problem has a user/use requirements nature. That is, its starting point is the “use” situation and the construction of the problem leads to the “user requirements”;
- The second is that the user requirements are converted into measurable engineering parameters;
- And finally, the approach makes use of an iterative design process where prototypes are tested by users and then altered by designers.

Ultimately, a user-oriented approach shapes technological solutions in function of end-consumer requirements, instead of product features [60]. In particular, the companies under analysis followed a direct value creation perspective given that throughout the production process companies and customers shared their resources and know-how in an ongoing, reciprocal and organized way [58].

Regardless of the customer segment, enterprises must produce something unique that consumers are willing to buy. By having them working closely in product development, companies are able to produce specifically for them and their needs. Hence, the fact that the analysed companies followed direct value creation methodologies in product development is expected and reveals their concern towards developing products that excel in product/market fit.

5.2 Key activities

As mentioned, the initial key activities of the companies under analysis combined R&D and user-oriented product development. However, another key activity that is imperative to any medical device company is obtaining legal certifications. As medical devices, not only must companies be authorized to develop such products, but also the products in question have to respect particular guidelines and show proved clinical safety and efficiency. Such matter will be continued later in this work.

Key activities change as companies mature. Indeed, all companies admitted to have shifted their focus towards go to market strategies as product development was reaching completion. It is to note, however, that such change is not radical. That is, although focusing more on product or market as they are developing a product or planning market entry, respectively, they perform both activities simultaneously. In fact, abandoning either of them would be disruptive for companies. In what concerns discarding R&D, such would harm companies given the dynamic profile of the technological industry. On the other end,
discarding marketing would have implications in creating awareness, engaging customers and taking advantage of potential market opportunities.

Still, in what concerns key activities, another detail worth mentioning is the relation between key activities and years of existence. Table 5.2 displays the years of activity and portfolio variety of each company.

Table 5.2 - Years of existence and portfolio variety of each company

<table>
<thead>
<tr>
<th>Company</th>
<th>Years since it was founded</th>
<th>Portfolio</th>
<th>Portfolio of WMDs</th>
<th>Years since the product is on the market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company B</td>
<td>9,5</td>
<td>Diversified</td>
<td>More than Product B</td>
<td>4,5</td>
</tr>
<tr>
<td>Company P</td>
<td>8,5</td>
<td>Diversified</td>
<td>Product P</td>
<td>4 (in Portugal)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2,5 (in The Netherlands)</td>
</tr>
<tr>
<td>Company O</td>
<td>4,5</td>
<td>Single product</td>
<td>Product C</td>
<td>0,5</td>
</tr>
<tr>
<td>Company T</td>
<td>4,5</td>
<td>Single product</td>
<td>Product T</td>
<td>1,5</td>
</tr>
</tbody>
</table>

When compared to Companies O and T, the others are approximately twice as old, and present a diversified portfolio. Further, Company B is the only whose portfolio includes more then one WMD, with an available SDK version of Product B.

In the case of Company B, its current key activities no longer focus solely on R&D. The company is divided in two areas: one that is technico-commercial (that deals with both sales and technical support efforts); and other that focus on the development of new products with potential of application in different areas. With this in mind, the company’s current key activities are sales and commercialization of its portfolio, as well as development of new products. The first is only possible after having accomplished a fully functional product, Product B. In turn, the later results not only from having the means to establish themselves as a development company, but also from the need to re-analyse their strategy, expand to new markets, and promote growth. It is therefore noticeable a sequence of proceedings, followed by their co-existence. Indeed, the company focused their efforts on R&D and product development, then on marketing and sales, and finally on the co-existence of the two. Such allowed the company to expand its portfolio once it created its first medical device. That is, this allowed the company to remain stable while studying new products to enter, and develop other markets besides cardiology.

Just like Company B, Company P also sought stability before entering novel markets. The difference was that while the first reached stability with sales from their medical device, the later reached stability before developing Product T. Nevertheless, similarly to Company B, there was an early stage directed towards R&D and product development, followed by efforts of marketing and sales setting, and finally a co-existence of the two, being that in this later phase the previous portfolio was being managed while Product P was under R&D.
In what concerns the younger companies, given that their products are already on the market, the key activities combine both R&D and go to market activities. What is noticeable though is that the later are still being settled. In what concerns Company T, their marketing focus is on customer relationships. On the other hand, Company O’s key marketing activities cover market assessment, marketing channels, and setting up sales channels. The reason why Company T is more focused in one marketing area in particular may be due to the fact that Product T is on the market for a longer period of time and hence, the market assessments Company O is still conducting were already concluded by Company T. Although founded around the same time, the team behind Company T already had experience in sensor development. This accelerated the technological design of the product and eventually can explain why their product is on the market for a longer period of time.

Another thing to point out regarding the younger companies is that the R&D activities are more focused on improving the existing product rather than on creating novel products to conquer new markets. This is understandable considering that the short period of time that the products are on the market for has not given these companies enough stability to proceed to developing new products, as was observed in Companies B and P.

Ultimately, although having different ages of existence, the younger companies are going through the same stages the older companies did in their early years. Assuming their future will be similar in what concerns reaching stability and then focus their R&D activities on creating novel products, a possible sequence of events can be drawn. In particular, if combining the conception of the value propositions with the apparent order of key activities, such sequence could be:

(i) Coming up with an idea;
(ii) Conducting market studies;
(iii) Combine idea with the needs discovered from market studies and conceive a solution;
(iv) Conduct R&D and product development under a user-oriented methodology;
(v) Achieve product market fit (pivot between iii and iv);
(vi) Define market entry strategies and proceed to sales;
(vii) Reach enough stability; and
(viii) Re-analyse BM and refocus marketing and sales to expand to new markets with the original product, and/or refocus R&D to conduct new product development processes.

The described sequence is a generalized one and the specificities of the paths each company follows deeply depend on its goals and resources availability. Further, it was made based on only four WMDs companies. Although being common to all of them, the
reduced number of companies under analysis and the absence of literature studying this matter hamper the validity of the findings.

5.3 Customer segments, relationships, and channels

As expected, the customer relationships and channel strategies are related to the customer segments of each company. In this subchapter each company will be analysed separately and comparisons will be throughout. Table 5.3 sums up information regarding the customers, selling and distribution channels of each company.

Table 5.3 - Most important customers, end consumers, selling, and distribution channels of each company. * And + make the link between the content of selling channels and distribution channels. N and I stand for national and international markets, respectively.

<table>
<thead>
<tr>
<th>Company</th>
<th>Most important customers</th>
<th>End consumers</th>
<th>Selling channels</th>
<th>Distribution channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>Cardiologists (mainly private health institutions)</td>
<td>Cardiologists</td>
<td>Direct contact (N) Distributors (I)</td>
<td>Postal services (N) Distributors (I)</td>
</tr>
<tr>
<td>P</td>
<td>Physiotherapy clinics (Dutch ones are the most important)</td>
<td>Physiotherapists</td>
<td>Distributors (N&amp;I)</td>
<td>Distributors (N&amp;I)</td>
</tr>
<tr>
<td>O</td>
<td>Doctors whose patients suffer from foot sensory loss</td>
<td>Patients Doctors</td>
<td>E-commerce Authorized resellers (selected pediatrin neuropathy centers and wound care centers)</td>
<td>UPS services</td>
</tr>
<tr>
<td>T</td>
<td>Orthopaedic surgeons and implant manufacturers, physiotherapists (in sports and health), and sports organizations.</td>
<td>Physiotherapists, sport researchers.</td>
<td>* E-commerce + Distributors</td>
<td>* Sales force distribution + Distributors (OEMs in health, and local distributors in sports)</td>
</tr>
</tbody>
</table>

- Company B

Once the product was adapted to ambulatory purposes, the customer segments were confined to the cardiology niche. Globally, this is a simple but diverse market. It
includes pediatric, non-pediatric, cardiology of rehabilitation, and physical rehabilitation. Additionally, and in concordance with what was said in Chapter 5.2 regarding the sequence of key activities and the development of novel products, the R&D department was able to downgrade the product to create a value proposition suitable for nutrition, which is potential new market.

It is to note that the company has an international presence, being Brazil its largest market. In this country in particular the main customers are private clinics. This market is characterized not only by a significant number of this type of institutions, but also by patients who prefer them to hospitals.

Company B adopted traditional methods in their customer awareness and engagement strategies. They acknowledged not having sufficient dimension to generate marketing buzz around the brand, and hence their approach to customer acquisition relies much on personal contact and very little on digital marketing strategies.

In what concerns national activities, the company follows direct approaches. It schedules visits to health institutions, and product deliveries are assured by postal services. Contrarily, on international grounds, local distributors assure both activities. That is, while on national ground direct B2C operations are under use, international territory is covered by indirect B2B strategies.

As far as digital marketing strategies are concerned, they are confined to the website (where, although not having an e-commerce platform, information on the product and contacts are provided) and to e-mails (which are send regularly as to keep customers engaged). In spite of trying to pursue social media marketing, Company B realized that the medical community is not one to use such platforms to conduct product searching. Instead, they count on information to get to them by means of conferences or visits.

Nevertheless, the expansion to foreign markets does not imply the obligatory use of distributors. For instance, the company is pursuing a different strategy in what concerns entering the Indian market, where the late westernization of the country led to a recent increase in cardiologic diseases, and created the opportunity the cardiological market. Given the extensive geographical area of the country, Company B preferred to enter it by partnering with a cardiologist, being hence backed by a KOL. By doing so, the company makes use of its influence in the medical industry to promote Product B and increase its hype.

- **Company P**

The customer segments of Company P are physiotherapy clinics. In particular, Dutch clinics are its most important costumers. The decision to expand to the Dutch market was due to one specific strategy, which was the need to find a market that was open to a
product capable of altering the daily routine of professionals. Such market was idealized by P as a small enough market that would allow us to be dominant, a financially free enough market that would allow us to invest, and that, ultimately, contributed to transform the company in a noteworthy entity in a relatively short period of time, and with a substantial amount of investments.

From all potential growth markets, the Dutch one was considered to be the most appropriate. There, physiotherapy education was recognized, local distributors were favorable, and its people are often open to innovation. It is to note, however, that the expansion to the Netherlands was only possible after obtaining venture capital, back in 2013.

Once having found their ideal growth market, the company followed a market development theory called “crossing the chasm”. It recognizes the existence of a significant separation gap, the chasm, between early and late adopters of technological solutions. According to it, companies should align their customer relationship market strategies. Hence, they should firstly focus on consumers willing to experiment new devices, and only then on late adopters who seek for fully functional products [61, 62]. Suitably, Company P manufactured the minimal viable product, that is, the most basic product early adopters could embrace, and only then did it focus on conquering the so-called late consumers.

Currently, Product P is used in more than 50 Dutch clinics, and neighboring countries are slowly starting to embrace it. On the other hand, in Portugal, where Product P was firstly commercialized, no relevant sales are being made. Further, although having a distributor that still performs some demonstrations, from a financial point of view the chain in this country has stopped. Having said that, the importance of selecting a proper entering market is evident is this particular company.

In what concerns customer relationships, these changed as the relation with distributors was being established. For a distributor to accept selling whatever product, the developing company must have a strong value proposition, and show evidences of sales. Accordingly, at first, customer relationships were assured by scheduling visits to clinics and conduction direct sales. Eventually, the company met someone with experience in both physiotherapy education and distribution of medical devices. Given the existence of sales and the proven efficacy of Product P, a distribution partnership was established. Currently, Company P focuses only on indirect channels. Hence, it relies on its distributors network to generate awareness, communicate with customers, and close sales.

- Company T
In what concerns Product T, it can be used for both medical and sports purposes. Just like the other companies, in the early days, customer relationships were based on direct sales, which eventually transformed into more specific marketing strategies. Hence, scheduling visits transformed into attending international trade shows, sending e-mail campaigns to contacts, and making a presence on social media platforms such as Twitter and Facebook. Contrarily to Companies B and P, the most important customers of this company include sports organizations. Considering that this market has a more modern and social mind-set, it is understandable the inclusion of social media on the digital marketing approaches.

The company uses both direct and indirect channels. While the first includes an e-commerce platform, the later refers to distributors. It is to note that distributors vary depending on the type of customer. For the orthopaedic market, the company makes use of OEM partners to grant them access to all the orthopaedic networks throughout the world. Such suggests that in what concerns orthopaedic applications, Product T is sold under white label branding by other companies that already have the outbound logistics of the supply chain figured out, as well as an established market position. On the other hand, for every other customer, distribution is assured by individual distribution partners, which are present in each country Company T operates in.

- **Company O**

Firstly, it is important to clarify why the end consumers of Company O include both patients and doctors. The utilization of the other products is either restricted to health facilities or, in the particular case of Product B, it can be worn daily but only under a doctor’s consent (since it is intended for ECG monitoring on a daily basis). Contrarily to all of them, Product O can reach patients by two ways. Either the physician recommends the acquisition of the product, or patients can buy it themselves and then make the information reach their doctor. Hence, while patients access useful information in a user-friendly manner, doctors can actually use such information for medical purposes.

As a consequence of the dual customer segments, the channels behind the BM follow a two-pronged approach. Yet, it was not always like this. Initially, the company set out to reach customers by applying online marketing focused on sales generation. What they verified was that patients were less inclined to purchase Product O when they did not have a medical recommendation than when they had their doctor’s endorsement. On the other hand, if the company relied only on the medical community as a distribution channel, they would be missing on a large number of the patients that do not have access to the company’s authorized resellers. Accordingly, although the patient being always the end user, there are two methods by which they can acquire Product O. Either directly via the e-
commerce platform, or indirectly by reaching out to their clinicians and respective authorized resellers. In turn, UPS assures product delivery from the manufacturing facility (which is done in-house) to the buyer.

In order to sustain their customer relationships, Company O invested in both offline and online marketing. While the first makes use of KOL engagement strategies and appearance on tradeshows and conferences, the latter is supported by strong social media presence. Such is expected given that by doing so, the company is able to appeal to both end-buyers.

Ultimately, all companies understood the buying cycle of its consumers as well as the limitations of their markets before establishing whatever strategies to create brand awareness and promote customer acquisition. Further, the fact that Product O could appeal to two types of buyers forced the company to establish buying channels suitable to both cycles.

Considering Companies B and P, while direct approaches are used in national markets, on foreign ones they follow B2B strategies and rely on distributors to assure customer relationships. Further, Company T also depends greatly on their distributors network to assure both national and international relations.

Accordingly, in what respects customer relationships and channels, it is important to have a deep understanding of the segment’s archetype, as well as good distribution partnerships. Once again, such findings are in agreement with the conclusions of the market studies presented in Chapter 2.3. These concluded on the fact that as patients are getting more familiar with technology, health institutions can begin to offer more complex services. Such has a direct impact on the openness of buyers and consumers towards the product, reason why working close to them as to explore their professional and buying cycles is important. Also, those studies mentioned that a strategic common ground in healthcare innovation BMs was taking advantage of established assets, which are, in this case, distributors and their network of contacts.

5.4 **Key partners**

The process of choosing partners to aid the development of a certain product is an arduous task. Indeed companies have to consider their necessities without discarding the optimization of the value chain.

The companies under analysis mentioned key partnerships to be established with suppliers of parts to be included in the final product, assembling and distribution partners, KOL, and OEMs. Contrarily to Company T, which does not conduct outsourcing activities, all
other companies do. In the particular case of Companies B and T, not only are all the parts of the final product outsourced, but also the assembling is made by elsewhere. Table 5.4 specifies each company’s key partnerships and outsourcing activities.

Table 5.4 - Key partnerships and outsourcing activities conducted by each company. The absence of acquisition or assembling activities in “Outsourcing activities” implies that such are conducted in-house.

<table>
<thead>
<tr>
<th>Company</th>
<th>Key Partners</th>
<th>Outsourcing activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company B</td>
<td>T-shirt supplier</td>
<td>Acquisition and assembling of components</td>
</tr>
<tr>
<td></td>
<td>Electronic components supplier</td>
<td></td>
</tr>
<tr>
<td>Company P</td>
<td>PCBs supplier</td>
<td>Acquisition and assembling of components</td>
</tr>
<tr>
<td></td>
<td>Enclosure supplier</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Assembling partner</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Distributors</td>
<td></td>
</tr>
<tr>
<td>Company O</td>
<td>Key opinion leaders</td>
<td>Acquisition of components</td>
</tr>
<tr>
<td></td>
<td>Electronic components supplier</td>
<td></td>
</tr>
<tr>
<td>Company T</td>
<td>Orthopaedic OEMs</td>
<td>No outsourcing activities</td>
</tr>
<tr>
<td></td>
<td>Distributors</td>
<td></td>
</tr>
</tbody>
</table>

Some companies depend solely on their capabilities and knowledge to develop products. That is, they use internal technology to produce, market, and sell the product all by themselves [63, 64]. Nevertheless, this requires great financial and organizational efforts, which young companies such as start-ups or even SMEs do not possess. In order to produce, these companies end up partnering with others capable of providing them with the missing resources. Accordingly, as B, P, O, and T are young companies, the mentioned key partnerships were expected. The development of their products was indeed based on the skills of the founding team, but with the help of external companies to provide them with resources and manufacturing activities. Such type of partnership constitutes open innovation methodologies.

Open innovation assumes that companies should combine internal and external ideas and go to market strategies in order to achieve technological advances [63]. That is, it considers R&D to be an open system where establishing partnerships potentiates beneficial BM alternatives such as reducing R&D costs, expand innovation potential and open new markets [63, 64]. In particular, Chesbrough [63] claims open innovation is...

...the use of purposive inflows and outflows of knowledge to accelerate internal innovation, and expand the markets for external use of innovation, respectively.

Risks and barriers associated to open innovation activities have been identified in a study that focused on both SMEs and large European companies [65]. The most frequent risks, which result from more complex businesses, were loss of knowledge, higher coordination costs, and loss of control. In turn, the barriers focused mainly on difficulty of
finding the right partner, unbalance between open innovation and daily business, and insufficient resources for open innovation activities. Also, most times stakeholders dismiss the importance of value appropriation because of the increased focus towards innovation, reason why appropriation mechanisms must be included in the BM [63, 65].

While investing solely on open innovation can induce lost of competences, closed innovation fails to satisfy the modern demand for increased innovation speed and reduced go to market periods [65]. A balanced combination of the two enables companies to use both internal and external resources to produce faster than competitors while preserving competences and IP. Ultimately, it aids companies conquering two areas, which are particularly important in the technology market: (1) developing innovative products; and (2) commercializing them in concordance to the market needs [66]. This co-existence of closed and open innovation was indeed visible in the companies being studied. As mentioned, the founding team is behind the technological concept of the product, and, inclusively, companies worry about value appropriation and copying risks. At the same time, acknowledging that the costs and time of conducting in-house manufacturing do not pay-off, they rely on their partners to aid them in such operations.

5.4.1 OUTSOURCING, SUPPLIERS AND DISTRIBUTORS

The decision to outsource is based on cost reduction measures (backed by the transaction cost theory) and general strategic value dimensions [67]. The transaction cost theory balances the costs of in-house manufacturing (covering transaction, contracting, coordination, and search costs) versus the costs of buying goods or services to other companies [67, 68].

With that being said, it is understandable the absence of outsourcing strategies in the operations of Company T. As mentioned before, prior to developing sensors for medical purposes, T and his team worked with sensors applied to smartphones and videogames. Thus, because they already had such technological knowledge, it is likely that the transaction costs theory did not apply to this particular case. Accordingly, in house manufacturing would be financially more beneficial than outsourcing.

As expected, companies that outsource named suppliers as one of their key partners. Indeed, they depend on them to manufacturer specific parts, crucial to the final product. Table 5.5 displays the strategic reasons behind suppliers’ choice. As far as decisions over distribution partners, the reasons were common to all companies and are also showcased in Table 5.5.

In what concerns choosing suppliers, it is to note that the first factor only applies to Company B. The final weight of the other factors as to do with performance goals each company wants to achieve, as well as what is strategically more convenient to them. For
instance, although ideally suppliers would be located nationally, Company P ended up having to reach out to foreign ones given the limitations and production costs associated to national producers. Hence, strategic decisions behind the choice of suppliers force companies to deliberate and prioritize parameters as quality, delivery, price, service, easiness of communication, process improvement, and supply chain management [69].

On the other hand, the strategies behind distributors choice were common to all companies. Ideally speaking, a combination of the three reasons displayed in Table 5.5 comprises beneficial circumstances to the company by increasing product disclosure and potentiating better market positioning facing competitors. Consequently, distribution partners are also used in raising customer awareness, assuring product delivery, and providing post customer support. Given the benefits distributors can bring to companies, choosing them was mentioned to be a challenge. Overall, companies considered the following issues when choosing the right distribution partners:

- Is it someone who sells medical devices? If so, will it sell competitor products?
- Is it someone who knows how to deal with the medical community?
- Is it able to provide technical support and trainings since the product in question is a technological one?

Table 5.5 - Mentioned reasons for choosing suppliers and distributors

<table>
<thead>
<tr>
<th>Strategic reasons for choosing suppliers</th>
<th>Strategic reasons for choosing distributors</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) Their presence from the beginning and consequent emotional bond;</td>
<td>i) Network of contacts;</td>
</tr>
<tr>
<td>ii) Shared determination to innovate;</td>
<td>ii) Local market reach;</td>
</tr>
<tr>
<td>iii) Supplier status (being certified producers of electronic components</td>
<td>iii) Current product set.</td>
</tr>
<tr>
<td>facilitates bureaucratic matters as companies do not have to conduct audits);</td>
<td></td>
</tr>
<tr>
<td>iv) Financial strategies (which is in line with what was aforementioned</td>
<td></td>
</tr>
<tr>
<td>regarding the transaction cost theory);</td>
<td></td>
</tr>
<tr>
<td>v) Geographic location and proximity control (it facilitates communications</td>
<td></td>
</tr>
<tr>
<td>and reduces costs given that both company and supplier are located in nearby</td>
<td></td>
</tr>
<tr>
<td>geographical areas); and</td>
<td></td>
</tr>
<tr>
<td>vi) Quality/price ratio</td>
<td></td>
</tr>
</tbody>
</table>

5.4.2 **Key Opinion Leaders**

Another type of key partner to be identified was KOLs. They are people whose status and credibility in a given industry influence the opinions and behaviours of an audience who is highly interested in what they have to say [70].

Given their inherent credibility, KOLs are seen as a method to validate a certain value proposition and minimize initial sales barriers customers may have. Hence, the
commercial benefits of such engagement strategy are: (1) the establishment of a trustworthy channel of communication with potential customers; (2) the capacity to influence demand; and (3) expanding communication by promoting word-of-mouth marketing [70, 71]. Nevertheless, in spite of not being to possible to describe with clarity the effectiveness of KOL, is it thought that their active presence in the marketing strategy of a company can persuade healthcare providers to alter their routine procedures when dealing with patients [72].

Furthermore, although not being mentioned as key partners, the expansion to the Indian market by Company B is also being made via a KOL instead of distributors. The main reasons for such decision is the fact that, as India is a big country, the company believed that following a brand recognition strategy would be better than to rely on one distributor, which would most likely focus on a single geographic area. Appropriately, the company partnered with a local doctor who, after having conducted tests with Product B, is going to share the results with its cardiology peers in conferences.

With that in mind, regardless of the market context (national or foreign), companies seemed to reach out to KOLs to authenticate and endorse the brand as a strategy to attract early customers and encourage initial sales.

5.4.3 ORIGINAL EQUIPMENT MANUFACTURERS

Finally, orthopaedic OEMs are a key partner of Company T. OEMs are entities that sell new and remanufactured versions of other companies’ products [73]. In this particular case, Product T seems to be sold as a white-labelled product to orthopaedic OEMs partners, who then sell it to the final customers.

Such strategy is beneficial to both parties of the partnership. By outsourcing materials, OEMs are able to reduce the production costs and focus their activities on product design and marketing [74]. Consequently, portfolio expansion and entering new markets become more accessible processes [74, 75]. Not only that, OEMs interest in suppliers is also motivated by the desire of improving product quality, generating new ideas, and finding solutions to technical design problems [76]. On the other hand, supplier companies, like Company T, can focus mainly on product development and excelling their technological skills given that distribution, shelf-space, and sales are assured by OEMs.

The establishment of strategic partnerships with those capable of providing the most appealing services was expected. This is also in agreement with existing market studies. Indeed, the studies reviewed in Chapter 2.3 mention taking advantage of external
As a common strategy to reduce operating costs and facilitate supply chain operations. Also, the absence of appropriation mechanisms capable of assuring a return in investments, which is a risk of undergoing open innovation activities, was mentioned in such studies as a potential barrier to technological progress.

As far as the issues considered by companies when choosing the right partners, although being directed towards distributors that operate in the healthcare industry, they are transversal to any company. Further, the concern over staff education is a common necessity in healthcare business models, as it was shown in the market study discussed in Chapter 3.2.2.

5.5 KEY RESOURCES, COST STRUCTURE AND REVENUE STREAMS

Resources wise, all companies mentioned their workers to be crucial for the company. Indeed, besides the daily operations of the company, employees are who retain the necessary know-how to conduct R&D, marketing, and early-sales activities. In fact, motivated and skilled workers are known to be a crucial element to any start-up or young company that aspires growth and success [77]. Hence, such result was expected since all companies are either start-ups or SMEs, whose activities are focused on R&D or marketing and sales.

Additionally, intellectual resources were also mentioned as key resources. Regardless of the type of industry, intellectual resources reinforce a company's value [78]. In particular, all companies mentioned holding IP rights. Patents are [79]...

... intellectual property rights that grant a temporary monopoly to commercialize an invention that would otherwise be free for others to use...

[They] defend a spot in technology space around the patented invention.

Further, the patent portfolio can be used as an indicator of the technological and inventive value of a company [79].

The companies under analysis mentioned different reasons for having submitted patents. Nevertheless, the advantages of owning IP rights are transversal. Overall, the presented strategic motifs were:

i) Protection measures;
ii) It provides higher financial attractiveness when looking for investments; and
iii) It potentiates an easier and better international trade.

The fact that these were the main reasons stated by companies was somewhat expected. All companies dedicate some of their efforts to R&D, and, by submitting patents, their freedom to conduct such activities is safeguarded by legal defensive blocking [78, 79].
Additionally, start-ups with patented software collect more venture capital investments and demonstrate better performances [80]. Particularly, this later situation occurred to Company P.

Besides IP, there are other legal obligations a developer of medical devices must obey. A company can only commercialize its products as being medical devices if these obey specific safety, performance, and quality parameters [81]. It is to note, however, that certification guidelines differ between and even within geographic regions. Accordingly, for a company to have presence in any country, the respective local authorities must clear its product specifications. Also, since these companies conduct R&D activities, they are required to incorporate standards in their managing systems. Many are issued by ISO, and the one associated to the development of medical devices is ISO13485 [81, 82]. The companies under analysis mentioned that the credibility inherent to possessing a “medical device certification” increased early sales. The intangible assets owned by each company are displayed in Table 5.6.

Table 5.6 - Intangible assets owned by each company

<table>
<thead>
<tr>
<th>Company</th>
<th>IP</th>
<th>Other intangible assets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company B</td>
<td>1 granted patent</td>
<td>CE mark, and ANVISA and ANATEL (both Brazilian certifications)</td>
</tr>
<tr>
<td></td>
<td>Trademark</td>
<td></td>
</tr>
<tr>
<td>Company P</td>
<td>1 granted patent</td>
<td>CE mark</td>
</tr>
<tr>
<td></td>
<td>1 pending patent</td>
<td></td>
</tr>
<tr>
<td>Company O</td>
<td>2 patents</td>
<td>FDA, CE mark, and Health Canada approvals</td>
</tr>
<tr>
<td></td>
<td>On-going PCT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Trademark</td>
<td></td>
</tr>
<tr>
<td>Company T</td>
<td>3 granted hardware patents</td>
<td>CE mark. Obtaining FDA and Asian certifications is an on-going process.</td>
</tr>
<tr>
<td></td>
<td>1 pending software patent</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Trademarks &amp; copyright</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Trade secrets</td>
<td></td>
</tr>
</tbody>
</table>

The intangible assets mirror the market occupation of each company. The fact that Company B runs operations since 2006 and does not own FDA certifications shows that it does not plan to enter the American market. B stated that such market is very close-minded towards foreign products, and typically it prefers to invest in national companies. As far as Company P is concerned, currently its efforts are more centred in increasing the number of European customers as well as on improving Product P. For such reason, the company has yet to acquire international certifications. Finally, although being on the market for shorter periods of time, the fact that Companies O and T either have or are on the process of having, respectively, international certifications indicates their plans of market expansion.
Additionally to human and intellectual, Company O further mentioned marketing and business development related resources. Such can be related to the fact that Product O is on the market for the least amount of time, and hence its go to marker strategy is still under adjustment. In fact, such is in line with the company’s key activities, which are focused on market assessment and setting up sales channels.

In what concerns the cost structure, the most important costs mentioned by each company are displayed in Table 5.7.

<table>
<thead>
<tr>
<th>Company</th>
<th>Most important costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company B</td>
<td>Human resources</td>
</tr>
<tr>
<td></td>
<td>Production costs</td>
</tr>
<tr>
<td>Company P</td>
<td>Human resources</td>
</tr>
<tr>
<td></td>
<td>Marketing</td>
</tr>
<tr>
<td>Company O</td>
<td>Material acquisition</td>
</tr>
<tr>
<td></td>
<td>Customer engagement</td>
</tr>
<tr>
<td>Company T</td>
<td>Marketing engagement</td>
</tr>
</tbody>
</table>

Generally, the most important costs can be related to the activities and resources mentioned to be crucial for each company. Nevertheless, it was not possible to specify whether the cost structure of each company was more cost or value driven. Either the interviewees were not familiar with the concepts in question and the provided answers were inexplicit, or given that some companies conduct activities that focus on cost and value simultaneously, it is difficult to label the respective cost structure.

Nevertheless, it was possible to determine that some companies made use of external incomes to support the R&D costs associated to the respective medical devices. Table 5.8 summarizes the profits originated by the products themselves, as well as other crucial sources of income.

<table>
<thead>
<tr>
<th>Company</th>
<th>Product related profits</th>
<th>Other important incomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company B</td>
<td>Product sales</td>
<td>Private investments</td>
</tr>
<tr>
<td>Company P</td>
<td>Product sales</td>
<td>Strategic alignment with revenue generated from one other product</td>
</tr>
<tr>
<td>Company O</td>
<td>Product sales</td>
<td>Non diluting sources of revenue (government funds)</td>
</tr>
<tr>
<td>Company T</td>
<td>Product sales</td>
<td>-</td>
</tr>
</tbody>
</table>
Ultimately, by themselves, the products in question only contribute to profits by asset sales. Notwithstanding, because developing WMD is a costly process, companies can most times profit from other sources or activities that contribute to the product. For instance, the commercialization of the toolkit (mentioned in Chapter 4.2) by Company P has allowed them not only to refresh the look of the company, but also to collect money that could be used in R&D activities related to Product P. Also, Company O made use of government grants to finance the development of their product. The fact that no alternative incomes were identified for Company T has to due with the local government not being very supportive and also to the fact that this company owns a single product portfolio. Accordingly, no strategic alignment of revenues could be made.

Although the information regarding the “key resources” and “cost structure” is in line with the structure of each company and the respective BM, no particular answers were expected. Such is due to the fact that no information linking this building block and WMDs was found in literature.

Finally, the market study reviewed in Chapter 2.3.2 suggests that creating “novel” revenue streams is common among healthcare innovation business models. However, when asked about revenue streams and sources of income, companies did not mention any particular type of strategy other than product sales, external investments and a possible strategic alignment with the revenues generated by other products. The absence of novelty may be due to the fact that the market study focused on innovations other than WMDs, which required more inventive revenue streams. Also, the concept of “novel” is not well explained in it. Nonetheless, the strategies mentioned by the companies assure value appropriation and profit, which are concerns specified by the study.

5.6 Positioning towards competitors

Overall, when asked about competitors, companies mentioned to have both direct and indirect ones. Regardless, all companies said to track existing and potential players. Table 5.9 showcases the strategic positioning of each company towards competitors.

In the particular case of direct competitors, Company B is the only who has been confronted with the commercialization of a product with very similar characteristics. Nevertheless, the company’s strategy is to go to market with competitive prices, which has made it preferable compared to competitors. Further, Companies B, P and T acknowledge the existence of innovative products capable of becoming direct competitors. Nonetheless, by comparison, these are seen as having lower performances and limited medical applicability. As such, the three companies rely on the increased value of their product to prevail over other products. On the other hand, Company O does not yet recognize the
existence of a product similar to theirs. Notwithstanding, the company still relies on the uniqueness and increased value of their product to succeed in the events of similar products entering the market.

Table 5.9 - Positioning of companies towards competitors

<table>
<thead>
<tr>
<th>Company</th>
<th>Positioning towards competitors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company B</td>
<td>Competitive prices&lt;br&gt;Uniqueness and increased value of Product B&lt;br&gt;Availability for working together</td>
</tr>
<tr>
<td>Company P</td>
<td>Uniqueness and increased value of Product P&lt;br&gt;Proved clinical evidences</td>
</tr>
<tr>
<td>Company O</td>
<td>Uniqueness and increased value of Product O&lt;br&gt;Open lines of communication and friendly approach&lt;br&gt;Availability for working together</td>
</tr>
<tr>
<td>Company T</td>
<td>Uniqueness and increased value Product T</td>
</tr>
</tbody>
</table>

In line with what was said, when competing against the traditional methodologies at use, companies rely on the same factors as before. In particular, Company P highlighted the importance of showcasing their value by conducting clinical trials aiming for attaining reimbursement. Such is relevant in the spectrum of insurance companies and their active role in the clinic’s decision-making process. Until now, insurance companies paid in function of the duration of treatment. However, they are starting to finance the institution with a limited budget with which the clinic has to demonstrate good treatment results. Such strategy increases the responsibility of the clinic to efficiently treat their patients and motivates their interest for more cost-effective treatment options. Ultimately, Company P believes that efficient and effective solutions will be prioritized over traditional or innovative products that lack clinical evidences. By doing so, in addition to evidence-based clinical information, Product P would also be backed by market evidences, which would increase the attractiveness by Product T when compared to potential competitors.

It is to note, however, that the main activities of Company P are in the Dutch market and that no other company mentioned the relation insurance companies/health institutions as relevant for competing against other methodologies. In that sense, no solid conclusion can be withdrawn in what concerns young companies using reimbursement as a common strategy for dealing with competitors, market entry, or any other operation.

Finally, Companies B and O were the only ones to mention openness towards potential competitors as a strategy to fight them, even if means two potential competitor companies combining forces to compete against a common player. The interest in establishing partnerships with competitors aiming to develop innovative products is in line with the open innovation approach mentioned in Chapter 5.4.
Notwithstanding, it is to note that the choice of partnering with competitors in R&D and product development activities does not seem to be associated to a particular type of company. Both Company B and O revealed openness to follow such strategy if the outcome seemed financially attractive and yet, they are opposites of one another. While Company B is the oldest company under analysis, their R&D department corresponds to more than 50% of their activities, and they have international sales, Company O is not only the youngest, but also its sales are still restricted to North America. Also, Company T, which is about the same age as Company O, did not mention the approach under discussion when asked about this matter.

5.7 Challenges

Overall, the challenges mentioned by the companies under analysis were the following:

- Acknowledging that external insight is valuable to the development of the product;
- Achieving exceptional product/market fit;
- Implementation challenges;
- The benefits of preventive care are still overlooked;
- Also, proving the preventive capability of a product is a difficult task given the complication that is evidencing that something did not occur because a certain product was used in favour of some other methodology;
- Acquiring unquestionable clinical evidences;
- Supplier identification;
- Identifying viable market expansion opportunities;
- Identifying distributors;
- Reimbursement strategies

The implementation challenges reflect on several aspects. Not only must companies and the health institutions educate the medical staff, which has associated costs, but also the medical community itself is most times reluctant to adopt new methodologies in their routine. In the particular case of the 4 products under analysis, all of them were well accepted by the medical community. However, such only occurred when these had proved clinical evidences and when doctors themselves approved the user interface. That is, the products were well accepted given its usefulness towards a specific problem, its trustworthy performance, easiness to operate, and delivery of results in user oriented formats.

Besides reimbursement, gathering unquestionable clinical evidences, and implementation, the other mentioned challenges seem to be transversal to other
industries. Indeed, identifying suppliers, distributors and expansion opportunities is always a risk that needs to be looked at carefully.

5.8 Game changing factors

By game changing factors for the company it is intended to understand if there were any particular actions that changed the course of the company for the better. With that in mind, presented in Table 5.10 are the game changing factors mentioned by each of the analysed companies.

<table>
<thead>
<tr>
<th>Company</th>
<th>Game changing factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company B</td>
<td>Not being close minded in regards of adapting the product to the actual needs of the market</td>
</tr>
<tr>
<td></td>
<td>Refocusing their efforts towards product development</td>
</tr>
<tr>
<td>Company P</td>
<td>Entering the Dutch market (which was only possible after receiving venture capital funding)</td>
</tr>
<tr>
<td>Company O</td>
<td>They believe receiving reimbursement could be game changing in the future.</td>
</tr>
<tr>
<td>Company T</td>
<td>Previous experience with high performance sensors</td>
</tr>
<tr>
<td></td>
<td>Develop specific software for specific markets</td>
</tr>
</tbody>
</table>

In what concerns Company B, being open to the market’s needs allowed them to identify a real need and hence develop a product capable of satisfying a demand in the cardiology market. Further, by refocusing their efforts towards product development, they were able to increase their potential for developing novel products and hence potentially entry markets besides cardiology.

Secondly, entering the Dutch market allowed Company P not only to expand to international grounds, but also to grow given the acceptance of the product by the local medical community. Also, acquiring such market validation is beneficial to attaining reimbursement given that it supports the proven efficiency of the product, obtained through clinical trials.

Regarding Company O, because it is still a young company, it did not point out specific strategies. Nevertheless, given the usefulness of Product O in the prevention of diabetic related complications, they believe they will reach reimbursement, which will then be game changing for the company.

Finally, just like Company B, Company T claimed that the development of highly specific products was been game changing for the company. Also, having technological experience eased the R&D practices, which in turn accelerated the product development process.
As mentioned, it took Company C many years to recognise the importance of developing technology as function of the market needs and problems. Accordingly, before re-adjusting its strategy, Company C encountered different difficulties.

In spite of receiving positive feedback, such was biased by the technological boom that was being lived at the time. So, in spite of being technologically interesting, the market opportunity of some projects was insignificant. Besides, and still in line with the great technological growth experienced at the time, there were others trying to do similar things that went to market first.

Although having to change their BM, Company C managed to keep the contacts that were established throughout its existence. Hence, by the time they accomplished a prototype interesting enough to make it into mass production, it was with those initial contacts that the company attracted its first customers. Currently, because they work with big name brands, they have a status that reinforces their credibility and, by itself, creates awareness for the brand. Since then, Company C has been highly focused on a very specific model of operations, which values, most importantly, the capability of volume manufacturing. That is, the capability of mass-producing their components. Thus, their whole business model is structured around it.

Concerning the nature of customer relationships, besides the attractiveness of its status, Company C limits its strategy by conducting customer relationship management. This methodology focuses on targeting high-interest customers with the purpose of building strong and lasting relationships that maximize customer value, profitability and shareholder value [83, 84]. Furthermore, customer relationship management is based on three considerations. First, this approach relates to achieving specific technological solutions; second, that these solutions are highly customer oriented; and third, that it contributes to growing shareholder value [83]. Accordingly, in what concerns finding potential customers, Company C has an internal function, market intelligence, responsible for finding, quote, “certain people in good companies”, with whom they can meet face-to-face. Besides, the company also attends conferences and trade-shows where they meet with people directly.

In agreement with what was mentioned, customers are one of the two key partners of the company. When starting a partnership with a customer, the company focuses on creating a truly valuable and custom made solution. Hence, their vast network of suppliers composes the second key partner. These provide them with the best software, electric components, or whatever is necessary to fulfil whatever requirements customers asked for.

Accordingly, and still in line with the need for volume operations, the company focuses on product development and manufacturing. In turn, its key resources are the workers who sustain these activities. Given the evolution Company C went through since the early days until its present stability, the workers have acquired a great deal of know-
how and understanding of the market, as well as of the manufactured products. In fact, the value of the company is not on its machines, but on how they are particularity set up for the production levels that are required, knowledge that resides on the workers.

Concerning the revenue streams, these come from the mass production operations. In spite of charging customers for internal costs, labour and material, that is not what generates profit. In consonance with the consumer relationship management approach, Company C restricts their choice of projects to those they are sure can make it into mass production, so that profit is assured. Further, although the prices being the same for sports related customers, those in the medical segment are more variable.

Following what was said, the business behind Company C is evidently value driven, given their concern of manufacturing highly customizable and high performance products. Finally, regarding its positioning on the supply chain, Company O does not require neither a retail store nor distribution channels. Thus, they direct sell their products to customers.

As far as IP is concerned, Company C owns some patents. However, it is generally more convenient for them to license the rights from those who own it. Hence, the company has a strong understanding of the IP sector, which allows them to envision what can and cannot be done with a certain technology. Such allows them to better plan the product development of a given project.

5.9.1 POSITIONING TOWARDS COMPETITORS AND CHALLENGES

Concerning competitors, in spite of acknowledging little competition from smaller vendors, because their activity is restricted to specific matters, Company C does not feel threatened by them. Overall, they view competitors as potential partners with whom they can do business with.

Company C characterizes its market as very young, and with great growth prospects. In the particular case of wearable medical devices, although forecasting big growths (as did the other companies), C highlighted the need to adapt to market changes. Notwithstanding, they rely on their many years of experience and know-how to outperform competitors and prevail over them.

The current difficulty of Company C is the ability to scale up manufacturing to the point where they can actually meet up with demand. Although being possible to do so, the required effort to educate new employees is a slow process, which delays the desired progression and could harm the current flow of operations.

5.9.2 GAME CHANGING FACTORS
Two game changing actions or strategies were identified by C. The first was the realization that the value proposition had to change in order to develop products more commercially appealing. The second had to do with the work environment of the company. Those in charge strive for maintaining a positive environment where the workers have all the tools they need to perform better.

5.10 ALIGNMENT BETWEEN DIFFERENT COMPANIES

Before proceeding to analyse the possible alignment between Company C and the other 4 companies, it is important to recall where they position themselves in the supply chain. Also, this section is helpful since it schematizes what has been described regarding each company.

5.10.1 SUPPLY CHAIN

In the current global marketplace, companies do not conduct their operations in an independent way, but rather interconnect them with the operations of other firms [85, 86]. That is, different companies coordinate their business relationships and obligations as to form a functioning supply chain [85]. As defined by The International Center for Competitive Excellence [87]...

... supply chain management is the integration of business processes from end user through original suppliers that provide products, services, and information that add value for customers.

A schematic view of typical supply chain process is displayed in Figure 5.1. The flows of information and goods enable suppliers, manufacturers, distributors, third-party logistics providers, and retailers to coordinate their individual activities to accomplish a common goal, that is increased operational efficiency, value creation, profitability, and competitive positioning. Ultimately, the supply chain allows:
- The acquisition of raw materials;
- The transformation of such materials into finished products;
- Increasing the value of such products;
- Their distribution and promotion to either retailers or customers; and
- Facilitation of information exchange between the different parties involved in the supply chain.

![Supply Chain Process Diagram](image)

**Figure 5.1 - The supply chain process. Source: Min, 2002 [85].**

The supply chain operations are based on two business processes: material management and physical distribution, which comprise inbound and outbound logistics, respectively [85]. While the first concerns the complete cycle of material flow, the second is related to customer service activities. Further, given that manufacturers have to produce in concordance with demand, they are the link between both sides of the chain. The specific operations of each process [88] are discriminated in Table 5.11.

**Table 5.11 - Activities conducted in each business process of the supply chain**

<table>
<thead>
<tr>
<th>Material management</th>
<th>Physical distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase and internal control of production materials</td>
<td>Order receipt and processing</td>
</tr>
<tr>
<td>Planning and control of work-in-process</td>
<td>Inventory deployment</td>
</tr>
<tr>
<td>Warehousing</td>
<td>Storage and handling</td>
</tr>
<tr>
<td>Shipping</td>
<td>Outbound transportation</td>
</tr>
<tr>
<td>Distribution of finished products</td>
<td>Consolidation</td>
</tr>
<tr>
<td></td>
<td>Pricing</td>
</tr>
<tr>
<td></td>
<td>Promotional support</td>
</tr>
<tr>
<td></td>
<td>Returned product handling</td>
</tr>
<tr>
<td></td>
<td>Life-cycle support</td>
</tr>
</tbody>
</table>

Establishing a fully functional supply chain is a complex process that involves a thorough selection of partners. Given that over including partners in the chain increases the complexity of both information and goods flow from tier to tier, it is important to identify those who truly contribute to value creation. Such eases the flow of information and goods and managing the rest of the supply chain becomes simpler [85].

**5.10.2 Alignment between Company C and the other companies**
Company C is a manufacturer of electronic components, for both sports and medical applications. It supports its manufacturing activities on suppliers of electronic parts, as well as on partners from who they can license technology. The company focuses on the mass-production of its products, which are then directly shipped to their clients, being the later responsible for the outbound logistics of the supply chain. Accordingly, in comparison to the supply chain illustrated before in Figure 7.1, Company C stands as a manufacturer, being that distributors and retailers are absent of the chain given the direct relation with customers. Figure 5.2 illustrates the supply chain of the company in question.

![Figure 5.2 - Scheme of the supply chain of Company C. Adapted from Min, 2002 [85].](image)

As far as Companies O and T are concerned, these can also be considered manufacturers given the in-house assembling of the final products. Nevertheless, they differ between them. While Company O depends on suppliers to provide them with product parts, Company T affects everything in-house. Other than that, the activities of both companies cover the delivery of products to the final customers, either by distributors or by direct channels such as e-commerce platforms. Hence, the supply chain includes not only the inbound, but also the outbound logistics activities. It is to note, however, that Company T also sells via OEMs. In this particular case, this partner assures the outbound logistics. Also, the OEMs are responsible for making the product reach the final customers. Figures 5.3 and 5.4 illustrate the supply chain of Company O and T, respectively.

![Figure 5.3 - Scheme of the supply chain of Company O. Adapted from Min, 2002 [85].](image)
Finally, both Companies B and P differ from Companies O and T on mainly one level. This is the fact that they both outsource the manufacturing of the final product. Hence, not only do they depend on suppliers of parts, but also on manufacturers. The product development activities conducted by both companies focus, hence, on R&D, product testing, and management of the information flow between the different components of the chain. Although having this in common, both companies differ on the fact that, besides resorting to distributors, Company B also approaches customers in a direct way. The supply chains of Company B and P are displayed on Figures 5.5 and 5.6, respectively.

Considering the present state of each company, conjecturing on establishing possible relations between them and Company C is senseless. Indeed, the fact that the four
companies are either start-ups or SMEs implies that they do not fulfill Company’s C requirements of volume production.

Nevertheless, hypothesising on the success of the four companies to a point where they reach mass production allows for some discussion. Assuming such growth, the fact that Company C has very restricted policies in what concerns new customers hampers the management of the supply chain by the growing company.

The analysis of Company C allows a better understanding on how a manufacturer of WMDs components positions itself in the supply chain of those who commercialize these technologies. They structure their BM as function of their capacity of volume production and the subsistence of the business depends on customers with a great volume of orders. Such is expected given that only by closing such deals is the company able to reimburse the investment made in machinery and other equipments.

Reconsidering the small growing companies who outsource components to companies like C, the scenario is different. The partnerships established with their current suppliers create a certain dependency that hampers the search for new suppliers. Indeed, the current ones already know the company, its products and the way it is organized. Therefore, the entire supply chain works as function of those suppliers. In the event of the company growing to a point where mass production services are required to satisfy demand, conducting searches for new suppliers is a complex process. New contracts with different suppliers would imply the restructuration of the supply chain. Further, doing so entails great investments and a strong organizational structure that small companies may not have. With that being said, that is a possibility of the growing companies remaining dependent on the current suppliers, because although necessary, not changing may be more viable than embarking on suppliers search.

Not only that, but the existence of suppliers with rigorous selection criteria further hampers the growing companies, given that their search spectrum becomes inevitably more limited. Thus, on a long term, the possibility of growing companies approaching others like Company C in the hopes of establishing newer, more suitable partnerships may be blocked.

Ultimately, the alignment between supplies and developers stands as a process where the two parts play determinant roles. From the growing company’s perspective, it is too dependent on the current suppliers. Further, such scenario will only change in a situation where the investment has guaranteed returns. On the other hand, from the perspective of the supplier company, unless the growing company becomes attractive under its parameters, it is likely that no interest is shown and that possible partnerships are overlooked.

5.11 Expectations for the Industry of WMD
All four WMDs companies share the same expectations for the industry of wearable medical devices. They expect to see an explosion of wearable technologies for a myriad of different health conditions. Further, considering the hot market that are wearable consumer electronic technologies (such as fitness bracelets and other fitness oriented devices) it is also acknowledged the possible rise of a new trend that is companies choosing to be authorized as consumer electronics instead of medical devices. Accordingly, the next step would be taking consumer electronics technologies and shift their value proposition as to start to impact both quality and quantity of life. By rejecting obtaining legal approvals, companies would be able to operate in a medical device capacity, without the restrictions, expenses, and legal complications of being labelled as one.

Finally, the necessity for a paradigm shift towards preventive technologies it was also recognized. The market is seen as more reactionary rather than proactive in addressing many health problems. As so, it still does not realize the advantages that such shift could induce in the healthcare system from both cost and patient perspectives.

The perspective of Company C is in line with the expectations of the WMDs companies. The company also forecasts an overlap between the medical and the sports segments as the origin of a new, broader segment called wellness. Further, Company C envisions the new archetype as people who have interest in measuring their bodies, and not as doctors who are highly interested in monitoring their patients. As such, they believe there will be a reduced need for developing serious products with medical device certifications, and a higher demand for textile products with a consumer electronics connotation.

Having said that, of all companies, Company O seems to be one whose path is more directed towards changing the ways via which people can access medical devices. Although Product O is classified as a medical device and not as consumer electronics, it can be acquired by people who are interested in tracking their foot pressure data, without advice from their doctor. The two-pronged approach at use suggests that the company has, intentionally or not, begun to follow the paradigm shift that it is believed to be the future of the industry.
6. CONCLUSIONS AND FUTURE IMPROVEMENTS

This work proposed to explore the BMs behind the commercialization of WMDs, an area that has outstanding growth prospects, but whose commercial background lacks exploration. Appropriately, it was intended to acquire objective and reliable information regarding this particular area of wearable products. Ultimately, not only was that possible, but information regarding challenges and expectations for the industry was also retrieved.

In what concerns the BM itself, the following where the most relevant findings:

- All companies followed user-oriented methodologies in the product development phase, which include a close work with both the medical community and the end-user;

- Much of the commercial success of the products in question had to do with excellent product/market fit in what concerns user experience and product content (both hardware and software), as well as on knowing how to approach customers, and having proved medical efficiency;

- In what concerns the origins of the value proposition, a possible difference can be highlighted from the sample under analysis. It is a fact that both Companies B and P started as university spin-offs and that P had previous experience in the field of rehabilitation. Further, from the four, Company B was the only that did not have a clear vision of the value proposition from the star, and that highly depended on market studies to find their way. Such might suggest that although having great technological insights, university spin-offs lack on market knowledge, condition that can delay the establishing of the company;

- Companies also seemed to follow somewhat of a pattern in what concerns their key activities and growth prospects. Once having developed a solution to a particular need, they strive for reaching stability with that one product before worrying about potential new products and new markets. That is, companies firstly focus on R&D, then on go to market strategies, and finally, once having reached stability, they refocus on R&D while still managing their other products;
- All companies start by directly approaching their customers. Nevertheless, the subsequent customer relationship strategies were not the same to all companies. With that being said, the strategies related to channels and customer management depend on the archetype of each customer segment and on its buying cycle.
- All companies need to follow ISO13485 regulatory requirements and have medical devices certifications. Further, they all feel the need to protect their technology either by legal concerns, to potentiate financial attractiveness, or both;
- All companies mention workers to be a key resource to the enterprise;
- Partners wise, it is not clear if there is a behaviour characteristic of the WMD industry. Indeed, all companies worry about choosing the right supplier and distribution partners;
- In what concerns revenue models, no apparent strategy seemed to be particular of the WMD industry. Even in the case of Company B outstanding the direct competitor by having lower prices, such strategy is neither novel, nor exclusive to the industry in question;
- The only companies to mention reimbursement as being important to their business strategy were Companies P and O, which are also the ones working with preventive technologies. Such suggest that reimbursement is mainly a concern of companies whose products target prevention rather then diagnostics.

Although some BM strategies seemed to be crucial for the success of the company, it is important to understand in what extent do they characterize WMDs companies in particular. Although having an international set of companies at different stages of development, and whose WD are intended for different uses, ultimately, the sample size is a small one. Accordingly, although there were some recurrent strategies and common challenges and concerns, more companies should be analysed as to reinforce the validity of the findings.

Also, all companies expressed similar expectations for the industry of WMD. Although expecting a continuous growth in the development of wearable devices, they do not expect it to happen under the condition of medical devices, but as consumer electronics. In fact, maybe WMDs are following a similar trend to the one of the early days od Company C where the technological boom made it look like every technology was interesting and had potential, Therefore, it is possible that although there is an overwhelming interest in developing all sorts of WMD, in the future people will only adopt the small portion of them that has not fell in disuse. In fact, such is in concordance with the Hype Cycle for digital business displayed in Figure 2.3. Also, considering the multitude of different products that perform the same or similar functions, it will be interesting to see who prevails over who and why.

As future improvements, it would be interesting to analyse a wider range of companies. As mentioned, such would allow validating the findings, confirming hypothesis,
and possibly uncovering other methodologies that are in use but were not disclosed by the analysed companies.

Also, given that all companies forecast an overlap between medical devices, well-being devices and consumer electronics, it would be interesting to study those types of companies as to assess if their BM strategies are that different from those of WMD (excluding the obvious absence of medical devices certifications) and if their future expectations include developing products that are not classified as medical devices, but that operate as one.

Finally, continuing the study on the relation between WMDs and its suppliers could also be an interesting aspect to cover, given that only one supplier, Company C, was analysed. Particularly, it could contribute to better understand the criteria behind these partnerships in the supply chain of WMDs, and hence better assist in understanding the market dynamics of the WMDs industry.
7. REFERENCES


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82. Kraft, M., *Framework conditions and requirements to ensure the technical functional safety of reprocessed medical devices*. GMS Krankenhaushygiene interdisziplinar, 2008. 3(3).
8. APPENDICES

8.1 INTERVIEW PROTOCOL

CHARACTERIZATION OF BUSINESS MODELS IN THE MEDICAL DEVICES INDUSTRY - THE CASE OF WEARABLE TECHNOLOGIES

<table>
<thead>
<tr>
<th>Date</th>
<th>Company</th>
<th>Product</th>
</tr>
</thead>
</table>

I. General info
Interviewee/Position:
Founded:
Product on the market since:

II. Opportunity
1) How did you become aware of the market opportunity and how did you take advantage of it?

III. Value proposition
2) How would you describe your product regarding its main characteristics and what problems would you say they are solving?
3) Did you change your value proposition? Why? That is, what major feedback/lessons did you get/learn that made you realize you had to make a change?

IV. Customer segments
4) How would you define the type of market you operate in?
5) What are your market segments? What are the main characteristics of each archetype?
6) Who is(are) your most important customer(s)?

V. Customer relationships
7) Regarding the process of creating awareness for your company and product, how do you attract and keep customers?
VI. Channels
8) What are your distribution channels? Have you tried different approaches? Which ones work best and why do you think so?

VII. Key activities
9) What are the key activities the company performs regarding - a, b, c, d - and on which do you focus the most?
   a. Value proposition
   b. Distribution Channels
   c. Customer Relationships
   d. Revenue streams

VIII. Key resources
10) What main resources are required for each mentioned key activity and on what resources do you focus the most?
    a. Value proposition
    b. Distribution Channels
    c. Customer Relationships
    d. Revenue stream

IX. Key partners
11) Who are your most valuable partners?
12) Are they responsible for particular activities or resources?

X. Cost structure
13) Do you find that your business is more cost driven or value driven?
14) Which are the most important costs in our business model?

XI. Revenue Streams
15) What are your revenue streams? Are there other revenue sources and what is the most important?
16) How do you deal with competitors?
17) How is your company attempting to change the game?
18) What are your expectations for the market of medical wearables and what are your biggest concerns? (...) With that in mind, what part of the business are you more focused on growing and what changes are you planning to do?
19) From your experience, what action/strategy did you find to be game changing for your company and why?
8.2 Consent Form

Title of study: Characterization of Business Models in the Medical Devices Industry - the case for wearable technologies

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Goals
- To study business model behind different companies in the industry of wearable medical devices;
- To compare the different business model approaches;
- To search for patterns in such approaches.

Methods
Conduct interviews with executives who commercialize wearable medical devices. The interview will last about 45 minutes. At the beginning of it, the participant (1) will be asked to sign the Consent Form, as to evidence their acknowledgement of the study’s purposes (2), as well as to approve the recording of the interview. The participants will be reminded of their right to interrupt the interview at any time.

The interviews will be transcript and codified as to extract relevant information for the investigation. The content is restricted to team members.

Requirements
The participants must be workers with executive positions in companies who commercialize wearable medical devices. There are no age requirements.

Risks
The risks/discomfort associated to the participation in the study are no greater than those found on a daily basis.

Compensation and costs
There are no associated costs for the participant.

Confidentiality
The collected data and the Consent Form will be saved separately. The latter will be saved in a safe place in Inesc Tec and it will not be given to any their parties. By participating, you understand and agree that the information collected throughout the present study can be used by Inesc Tec and published/given to others outside Inesc Tec. Nevertheless, Inesc Tec assures that your name, address,
contact information and other direct personal identifications will not be mentioned in any publication or promulgation of the data or results.

Throughout the present study, the investigators compromise to respect the following steps as to protect the participant’s identities: (1) each participant will be identified with a number; (2) The investigators will record e collect the data, by associating them to the number and not the name; (3) Any original recording or document with data collected throughout the study will be secured in a safe place, to which only the investigators can access.

Permission
I understand that the investigators might want to use the recording technologies to record the interview as to obtain better precision in the collected data. I hereby allow them to do so.

Yes_______ No________

Rights
Your participation is voluntary. You may interrupt it at any time. No penalties or lost of benefits or rights arises from either refusing to participate, or interrupting your participation in the study. The investigator may remove you from the study for several reasons. If such may happen, you will not be harmed in what concerns the rights or benefits contemplated in the present study.

Right to ask questions and contact information
In the events of having any questions about the study, please do ask them. If later on you have any questions, you want more information on the study, or want to be left out from it, please contact any of the investigators by e-mail or phone, in concordance with the information available on the first page of the consent.

Voluntary Consent
By signing bellow, you agree with the information above written, which was also verbally explained to you by the investigator, and all your questions were answered. By signing the present form, you accept to participate in this investigation.

______________________________  ______________________
Signature of participant  Date

I certify that I have explained the nature and purpose of the present investigation, and that I have discussed potential benefits or risks inherent to participating in it. Any question to be asked by the participant was answered and future questions will be promptly answered.

______________________________  ______________________
Signature of the investigator who got the consent  Date