DESIGN STRATEGIES FOR THE DEVELOPMENT OF HOME USE MEDICAL DEVICES: A STUDY ON CPAP DEVICES

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ABSTRACT

DESIGN STRATEGIES FOR THE DEVELOPMENT OF HOME USE MEDICAL DEVICES: A STUDY ON CPAP DEVICES

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Medical device development and design (MDDD) is one of the sectors with the highest level of safety regulations offering almost risk free products. Actors participating in the development process of these devices (governments, investors, non-governmental organizations, patients, etc.) not only create these highly strict regulations but also define boundaries for the design space in which design strategies are structured. These requirements eliminate suspicions over safety issues and also create a hard shell for product designers disabling the use of possible design strategies regarding user experience. While technological developments create opportunity of moving personal medical devices into daily life, relationship between these medical products and other domestic ones should be constructed skilfully in order to avoid contradictions which can even result with stopping the use of these technologies. Although healthcare mobile apps have become popular and widely used in the last decade, medical devices which are expected to be used by non-professionals have not fully adapted to the daily life yet. The goal of this dissertation is proposing a guidance for design professionals with a set of design strategies that can be employed in the MDDD process. In order to achieve this goal, a field study with 30 participants has been carried out. CPAP device users are selected for the

field study because CPAP is one of the widely used home use medical devices manufactured in the Ankara region.The field study is composed of semi-structured interview questions and scales about their experiences referring to their devices and Obstructive Sleep Apnea (OSA) . The thesis concludes with a checklist structured on the findings of the field study which includes suggestions as strategies for designers in design and development of home use medical devices.

Keywords: Home use medical devices, medical device design, CPAP, design strategies.

ÖZ

EVDE KULLANILAN TIBBI CİHAZLAR İÇİN TASARIM STRATEJİLERİ: CPAP CİHAZLARI ÜZERİNE BİR ÇALIŞMA

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Medikal ürün geliştirme ve tasarımı en yüksek güvenlik düzenlemelerine sahip olması sayesinde risk faktörünü neredeyse ortadan kaldıran ürünler sunmakta olan sektörlerden biridir. Ürünlerin gelişimine katılımda bulunan aktörler (hükümet organları, yatırımcılar, sivil toplum örgütleri, hastalar, vb.) yalnızca bu keskin düzenlemeleri yaratmayıp tasarımcıların tasarım stratejilerini yapılandırdıkları hareket alanlarını da belirlemektedirler. Bu düzenlemeler güvenlik konusundaki şüpheleri ortadan kaldırmasına rağmen ürün tasarımcılarının kullanıcı deneyimine yönelik olası çözümlerine engel olabilmektedir. Teknolojik gelişmeler kişisel medikal ürünlerin gündelik hayata girmesine olanak sağlarken, ileride ürünlerin kullanımına engel oluşturabilecek ikilemlerden kaçınılması için bu medikal ürünlerin diğer gündelik eşyalarla olan ilişkisinin doğru bir şekilde yapılandırılması gereklidir. Mobil sağlık uygulamalarının son on yılda popüler hale gelmesi ve geniş bir alanda kullanılmasına rağmen profesyonel olmayanlar tarafından kullanılması beklenilen tıbbi cihazlar gündelik yaşama henüz tam anlamıyla uyum sağlayabilmiş değildir. Bu doktora çalışmasının amacı, medikal cihaz tasarım ve geliştirme sürecinde tasarım profesyonellerinin kullanabilecekleri bir takım tasarım stratejilerinin bulunduğu bir kılavuz sunmaktır. Bu amaçla 30 katılımcı ile bir saha

araştırması yapılmıştır. Saha araştırması için evde geniş çapta kullanılan cihazlardan biri olması nedeniyle CPAP cihazları seçilmiştir. Saha araştırması kullanıcıların cihazları ile ilgili deneyimleri ve uyku apneleri hakkında yarı yapılandırılmış mülakat sorularından ve ölçeklerden oluşmaktadır. Tez saha çalışması bulgularından yapılandırılmış evde kullanılan medikal cihaz tasarımı ve geliştirilmesinde öneri bağlamında stratejileri içeren bir yapılacak işler listesi ile sonuçlanmaktadır.

Anahtar Kelimeler: Evde kullanılan tıbbi cihazlar, tıbbi cihaz tasarımı, CPAP, tasarım stratejileri.

To my family

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I would like thank my dearest friends Aykut Coşkun, Semih Danış, Aslı Günay, and Sedef Süner for their support and encouragement through my thesis journey. Their positive supports had made me to believe that I can continue my study. I would like thank to my colleagues Süha Süzen and Lütfi Hidayetoğlu for their support in hard times. I would like to thank all participants in the field study who shared their experiences and thoughts. Their insights enabled me to come up with this study.

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LIST OF ABBREVIATIONS

ABBREVIATIONS

ACTI	Attitudes to CPAP Treatment Inventory
CHI-5	CPAP Habit Index 5
CPAP	Continuous Positive Airway Pressure
FDA	Food and Drug Administration
HCI	Human Computer Interactıon
MDDD	Medical Device Development and Design
OSA	Obstructive Sleep Apnea
R&D	Research and Development
SEMSA	Self – Efficacy Measure for Sleep Apnea
SGK	Social Security Institution
SME	Small and Medium sized Enterprises
UEQ	User Experience Questionnaire

CHAPTER 1

INTRODUCTION

This dissertation started with a projection for future healthcare economy. As witnessed in the pandemic, the healthcare economy has a direct effect on the wellfare of the society. The increased healthcare expenditures and budget in national economies require a new shift in healthcare technologies that enables people to maintain their health with their own capabilities. Although healthcare professionals work devotedly in these hard times, healthcare systems encounter serious problems once increased demand for healthcare services are required. Due to both economic and labour constraints, healthcare technologies should be adapted to the capabilities of patients with a diverse range for the decentralization of healthcare.

1.1 Motivation and importance of the topic

In 2008, FDA Center for Devices and Radiological Health (CDRH) announced decentralization of healthcare as one of the leading future trends (Herman & Devey, 2008). The concept does not only include smart home appliances, but also every technology used for carrying healthcare tasks outside healthcare facilities such as mobile phone applications, point-of-care concepts, etc. Since then, researchers have made studies about efficiency, barriers, opportunities, costs, and other features of home healthcare. In April 2010, FDA launched Medical Device Home Use Initiative with the purpose of presenting methods for safety issues in home use medical devices (Fu et al., 2012). The document was developed as an announcement of short list of items to do with the purpose of successful transformation of medical technologies into homecare context. The document was followed by a guidance developed in

2014, later updated in 2016, with a list of items to consider in development of medical devices under four main topics namely conditions in use environment, user considerations, design considerations, and human factors (FDA, 2014).

In a broad sense, attention towards home healthcare can be explained with two reasons (see Figure 1-1). The first reason is the increasing share of people with chronic illnesses and disabilities in the population. Many health problems that used to be entitled as incurable and desperate such as cancer, or genetic disorders, are becoming more manageable and transform into chronic conditions. Thanks to advancements in medicine, people with these health problems can continue their lives and take their part in daily life. However, these developments address new issues in healthcare to be dealt with. To illustrate, increase in elderly population results with a need of labor for caring services. While some caregiving services are provided for certain patients or disabled groups such as veterans in USA, it is not possible for all patients to receive homecare service without financial resources. Along with the financial resources required for these services, creation of human resources with technical background is another serious problem because training of this new workforce is not affordable by existing financial bodies. These new issues in healthcare economy results with the second reason as the inadequate level of capital in healthcare economy necessary for managing this growth in patient population. In terms of healthcare expenditure, USA spent almost 18% of GDP for healthcare in 2019 (Centers for Medicare & Medicaid Services, 2020) and increasing amount of expenditures result with radical arrangements in reimbursement and social insurance policies such as retirement requirements and health insurance ranges. Financial concerns also affect human capital in healthcare industry. Workload of healthcare professionals gets heavier and healthcare facilities make deductions in labor to cope with increasing expenditures.

In order to deal with the current condition, healthcare agencies are in favor of decentralizing healthcare and shifting most of the activities out of healthcare facilities. In this new model, the financial burden of healthcare is likely to be transferred from governments and private agencies to individuals. Moreover, transfer

of required workforce to non-professional users will result in important amount of savings (see Table 1-1). Along with this transformation, devices used in medical applications will adapt to patients and relative stakeholders requirements. With the help of emerging technologies, compact and mobile medical products will be more prevalent. Mobility of medical technologies will also affect use environments of the medical devices. Data sharing and continuous monitoring will transform every possible environment into medical facilities. Not only smart home applications, but also outdoor spaces, offices, and entertainment venues will be environments where we get medical feedbacks thanks to remote monitoring information systems.

Table 1-1: Comparison between costs of inpatient care and homecare on monthly basis
(adapted from FDA (2010))

Condition	Hospital costs	Homecare costs	Dollar savings
Ventilator-dependent adults	$21,570	$7,050	$14,520
Oxygen-dependent children	$12,090	$5,250	$6,840
Chemotherapy for children	$68,870	$55,950	$13,920
Congestive heart failure in the elderly	$1,758	$1,605	$153
Intravenous (IV) antibiotic therapy	$12,510	$4,650	$7,860
Source: National Association for Home Care and Hospice (NAHC), 2008			

Still, medical companies need to transform their perspectives and develop required tools for home healthcare systems because there is no regulation or consensus on the features of home healthcare systems. Privacy of patient records on digital medium, safety dimensions in home use medical devices, and effect of user typologies on medical products are some of the important issues firms need to address in terms of development and design of home healthcare products. Thus the contribution of designers in home healthcare products is an important topic which should be studied in the next decade of medical industry.

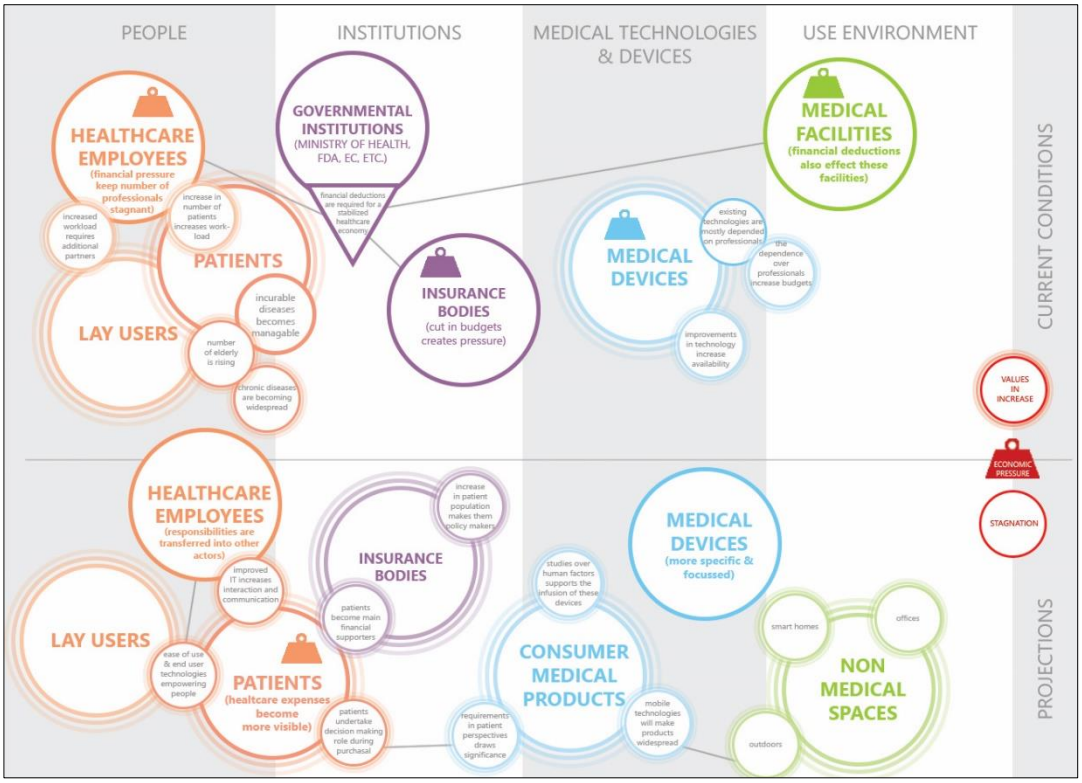

Figure 1-1: Trends and projections in healthcare

1.2 Aim and scope of the thesis

The aim of the study is developing a guidance checklist for designers which mentions important issues to address in MDDD processes with potential areas for idea development and improvement. The reason behind this approach is the fact that a major portion of human factors studies in the field shares the use of traditional research methods such as interviewing and questionnaires in order to address usability and patient adherence issues. These studies agree upon barriers against the execution of other research methods due to both requirements of time and skilled labor. On the other hand these studies share a common ground on their findings. These findings do not go beyond the side effects or statistical measurements of the success rate of these devices. Thus, designers may still benefit from in-depth information regarding users' perceptions and demands from management or treatment of their health problems.

The scope of the thesis is narrowed down to home use medical devices. In terms of the hierarchy of the actors influencing design and development of these products, patients would have more importance on the development of these devices compared to other devices, due to fact that patients become the main user group. Naturally, medical professionals are still important in this process due to their valuable scientific contributions. In addition, regulations will still play a crucial role in terms of device safety. However, heterogeneity and uncertainty of this relatively new user group needs a different approach.

In order to conduct fieldwork with available real users, homecare devices which are supported by the national health insurance body of Turkey (SGK) are selected as the main group of devices. Due to availability of users, devices are narrowed down to CPAP devices which are used by patients with sleep apnea in their homes. This user group mainly includes patients and their next of kin. As these users lack professional medical background, other professional users who are also taking part in homecare (e.g. retired healthcare professionals and homecare consultant teams) are excluded in participant selection.

1.3 Research questions

The main research question for this thesis is:

What are the key points in the development of MDDD of home use medical devices that designers should take into account?

In order to offer strategies for the designers to undertake the MDDD process of home use medical devices, the thesis attempts to explore the following set of research questions through the literature review.

1. Understanding the current state of the MDDD process in Turkish and foreign industries:

a) Which stakeholders take part in requirements elicitation of home use medical devices?

b) What is the role of end users in the MDDD process?

2. Understanding tools and methods employed in the MDDD process:

a) Which design methods have been adopted in MDDD?

b) What kinds of user information are sought by industrial designers in MDDD projects?

c) What are the barriers for industrial designers in terms of user research in MDDD?

3. Exploration of ways for integrating design research methods in MDDD process:

a) Which characteristics of end users affect the selection of design research methods?

b) How do requirements of design research methods affect their viability in the MDDD process?

The thesis attempts to explore the following set of research questions through field study.

a) What are the characteristics of CPAP lay users?

b) What are the constraints with regard to medical therapy in CPAP design?

Lastly, the discussions over the findings of the study focus on the following question.

a) Which strategies can be followed by designers for the design and development of home use medical devices?

1.4 Structure of the thesis

The thesis is structured under eight chapters.

In Chapter 1, the motivation and importance of the topic is explained through a brief explanation of current trends and future projections of healthcare economy. Additionally, aim and scope of the thesis is stated followed by research questions.

In Chapter 2, a summary of literature review addressing the first set of research questions. The literature review is explored in four sections. In the first section, important terms related with home healthcare are explained. In the second section, research areas influencing home use medical devices are mentioned. In the third section, user studies in healthcare research and industrial design are compared in terms of methods and participation.

In Chapter 3, practical factors influencing the development and design of home use medical devices are addressed. The term 'practical factors' means the actors and agencies which have an influence over development of home use medical devices. In the last section, existing models developed for the sake of a successful MDDD process are illustrated and evaluated in industrial design perspective.

In Chapter 4, the methodology of the study is explained in terms of the research questions, stages of the study, and criteria considered during the selection of CPAP devices.

In Chapter 5, the field study conducted with CPAP users is explained in terms of aim of the study, participant selection, data collection method, design of the survey questions and scales used in the survey.

In Chapter 6, the findings of the field study are mentioned in the structure of the survey as illustrated in the previous chapter.

In Chapter 7, the findings of the study are discussed and turned into a checklist for designers that points out important issues to address in MDDD process in terms of users' expectations.

In Chapter 8, the conclusion briefly explains the main points in the thesis by revisiting the research questions, mentioning contribution of the thesis, limitation of the study along with recommendations for further study.

CHAPTER 2

BACKGROUND OF HOME HEALTHCARE

In this chapter, the concept of home healthcare will be explored for better understanding the current trends in both theoretical and practical aspects. Prior to the exploration of contributing literatures and actors influencing the development of home healthcare products, frequently used terms in the literature will be briefly explained with their definitions.

2.1 The development of the concept of home healthcare

In order to clarify the field of home healthcare, some concepts and terms need to be clarified. Although some of these definitions are familiar in everyday life, they are still worth mentioning to avoid confusion and misunderstandings. Also the definitions are structured beginning from the widest scope narrowing down to home use medical devices.

2.1.1 Healthcare

According to Merriam-Webster online dictionary (n.d.), healthcare is defined as "efforts made to maintain or restore health especially by trained and licensed professionals". This definition covers every service and activity carried out by professionals in medicine and related professions, and it is structured on professionals' capabilities. In spite of the fact that it is not possible to overlook the roles of professionals in healthcare, it is fair to respect and mention the future increasing role of nonprofessionals in healthcare.

2.1.2 Public Health

Public health deals with improvements in the dimensions of health within population. WHO (World Health Organization) refers to public health as “all organized measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a whole” (WHO, 2013). Although questioning the goals of public health is politically incorrect, strategies targeting these goals create conflicting issues. Prolonging lifetime in public is a common forecast of most future studies in healthcare. However, increase lifetime also creates the rise of chronic conditions in the elderly. On the other hand, it would also be expected to be able to increase the quality of life together with a prolonged lifetime. Healthcare expenditures for public health and social insurance are also expected to raise in parallel with this trend.

2.1.3 Medicinal products

Synonymous with pharmaceuticals, medicinal products refer to any substance used for prevention, treatment, or diagnosis of diseases (SANCO, 2006). The reason of mentioning this term is to avoid any confusions between medical product and medicinal products.

2.1.4 Medical device

Another essential term which should be mentioned is ‘medical device’. The importance of this term arises from the determination of objects that are both responsible against and under the authority of laws and regulations formed by local and international agencies. Definitions of FDA (United States Food and Drug Administration) and SANCO (European Commission Department for Health and Consumers) can be considered as main references because these two agencies are responsible for healthcare regulations of the United States and European Union

which hold the majority of global medical industry and market. As stated in the definitions of SANCO and FDA (Table 2-1), the range of medical devices does not only include electronic devices in healthcare but also any related article for the purpose of prevention, treatment and monitoring of health. Thus, any product aiming home use (e.g. accessories for disabled users, informative products for Alzheimer patients, feeding tubes for elders with dementia, etc.) are also responsible against these agencies due to being regarded as a medical device.

Table 2-1: Definitions of SANCO and FDA for medical devices

SANCO'S definition for 'medical device'	FDA's definition of 'medical device'
"Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: •Diagnosis, prevention, monitoring, treatment, or alleviation of disease •Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap •Investigation, replacement, or modification of the anatomy or of a physiological process •Control of conception" (SANCO, 2012)	"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: • recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, •intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or •intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes" (FDA, 2013b)

2.1.5 Home use medical device

In addition to the definition of medical devices mentioned above, the definition of home use medical devices is necessary in order to define use environment and user contexts of these products. FDA defines home use medical devices as:

> "A home use medical device is a medical device intended for users in any environment outside of a professional healthcare facility. This includes devices intended for use in both professional healthcare facilities and homes.
>
> -A user is a patient (care recipient), caregiver, or family member that directly uses the device or provides assistance in using the device.
>
> -A qualified healthcare professional is a licensed or non-licensed healthcare professional with proficient skill and experience with the use of the device so that they can aid or train care recipients and caregivers to use and maintain the device"(FDA, 2013a).

2.2 Areas of research influencing home use medical devices

Transition towards home healthcare from current medical device industry requires the development of new products and application of new technologies which are compatible with home use context. Apparently, development of these medical devices and consumer healthcare products mostly overlaps with the domain of medical device development and design (MDDD). Although studies carried out in MDDD are quite comprehensive, a map of research areas influencing home use medical devices is helpful. In Figure 2-1, research areas and topics are illustrated in relation to their impact over MDDD in home healthcare. As seen in the diagram, design and development of home use medical devices is linked with various topics which are also frequently mentioned in design research studies (i.e. human factors, ergonomics, regulations, positive wellbeing, etc.). Illustrating these relations in two dimensional graphics was problematic in terms of mentioning the interaction between peripheral literatures. For instance, positive technology studies which are rooted from positive psychology almost target similar aims with most design for experience studies in the literature, while experience design mostly benefits from

emotion psychology and has turned into a dominant area of design research such as Human - Computer Interaction (HCI). In the following sections, the state-of-the-art in these areas will be covered.

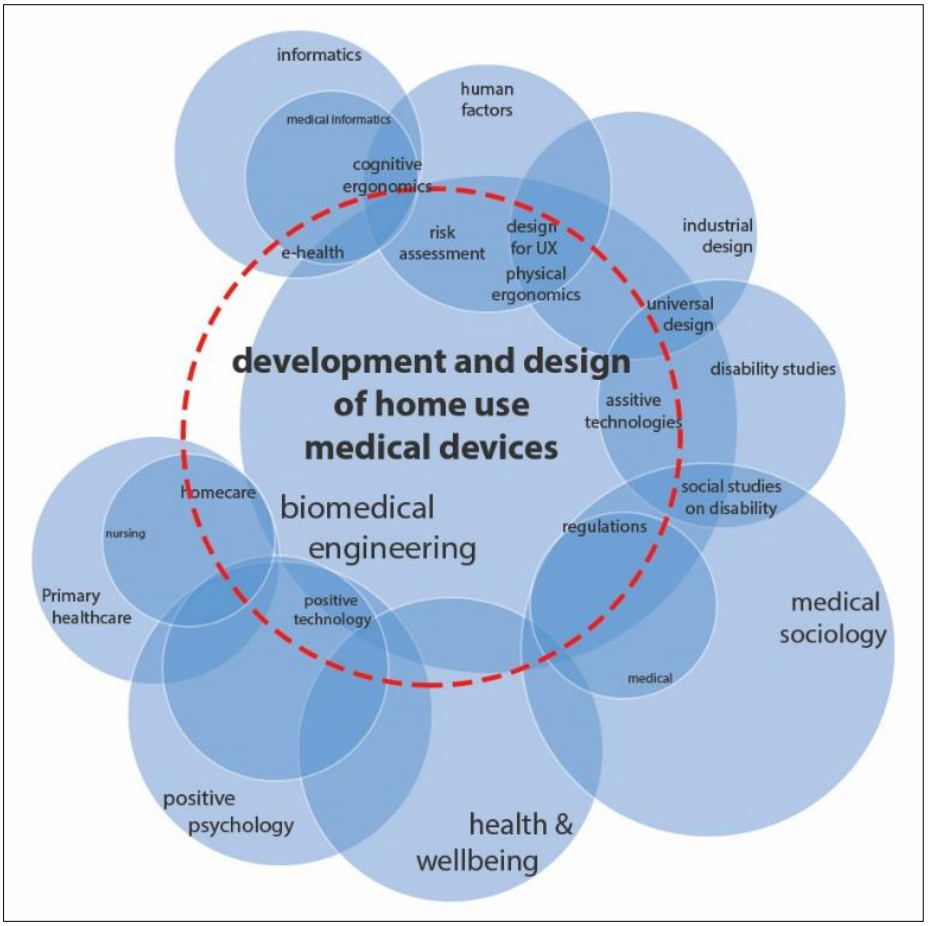

Figure 2-1: Areas of research influencing home healthcare

2.2.1 Primary healthcare

The literature of primary healthcare mainly focuses on interaction between the healthcare recipients (patients) and healthcare professionals and nonprofessionals who are in contact with them in the first place. Most of the abovementioned actors are nurses, physicians, care givers and next-of-kin. Due to most healthcare services being carried out by nurses and equivalent healthcare technicians, a significantly related area of study can be stated as nursing theory. In spite of the fact that the author

has not come across studies of nursing theory during literature survey about the technological aspects of home healthcare products, it is still a source of knowledge which should not be missed by product designers dealing with home use medical devices because most home healthcare services are carried out by these professionals and practices regarding homecare are useful for designers having a grasp on use scenario of these technologies. According to statistical analysis, homecare service expenditures in Turkey was stated as 2 million Turkish Liras for the year 2011 and 350 million for the year 2012 (TUİK, 2020). Although the rise in the values seems speculative, increase in the number of private homecare firms and educational programs of home nursing should not be missed, along with funds allocated for next-of-kin who are involved in their relatives' palliative care.

Beyond the recent financial impact of homecare in healthcare economy, studies in nursing journals also give important insights on the emotional experiences related to care giving activities. Studies about the emotional demand of care giving on homecare workers show that professionals encounter serious emotional demands (Zapf, 2002; Christiansen & Nielsen, 2007) which can result with depression (Netterstrøm et al., 2008). Considering that professional homecare workers and nurses are treating the caregiving as a part of their job, it is fair to consider these emotional demands as a part of their work. Despite the negative emotional demands, caregivers also gain positive experiences such as satisfaction of helping and improving their patients' conditions (Ebenstein, 1999). As medical technologies allow patients with chronic conditions to be monitored and treated in home environment, these experiences are likely to be transferred into the home use context. Moreover, due to the increased financial burden of caregiver salaries, services of monitoring and use of medical devices will be carried out by next-of-kins more often in the near future. However, this will also transfer responsibilities of professionals to patients' relatives which would also affect their social wellbeing in terms of restrictions in daily life activities, changes in privacy in contrast with more confidence in themselves and more comfort compared to hospital care (Munck, Sandgren, Fridlund, & Mårtensson, 2012). To sum up, existing studies over

homecare and experiences of homecare professionals would help designers to foresee upcoming product experience issues concerning home use medical devices.

2.2.2 Disability studies

Considering the fact that disabled people form a respectable social group in the society, disability is an interdisciplinary subject defining and evaluating disability from different perspectives. Definitions of disability used in different disciplines, which are illustrated in Table 2-2 (Grönvik, 2007), are useful for understanding the dimensions of disability. As seen in the table, disability studies address issues not only related with functional capabilities but also with other components influencing their wellbeing such as disabled rights, working conditions, education and transportation.

Table 2-2: Definitions of disability in different perspectives

Type of definition	Criteria	Examples
Functional Definition	Disability as a lack of or restrictions of bodily functions.	Statistical bureaus, medical professions (Abberley, 1980; UN, 1990; WHO, 1980).
Relative Definition	Disability appears in the relation between a person with impairment(s) and inaccessible surroundings.	Disability movement, policy-makers (Söder, 1987).
Social Model of Disability	Disability is the oppression of and a barrier against people with impairments	Disability Movement (Oliver, 1990).
Administrative Definition	Disabled people are those categorized by the welfare state as being in need of/or eligible for certain support systems.	Welfare authorities (Stone, 1984).
Subjective Definition	People perceiving themselves as disabled, irrespective of the basis of such perceptions.	Disability movement. (Wendell, 2001)

In terms of product development and medical technologies for disabled users, disability studies focus on this issue in the area of research called assistive technologies. Assistive technologies can be defined as any product, software or article aiming to improve or maintain functional capabilities of disabled people while promising independency ("Assistive Technology Act," 1998). Assistive technologies do not only deal with physical disabilities which are more obvious and visible in our daily lives. Robitaille (2010) defines the types of assistive technologies in ten groups (Table 2-3). According to this classification, assistive technology does not only deal with the repairment of functional deficiencies but also with the adaptation of current technologies that play a crucial role in the efficiency of daily life activities. To exemplify, the integration of the internet into education and business life has started a paradigm shift while disabled users have confronted a barrier against the adaptation of a completely new way of communication. The same obstacles can also be seen in the diffusion of television and telephone. Considering that these technologies should be equally available to all minor user groups, one major topic of assistive technologies is the development of enabling technologies for disabled people.

Table 2-3: Classes of assistive technology devices

Classes of assistive technology devices according to their objectives.	
Architectural elements, such as adaptations to the home and other premises	Sensory elements, such as aids for communication and hearing
Computers, such as software and hardware	Aids for independent living
Controls, including environmental controls	Modified furniture and furnishings
Prostheses and orthoses	Aids for personal mobility, including wheelchairs
Aids for recreation and sports	Services, such as device selection and training

Disabled people are also addressed in product design as user groups that should be considered in the design process. Originated from architecture, design for all (DfA),

universal design, and inclusive design perspectives show that product designers are responsible for developing products and systems which can also be used by the elderly, disabled people and other special user groups (Story, Mueller, & Mace, 1998). Alongside the technical features of these products, design researchers also focus on user experience and the role of users in the design development process (Desmet & Dijkhuis, 2003; Silvers, 2010; Cook & Adams, 2010; Choi & Sprigle, 2011). Considering the fact that, both chronic illnesses (including genetic illnesses) and disability are major causes of using home healthcare services and products (Wendell, 2001; WHO, 2002; Wolff, Boult, Boyd, & Anderson, 2005), MDDD projects targeting home healthcare should benefit from the insights of previously undertaken assistive technology projects.

2.2.3 Patient adherence

Terminology referring to the degree of involvement of end users and engagement of users in new product development in medicine and other disciplines (i.e. engineering, industrial design, HCI) show differences. Although they share common grounds in terms of the main requirements for structuring a successful communication between new product development teams and end users, use of different terms requires a brief explanation.

To begin with, it is necessary to start with the term ‘compliance’ which can be defined as the degree of patients obeying medical professionals’ treatment procedures (Haynes & Sackett, 1979). The term positions professionals as superiors in hierarchy who tell patients what to do in the treatment process. Compliance has been widely recognized and used especially in medication and healthcare economics in order to increase the efficiency of use of drugs as prescribed. In compliance, patients have to follow the prescription. Moreover, the literature criticizes the term as blaming patients and labelling them as unsuccessful in negative outcomes (Gould & Mitty, 2010). Therefore, the term has evolved and turned into a new one called ‘adherence’. Different from compliance, patients’ freedom to follow or withdraw

from treatment is recognized and issues regarding the treatment are shifted according to the patients' individual characteristics (Kaufman, 2009).

Due to this passive state of patient in treatment, the term 'concordance' later emerged which means the idea of both patients and prescriber taking part in and agreeing upon the treatment procedure (Segal, 2007). This more democratic approach towards the roles of actors does not only give patients a chance to express their wishes and complaints regarding the existing treatment regimens but also makes patients more responsible of their own health conditions. As mentioned earlier, this shift in responsibilities and labor in the healthcare economy promotes increase of home use medical devices and consumer medical devices.

2.2.4 Design for user experience

Design for user experience can be dated back to design & emotion studies that started in the late 90s as well as the concept of experience economy studied by Pine and Gilmore (1998). Before the development of this movement in design research, it is fair to say that user studies in product design mostly consisted of usability studies purposing the level of functional requirements fulfillment. In addition to analyzing functional features of the products, complex dimensions of experience also draw attention from other disciplines in these years (Desmet & Hekkert, 2007). Along with the design & emotion studies, design researchers made use of other disciplines. Basically most of these studies were addressing the underlying reasons of users' choices and judgments about their products during the stages of interaction with their products. Before that, most of these studies were using sub-disciplines of psychology meanwhile utilizing applied disciplines and technical sciences (Hekkert & Schifferstein, 2008). The disciplines most frequently referred to for contributing to product experience are illustrated in Figure 2-2.

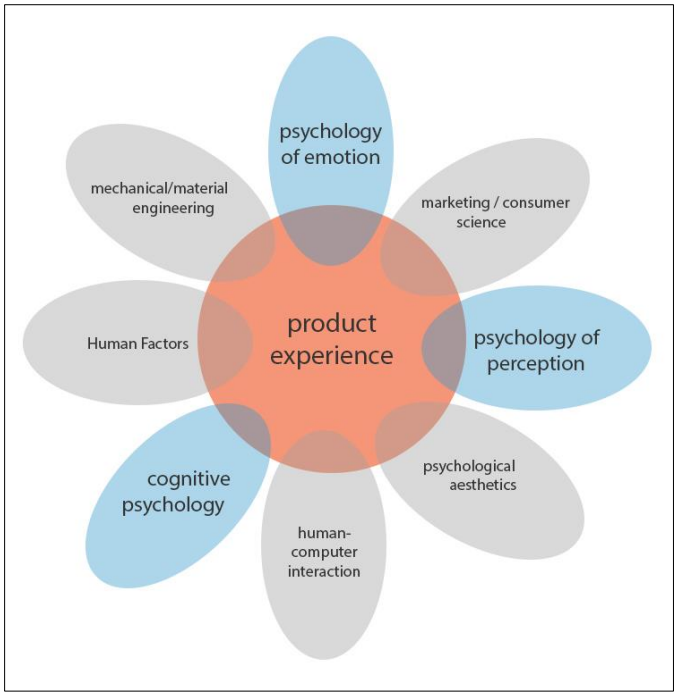

Figure 2-2: Disciplines contributing to the field of product experience (adapted from Hekkert & Schifferstein (2008))

Current studies over product experience are focusing over numerous issues regarding the emotional experiences that products evoke. In order to study these emotions first priorities are determination of these emotions and classifications of these emotional conditions in relation with each other. Although taxonomy studies carried out by linguists are found to be comprehensive, they include words which are no longer used in daily lives (Desmet, 2012). Still, they can be regarded helpful before empirical studies. Design researchers tend to classify emotional experiences in two basic levels as positive and negative emotions, and design researchers are more interested in positive emotions compared to others (Schifferstein & Desmet, 2010; Desmet, 2012; Fokkinga & Desmet, 2013). Positive emotions may be helpful for creating attachment and improve user satisfaction, but it should also be noted that emotions do not exist in isolation and they are in a dynamism (Aaker, Drolet, & Griffin, 2008). They can become more apparent or fade away in the following phases of products' lifecycles. Moreover, positive emotions aimed for in a particular product can conflict with users' specific goals of their wellbeing or positive emotions can

encounter other emotional conditions (particularly negative ones) in time. According to Schifferstein & Desmet (2010), people are in favor of positive emotions when mixed emotions are present. It is fortunate especially with patient experiences in homecare context because most negative experiences are inevitable due to available treatment procedures and technologies. Moreover, purchase and discourse of satisfaction with these products are not in a consumerist manner. For instance, a patient cannot return a medical device in two weeks just because they do not feel satisfied, find an alternative product or demand reimbursement from social insurance bodies. In fact, these tradeoffs are also drawing attention in behavior studies (Aaker et al., 2008; Desmet & Hekkert, 2007; Ozkaramanli & Desmet, 2012).

In addition to studies dealing with the interaction of multiple or even mixed emotions, using negative emotions in product experience is another interesting perspective worth mentioning. Fokkinga and Desmet (2013) use negative emotions to create rich experiences that include negative emotions as well as positive ones in order to construct the desired conditions for a limited time followed by evading from them and resulting with a predefined positive experience. In the study, the process is defined in three stages, namely, emotion selection, emotion elicitation and emotion reversal. According to this process, designers firstly select specific emotions to be felt, secondly applicable ways of provoking these emotions are structured and lastly the process is completed with the creation of a protective frame which diminishes the effect of negative emotions and changes the overall experience into a pleasurable one. Although this approach can be regarded as unfamiliar in product experience, most people had this kind of experience in entertainment activities and arts (Benford et al., 2013); such as movies (horror, drama, thriller, etc.), amusement parks (rollercoasters, dark rides, etc.) or outdoor sports (bungee jumping, sky diving, survival trainings, etc.).

2.2.5 Positive technology & wellbeing

Along with studies about positive user experience in design research, positive technology (PT) researchers are also focusing on the relationship between wellbeing and technology. In order to understand the standpoint of positive technology, definitions of wellbeing and components of this concept should be explored. Thus, initial terms and theories are mostly structured in positive psychology (PP) perspective. To begin with, PP is the scientific area of psychology aiming a transition from repairment of mental deficiencies to building best qualities in individuals' lives and society (Seligman, 2002). In terms of PP, wellbeing is mostly referred to as subjective wellbeing and psychological wellbeing; while the former is based on cognitive and affective evaluations of people about their own lives (Diener, Lucas, & Oishi, 2002), the latter deals with lifelong self-developmental perspectives (Ryff & Singer, 1996). In the subjective wellbeing studies, wellbeing is defined by three different theories, namely, hedonism theory, desire theory and objective list theory. In hedonism theory wellbeing is explained as the optimum achievement of pleasure. In this kind of wellbeing, emotions are emphasized as being tools and enablers of wellbeing, which is very similar to emotional design statements. In other words, in both literatures positive emotions are mentioned as facilitators of positive wellbeing. In desire theory, a person's wellbeing is defined as the degree of satisfaction in terms of the individual's desires. Objective list theory, composes lists of items of wellbeing which are not covered by none of the two theories, such as meaningful achievements in life like knowledge however it can be stated that all items which are included in the previous two theory can be included in this theory (Fletcher, 2016).

PT's perspective and aim can be summarized as shaping current and emerging technologies for achieving better quality of personal experiences and wellbeing (Botella et al., 2012; Riva et al., 2012; Wiederhold & Riva, 2012). With this in mind, PT scientists classify qualities of technologies in three levels (Riva et al., 2012). As seen in Figure 2-3, these three levels are closely linked with the three theories of wellbeing. In fact, it is derived from sub disciplines of the psychology literature. In

this sense, technologies can be used for positive experiences by widening emotional repertoires (Fredrickson, 2001) or creating challenges parallel with available capabilities (Csikszentmihalyi, 1991) and lastly creating mediums for individuals to share their adjacent goals and then creating a common goal which is structured on individuals' shared experiences.

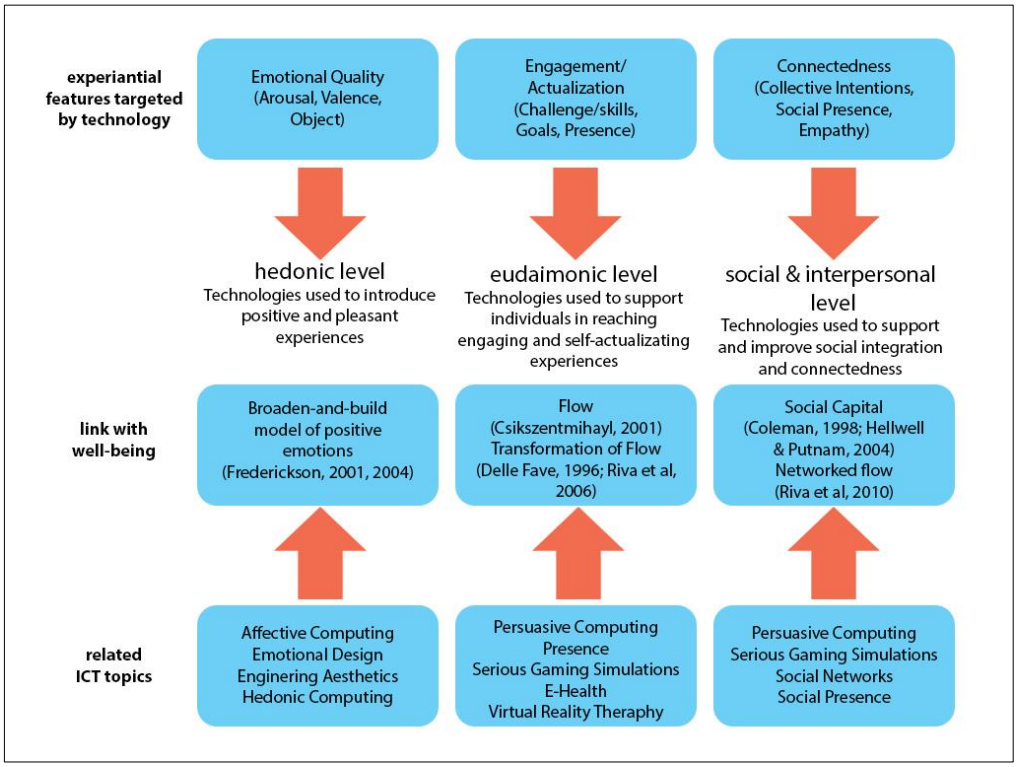

Figure 2-3: Classification of positive technologies and related information communication topics

2.2.6 Medical informatics

Studies over information management in healthcare can be dated back to first attempts over management of medical records in the early 20th century (AHIMA, 2013) much before introduction of digital technologies in healthcare. With the development of information technologies capable of both storing and processing large amount of data, healthcare has also been transferring their information and knowledge into digital medium. From the patients' perspective, they no longer need

to physically carry medical images or reports (CAT scans, X-rays, test results, etc.) with them and they can simply share their records beyond physical limitations. To illustrate, people no longer need to go abroad for getting opinion from a specialist in a foreign country. Moreover, they can get information about specialists before getting into contact or visiting their clinics. From the perspectives of healthcare facilities or managerial bodies, patients are directed to the most suitable specialist available or protection and management of patients' records are easier, faster and cheaper compared to traditional methods. Lastly from the physicians' perspective, medical doctors can scan available treatment procedures and their success rates before practice.

Informatics in medicine is widely working on the role of information technologies and management of knowledge, information and data in healthcare. The discipline also created its own sub disciplines according to their interests such as medical informatics, healthcare informatics, e-health, clinical informatics and nursing informatics. Some of the important topics being studied in medical informatics can be summarized as; communication between patients and healthcare professionals (Finch, May, Mort, & Mair, 2008), emerging technologies in home healthcare for chronic conditions and disabilities (Campo, Hewson, Gehin, & Noury, 2013; Hsi-Feng & Jiann-Liang Chen, 2009; Kosta, Pitkanen, Niemela, & Kaasinen, 2010), management of new healthcare system, and information safety.

2.2.7 Human factors studies in medical device development and design

Human factors (also known as ergonomics, human factors engineering, usability engineering, etc.) is an area of study focusing over the role and interaction of people with surrounding products or systems with an interdisciplinary view including product design (Karwowski, 2005; Sanders & McCormick, 1993). Due to the interdisciplinary medium, human factors is currently dealing with numerous topics. Still, International Ergonomics Association (IEA) managed to classify the domains

of ergonomics under three groups in 2000 such as physical ergonomics, cognitive ergonomics, and organizational ergonomics (IEA, 2010).

Although human factors address various subjects, it is fair to point out that human factors studies in healthcare are dominated by safety studies. It is natural to expect this condition considering the fact that any human error or malfunction with medical devices is a receipt for disaster in terms of patient safety. Thus, developing risk free devices in healthcare industry is the most prominent subject from all actors' perspectives. Still, development of human factors in healthcare is criticized as being slow (Hignett, Carayon, Buckle, & Catchpole, 2013). Along with the increase of investments on human factors in the healthcare industry (Wiklund, 2011), the recent changes in FDA's expectations regarding human factors in the approval process (FDA, 2011; M. F. Story, 2012) show us that human factors studies will increase exponentially in the following years. Moreover, market penetration of home use medical devices addresses lay users as a new actor in MDDD which is worth studying (Bitterman, 2011; Fex, Flensner, Ek, & Söderhamn, 2011; Hignett et al., 2013; Lemke & Mendonca, 2013; Logan, 2013; Martin, Norris, Murphy, & Crowe, 2008; Martin, Barnett, Martin, & Barnett, 2012). FDA (2012a) also published a comprehensive draft guidance for the development of home use medical devices including important issues to be considered in terms of use environment, human factors, user considerations, labeling, postmarketing, and functional device requirements. Moreover, answering functional requirements and safety does not guarantee satisfaction with home use medical devices (Thomson, Martin, & Sharples, 2013). Thus, studies questioning user engagement can help improving the success rate of these emerging technologies.

2.3 User studies in healthcare and industrial design

User research and studies carried out with these stakeholders are prioritized and more frequently mentioned in almost every discipline. In order to understand the contribution of users and compare their roles in healthcare research and design

research, it is necessary to review sources focusing on their methodological perspectives. In addition, critical essays on participation should also be included. Thus, in the following three subtopics, these issues are explored.

2.3.1 Methods used for user studies in healthcare research

Before mentioning theoretical frameworks and research methods employed in healthcare research studies, it is important to keep in mind that various groups with different backgrounds are referred to as users in MDDD. In addition to medical professionals such as physicians, nurses and care givers, there is also a growing group composed of non-professional users called lay users, which is explored deeper in the following chapter. Concerning theoretical frameworks, the healthcare research literature shares the same approaches (i.e. phenomenology, ethnomethodology, grounded theory, etc.) as social sciences and has positivist stand in quantitative methodologies.

In terms of research methods, both qualitative and quantitative methods are frequently carried out in the studies. In contrast to the wide perspective including different theoretical frameworks, especially MDDD studies benefit from a very limited number of research methods. Although user needs elicitation is accepted as an important factor in the MDDD process, data collection methods applied in healthcare research literature are determined in a few selected ones such as interviewing, observation and focus group sessions (Finlay & Ballinger, 2006; Maltby, Williams, McGarry & Day, 2010; Roberts & Priest, 2010).

Methods for needs elicitation:

Interviewing & questionnaires:

Parallel to the exploration of case studies in Table 2-4, interviews, followed by content analysis is one of the most common methods for data collection (NHS, 2010). This combination is criticized as being time consuming and dependent on the researchers' abilities (Priest & Roberts, 2010). On the one hand, analyzing quantitative data by means of content analysis followed by statistical analysis still

makes this approach a justifiable option for reliability and generalization of conclusions. On the other hand, generalization of the user requirements in MDDD is also mentioned as a non-preferred option due to the unpredictable variables in use environments (FDA, 2012b) and the heterogeneity of patient profiles (J. Martin et al., 2006).

Semi structured interviewing is widely employed during need elicitation for end users as in Table 2-4 (Grocott, Weir, & Ram, 2007; J.Choi, Y.Jeong, & I.Arriaga, 2012; Lang, Martin, Sharples, & Crowe, 2013; Martin Jennifer et al., 2012; Money et al., 2011; Thomson et al., 2013). The interview sessions are followed by a content analysis. In all studies interview sessions are transcribed and coded in certain themes. The codes are grouped into themes and relations between these clusters are analyzed. In Grocott et al. (2007)the research team carries out two additional study procedures by using the TELER method, a questionnaire method which is used for measuring quality of care and physical conditions of the patient. The method translates verbal expression of certain problems such as pain or other symptoms into numerical values which helps researchers and clinicians take chronological data about their patients and analyze these values and turn them into statistical output.

Table 2-4: Research methods which have been employed for user studies in healthcare

Research method	User studies in healthcare
Semi-structured and in-depth interviewing	(Grocott, Weir, & Ram, 2007; J.Choi, Y.Jeong, & I.Arriaga, 2012; Lang, Martin, Sharples, & Crowe, 2013; J Martin & Barnett, 2012; Money et al., 2011; Thomson et al., 2013)
Design ethnography, probes	(Axelrod et al., 2011; Hassling, Eriksson, Timpka, & Nordfeldt, 2005; Wherton et al., 2012)
Cognitive walkthrough	(D. Kaufman et al., 2003; Malhotra, Laxmisan, Keselman, Zhang, & Patel, 2005; J. L. Martin et al., 2008; Namshirin, Ibey, & Lamsdale, 2011)
Behavioural mapping	(Askim, Bernhardt, Salvesen, & Indredavik, 2014; Bernhardt, Dewey, Thrift, & Donnan, 2004; Kuys, Dolecka, & Guard, 2012; Shepley, 2003)
Diary taking	(Crabtree et al., 2003; Junnila et al., 2010; Rinaldi, Martin, & Gaddi, 2011; Strochlic & Mulcare, 2013)
Heuristic evaluation	(Choi & Sprigle, 2011; Corinna et al., 1999; Malhotra et al., 2005; Matern & Büchel, 2011)
Contextual inquiry	(J. L. Martin et al., 2008; Sharples et al., 2012)
Prototyping	(Aitchison et al., 2009; Bostelman, Chang, Ryu, Agrawal, & Johnson, 2010; Browne & O'Sullivan, 2012; Johnson & Moultrie, 2012)

Methods for usability testing:

In addition to interviews, observations and questionnaires, more specific research methods are also used in MDDD case studies. Among these, the most prominent methods are dealing with product interfaces such as cognitive walkthrough and heuristic evaluation and think aloud protocol (a.k.a. think aloud). These methods are mostly employed in usability tests of healthcare information systems and interfaces of medical devices. Due to overlapping uses and shared aim of the three methods, it is beneficial to give brief definitions.

The cognitive walkthrough method briefly measures the level of success of users during performing tasks. For the sake of this, the features of the device is studied by the product development team and the sequence of actions necessary for performing these tasks are listed step by step. During the testing procedure, the data can be recorded by various equipment such as audio recording, video recording and software specific for recording steps of use during previously developed scenarios.

Kaufman et al. (2003) use cognitive walkthrough in order to analyze a telemedicine system developed for monitoring diabetic patients in the US. The study starts with a brief analysis of the tasks of glucose monitoring device and the telemedicine interface called goals, sub goals, actions and system response. After that, a field study is structured over the outcomes of the cognitive walkthrough. During the field study, patients are asked to perform certain tasks and express themselves during use by *think aloud* protocol in order to see the barriers against adoption of the developed telemedicine software.

Different from the previous study, Namshirin et al. (2011) carry out cognitive walkthrough about infusion pumps with real clinical users along with additional methods. The infusion pumps were first studied with heuristic evaluation by experts and possible medical errors were listed after the cognitive walkthrough carried out with clinicians from various medical backgrounds. The second phase of cognitive walkthrough is mentioned as a usability evaluation which asks participants to perform tasks in real world scenarios. Finally, the study concludes with a two-week real clinical trials to validate the findings of the previous collaborative methods. In other words, the study encourages including experts from various disciplines as well as users before development of design solutions and detailed prototypes.

Jaspers (2009) compares three usability methods: heuristic evaluation, cognitive walkthrough, and the think aloud. The author calls heuristic evaluation and cognitive walkthrough as expert based, and the think aloud as user based. The aim of the paper is mainly defining the advantages and disadvantages of each method in order to help new researchers to choose the most appropriate ones. In the findings heuristic evaluation is referred to as easy to apply at low cost. However, the gap between real users and the experts is the main disadvantage of the method which may result with the missing of more important medical errors. Therefore experienced usability experts are required for a successful study. In terms of cognitive walkthrough, the method requires a detailed analysis of the features of the devices structuring the task sequences. This allows researchers to understand the use scenarios of the device. Still, developed guidelines do not help researchers to have a better grasp on the

context of use and user characteristics. In spite of that, the method is referred to as useful for identifying usability problems in cases which time and financial barriers do not allow to carry out field studies. Lastly, the think aloud protocol is mentioned as the most useful technique for understanding users capabilities at higher costs. Compared to previous expert based techniques, the think aloud protocol is focused on the user side of systems while others include usability problems concerning other actors in the product use scenario.

Behavioral mapping:

Behavioral mapping is another research method used in healthcare research. Case study examples in Table 2-4 show that behavioral mapping has mostly been used for the analysis of healthcare facilities, such as hospitals and caring homes. Although behavioral mapping promises great use in the analysis of daily lives of chronic patients in home context, most studies targeting this subject are still carried out with either interview sessions isolated from their environment or use of probes and diary taking with verbal expressions which can result in privacy concerns of people. Although privacy is a major barrier against the application of this method, video recording is not always necessary for this technique. If the research goal is more related to locations where people spend their days rather than observing and evaluating their activities, technologies as proximity sensors and motion sensors with gyroscopes can still be useful.

Kuys, Dolecka & Guard (2012) use behavioral mapping in order to determine the activity level of patients in the hospital environment. The activities are classified according to the location, type of activity and people spending time with the patients. Shepley (2003) compares two different layout plans for neonatal intensive care units by use of behavioral mapping, followed by interviews and questionnaires. Before the findings, previous studies specific to design of healthcare spaces are mentioned with amounts of activities in terms of distance and daily tasks. The use of interview and questionnaire in the study helps to measure the perception of the qualities of the revised plan and compare it to the findings obtained from behavioral mapping.

Bernhardt et al. (2004) and Torunn et al. (2014) study the positive effects of physical activities compared to bed rest among stroke patients' early phase. During the observation, behavioral mapping is used by setting numerical values to different types of activities ranging from no movement to climbing stairs. In addition to demographics, participants are classified according to other medical descriptive scales about the severity of their conditions. In addition, the area of activities and interaction with other people are also included in the first study.

Methods for Longitudinal Studies:

Longitudinal studies refer to researches which that focus on changes in findings from a certain study in longer periods of time. Although a study clearly answers the current situation, some areas of research specifically require this kind of repeated field studies and records in order to develop related theories. Green and Thorogood (2004) address how public records are used in medical sociology. Most retrospective public health studies also benefit from these studies. Apart from these, technology acceptance and user adherence studies also require this approach because patients' perception regarding a device can change in time and end up in non-adherence even though usability studies prior to marketing show a fast engagement for lay users.

Diary keeping:

Diary keeping is another research method for conducting user studies in MDDD. Studies benefit from this method as a tool for remote monitoring in design ethnography in which researchers cannot get in a continuous one-to-one contact with participants. Beyond eliminating physical barriers between the researcher and participant, diary keeping is a technique used in longitudinal researches due to its nature requiring time period and observation of changes in certain parameters within this time. Diary keeping technique can diversify from being unstructured to fully structured according the research aims. Although the term diary refers to taking notes on daily activities and memories without any limitation, researchers can narrow down the content of the study to certain measures. Besides, diaries can make use of scales, multiple choice questions, diagrams and other tools used in interviews and

questionnaires. One major barrier against successful implementation of diary keeping is the workload of performing / following the procedure. In order to ease participants' work in the study, researchers can develop printed forms and use digital medium such as audio / video records and web sites.

Wilkund, Kendler & Yale (2011) define the advantages of diary keeping as a good model for studying real world learning curve of new medical devices and compare it to other aforementioned usability techniques; diary keeping focuses on changes on usability and perception of the device rather than intuitiveness of the device. In addition, the repetition of device use is important. In other words daily use products require less time while devices with weekly or monthly use should include enough repetition in order to develop muscle memory.

Design ethnography, probes:

Ethnographic studies and cultural probes are rarely used as methods in MDDD. In fact, these methods are used for including patients in the idea generation stage and development of inspirational sources for NPD teams. Although the use of ethnography as a generative tool is rare in medicine, observation is a major kind of research technique in healthcare for the sake of evaluating the current state of the participants. However, the term observation refers to a group of techniques including remote monitoring, behavioral mapping, and various user testing procedures. Apart from observation, cultural probes, which make use of photographs, personal belongings and daily notes, help NPD teams to understand the qualities of patients. The term patient is mainly constructed on the health problem of the end user but other personal qualities specific to each participant in studies give clues about their daily lives. One problem with the use of probes during MDDD is the lack of a scientific measure and their place in the hierarchy of requirements.

In terms of using cultural probes beyond observation of patients for the sake of diagnostic purposes, Wherton et al. (2012) carry out a series of interviews which are supported by digital images and notes taken between the interviews. The aim of the study was to understand the use of cultural probes in determining the possibilities of

attachment of new assisted living technologies in elders' lives. In order to understand the daily lives of the participants, the research team developed a notebook called 'life scrapbook' and used a digital camera for collecting images. During the study, physical condition, literacy problems and technological boundaries limited the completion of the tasks of the study. On the one hand, digital images have been found the most applicable type of data and source to be generated by the participants. On the other hand, items expected to be generated by the users in the life scrapbook as plan of the homes or open ended notes need to be supported with use of diagrams or developed by the researcher in the first visit.

Methods for design validation:

Usability testing methods mentioned in the previous sections can also be included in this group due to their roles in the evaluation of developed design solutions. In addition to these methods, use of a working product rather than a simulation, or reflection of use in testing enables product development teams to make judgements about the physical features of these devices in terms of their engineering design and durability.

Prototyping:

One frequently used research method in MDDD is prototyping. The method aims for the validation of design solutions with prototypes evolving from low-fidelity ones into more developed and detailed models. Although this method is useful for participants to make judgments based on a three dimensional material and contribute to ongoing evaluation of form and product, Buxton (2007) criticizes the fact that participants usually perceive prototypes as final products rather than working models to be developed further. One major reason for this is the presence of an already working product and increased financial investment makes companies head towards finalizing the project in short term.

At this point it is useful to make a distinction between what prototype can mean for designers and NPD teams. In engineering design, prototype mostly refers to a fully

working replica of the finished product that enables to carry out use tests. The idea does not change very much in MDDD. In most biomedical engineering case studies prototypes are being used as a means of design verification by means of structured use tests. Testing a medical device can be considered as a completely different task to study as in Browne & O'Sullivan (2012).

Moreover, the outcome expected from an NPD project also affects the use and development of prototypes. Johnson & Moultrie (2012) studied to develop a technology confidence scale helping MDDD teams to measure and make judgements on how to transform a new technology into medical devices. Due to absence of successful examples and uncertainties at the early stages of projects, it is not clear how to measure whether these new technologies are ready for use. The direct link between the necessity of a new technology and success rate of a device turns the fuzzy front end of MDDD into a risky position which is not very desirable for most medical device manufacturers with limited financial capabilities. The perception of high risk level in new technology use, positions the development of prototypes prior to design verification much after idea generation of the projects is completed. In other words, MDDD projects which are solely dependent on successful implementation of a new technology in medical devices can miss the opportunities of contributions which can be generated by better understanding the end users' expectations.

However, prototypes do not always have to duplicate most properties of a product. In other words, it is possible to widen the concept of prototype to 3D representation of a product which is frequently called modelling. In design it is referred to using various terms, such as white models, experimental models, mock ups or even paper models. The methods used in industrial design is mentioned thoroughly in the following section.

2.3.2 Methods used for user studies in design research

In this section, research methods used for user studies in industrial design are explored in categories as the form of analyzing and communicating findings, their primary purpose of use in the design process, and their origin. This kind of categorization is helpful for a deeper exploration of different kinds of methods and make comparisons both in the design research discipline and from the perspective of healthcare research. Due to the extensive range of methods, in this thesis, the book by Martin & Hanington (2012) is used as a template for exploring these methods Methods mentioned in their book are first listed and then scanned and some of the methods are excluded due to mainly addressing a whole group of other methods. The variety of research outputs in design research and aim of these methods are illustrated in Figure 2-4.

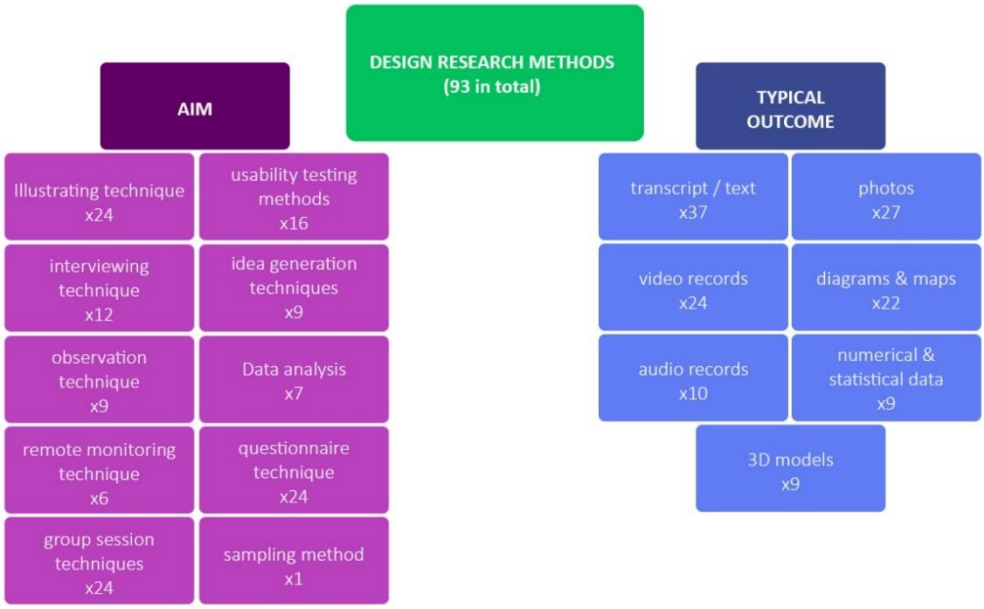

Figure 2-4: Aim of use and output mediums of design research methods

Type of data:

The type of data derived from methods and the ways in which research findings are communicated, are mainly divided into two groups as quantitative and qualitative.

Quantitative methods are widely adopted in positivist theoretical frameworks (i.e. natural sciences) aiming to find one true knowledge which can be transformed into numerical values and generalized into related cases. In design research quantitative data is desirable when the researcher seeks ways of measurements in order to make comparison between research findings. Due to this, it is frequent to encounter qualitative data derived from research methods such as interviews and even observations are transformed into numerical values and statistically measured.

However, most research questions in social sciences (including design research and user studies) depend on variables constraining the generalization of research outcomes. Thus, ethnographic research methodologies have been widely adopted in design research since the 1990s (Tore Yargin, 2013). In addition to problems with generalization of the knowledge, one other reason for wide use of qualitative research approach in design process is the fact that most designers are more interested in acquiring in depth knowledge about their research subject.

Seventy four out 97 of the design research methods gather qualitative data. Twenty three methods which make use of quantitative data are composed of usability testing methods and monitoring techniques. The reason of using quantitative data especially in user tests is the requirement for analysis frequency of incidents that occur during use and set the hierarchy between these errors in order of importance.

Goal of research:

Firstly, research design depends on what researchers expect from the findings of their studies. Thus, the integration of the design research into a design process can be regarded as an important factor. Selected design research theorists define integration of the research as explorative, evaluative and generative. While an explorative approach makes researchers aim to draw existing demands and possibilities in early stages of the design process (i.e. planning, project briefing, etc.), an evaluative approach allows researchers to test and validate refined design solutions in the last stages of the process prior to market penetration. Both explorative and evaluative goals are shared in design research and healthcare research in order to structure the

project brief including requirement elicitation, and verifying / validating design solutions before the following stages.

The third group of methods are generative design research methods. These methods generally aim development of ideas through the design process. The terms participatory research and collaborative design becomes important in this type of methods which are used interchangeably. Collaborative design is better suited to the idea of integration of users in the actual design phase because participation can also mean including end users as source of information for explorative purposes or validation of design ideas. Different from most MDDD case studies, generative approach is relatively new and democratic which aims developing design solutions and preliminary design ideas with the active partnership of users. Generative methods and tools compose almost a quarter of all methods. Accordingly, these methods can be valuable for researchers who aim to include lay users more actively throughout the design process.

Origin of the methods:

The origin of the methods is also used for categorization. Hanington (2003) categorizes these methods in three groups as traditional, adapted, and innovative. According to his classification, many traditional methods, which are used in almost all research areas (i.e. interviewing, questionnaires, focus groups) exist in order to carry out successful user studies.

Following these traditional methods, methods developed in other disciplines can also be adopted in design research. To illustrate, eye tracking which originates from HCI, is now widely used in many other research fields for evaluative purposes such as user testing.

Lastly, innovative methods are described as new ways of collecting user information, which are developed by design researchers. Innovative methods are mostly suitable for generative researches that allow researchers to develop means of communication with participants on issues that are difficult to discuss with traditional methods.

Type of research output:

Although wide use of traditional research methods such as interviewing and observational studies in most disciplines limits the output of research methods to verbal expressions and video recordings, nature of using and developing effective communication tools in design helps designers to generate and utilize different mediums for communicating research findings beyond words in order to help NPD teams to better understand and feel empathy with the real world users.

Ethnographic research methods developed in social sciences generate inspirational outputs that are called narratives, a term which is also frequently mentioned in healthcare research. The term narratives refer to stories and lived experiences that are told by people / users which helps researchers to understand the links between the events and cognitive mechanisms of generating meanings and emotions. Although these lived experiences are mostly transferred by interviews, it is possible to use other mediums for probing untold experiences. Two of these mediums frequently used are visuals such as video recordings, and photos, which are mainly used in observational studies and usability tests. Use of visuals especially in usability testing helps design researchers to better understand both ergonomics and use scenarios of the products because it is not easy to describe actions clearly by words. Moreover photos are another source of information for design researchers because they help both researcher and participants to express their ideas better during interviews.

Another form of output of design research methods are diagrams which are useful for analyzing and making connections between the findings. Although it can sound very obvious for designers, engineers and software specialists to use graphic elements to illustrate their ideas, it is not very common for research professionals in other disciplines. Especially in human factors and biomedical engineering literature in MDDD, the research findings are mostly expressed by means of quantitative values and verbal expressions which still need to be reconstructed by their audiences to be utilized in future product design studies. Beyond clearly understanding the links

between the findings of studies, use of predeveloped graphic tools are also excellent mediators for researchers in terms of better expression of the research methodology to their participants and for users who take part in these studies to better express themselves in easier ways.

One other major type of output which is very specific to design research is 3D models. As mentioned in prototyping in the previous chapter, 3D models are useful not only for validating the developed designs but also for giving participants and NPD teams a medium to communicate for evaluation of potential possibility driven designs. In this sense, understanding 3D models as an ongoing/changing working medium for effective communication rather than a final product, gives these two different actors a chance for directly intervening in the design phase.

2.3.3 Comparison between healthcare research and industrial design regarding participation

All research methods mentioned in healthcare research compose a part of methods which are also employed in the product design discipline due to the fact that MDDD is also an area of product development focusing on user need elicitation and product testing. However, the range of methods used in medical case studies can be regarded as mostly constituted by more traditional methods that prioritize the contribution of professionals' abilities during the development of knowledge. Compared to case studies from other areas of design research (i.e. service design, HCI, etc.), the role of users (especially lay users) is reduced to the level of passive research participants that contribute to the verification of assumed demands and developed design solutions. Due to the fact that users' involvement in healthcare economy originates from political movements of disabled groups, the terminology referring to this issue is also political. Beresford (2005) defines participation of users in two categories as consumerist and democratic. The first category is called consumerist, which improves service systems without the aim of distributing power. The second category is the democratic level that aims improving people's lives with emancipatory research whereby people are empowered by having greater control over their

conditions. Sanders (2008) defines participation in design in a similar manner, which is called as expert mindset and participatory mindset. In expert mindset, designers see users as subjects (source of data, consumers, etc.) in their design activities, while in participatory mindset users are perceived as independent experts with unique experiences allowing to be co-creators in the design act.

In addition to this politically correct stance on participation in healthcare, the power relations between actors in healthcare is another issue, which should be questioned for real world applications. After accepting users and patients as an inseparable part of healthcare research, researchers should define the criteria of this partnership between users and experts. In this perspective, partnership with lay users in healthcare requires a detailed evaluation of interdependence between other related actors.

CHAPTER 3

PRACTICE OF MDDD

In this chapter, practice of medical device development and design are explored. For the sake of this, firstly actors influencing the MDDD process are pointed out. Secondly, models of MDDD published in engineering design and biomedical engineering disciplines are identified. Thirdly, sectorial reports illustrating overall features of Turkish medical industry are mentioned in order to discuss the likelihood of using MDDD models at local conditions in the last section of discussion.

3.1 Actors influencing the MDDD process

In order to have a better grasp on the dynamics of MDDD practice, relevant actors with influencing role on medical devices should be examined. In addition to influential actors, lay users are also pointed due to their role in home use medical products.

3.1.1 Medical device manufacturers

Features of medical device manufacturers can be stated as various due to the comprehensive definition of medical device which is mentioned earlier. Due to the inclusive definition, medical devices vary; starting from low technology medical consumables such as oxygen tanks, up to high technology devices such as CT scanners. The difference between these products also affects the features of manufacturing companies. In terms of scale, producers in medical device industry include both large scale international companies (i.e. Philips Healthcare, GE Healthcare, Siemens, Johnson & Johnson, etc.) and local small and medium scaled enterprises (SMEs). While large scaled companies are dealing with manufacturing

diverse type of devices, SMEs are mostly dependent upon few kinds of products and medical technologies. As Eatock, Young & Dixon (2009) pointed out, scales of medical device producers are closely related with their product strategy and R&D activities. According to the study, most SMEs in the sector are dealing with the development of major upgrades in medical technologies, while the majority of projects carried out in international leading firms are dealing with minor upgrades.

3.1.2 Consultants in medical device industry

Consultants in MDDD process can be divided into two groups, as specialist firms contributing to product development phases, and healthcare professionals who play a role in the definition of requirements and clinical trials of medical devices. The first group of specialist firms refer companies which are equipped with qualified experience in particular issues such as biomedical technologies, engineering design, human factors, and product design. On the one hand, consultants of biomedical engineering and engineering design are dealing with the development of new medical technologies such as medical imaging, tele-healthcare, and software applications. On the other hand, product design and human factors consultancies are dealing with the transformation of these technologies into specific products. The second group of consultants, who are healthcare professionals in medical industry, are also essential in MDDD because most companies still define clinical needs and possible improvements in medical devices by means of informal suggestions raised by this user group. Additionally, healthcare professionals also play crucial role in the design validation stage of the MDDD process.

3.1.3 Regulatory agencies

Considering that medical devices are expected to match diverse regulations and pass evaluations of governmental institutions, influence of regulatory agencies on MDDD is inevitable. Two leading agencies shaping regulation and requirements in medical

device can be mentioned as FDA and SANCO. Moreover, due to the leading share of US in global healthcare expenditure (OECD, 2012), it is fair to claim that FDA also has influence on regulations carried out in the EU. In order to take part in these two largest markets, the FDA approval is needed in USA, while the CE mark is needed in EU. Although getting these approvals can sound as a testing phase on the manufactured product, the reality is different. Getting these approvals and their continuum is depended on stages that also include the product development, manufacturing and post-marketing phases. In the case of USA, FDA demands a design history file to ensure product development and the manufacturing process is handled according to specific requirements of the product. Also, regulatory agencies carry out periodical visits checking manufacturing conditions in terms of precision, sterilization, etc. Unless firms are approved by these regulatory activities, agencies have the authority of serious interventions such as call backs, heavy fines, and judicial penalties.

3.1.4 Funding agencies

Funding is another important factor influencing the MDDD process in two aspects. Firstly, most companies, especially SMEs, need financial supports in order to carry out their R&D activities during MDDD. Thus, companies frequently apply to innovation support programs which are sponsored by either governmental institutions or private investment enterprises. Secondly, reimbursement is an essential topic to be considered in MDDD. The reimbursement possibility and share of support promised by social insurance institutes define the potential market of medical devices. A helpful case to illustrate this is iBOT, which is a powered wheelchair developed by DEKA Research and Development in 2001. The company developed this assistive technology device mainly targeting American veterans who returned from military service. Although the product was revolutionary in terms of using emerging technologies in the early 2000's, the company could manufacture the product for only six years. The main reason behind the discontinued product is the

fact that, in 2006 reimbursement agencies in America (Medicare) declared that features expected from a wheelchair can be utilized by other more available wheelchairs and iBOT will no longer be reimbursed by government healthcare budget. Announcement of Medicare has resulted with shut down of iBOT manufacturing and shareholders sought ways for saving their products by their NGO ("Save the İBOT," 2013). In 2016 DEKA Research and Development has started a cooperation with Toyota and the device is filed as a Class II device by FDA and the third generation of the device has been being manufactured since 2018.

3.1.5 Lay users

In terms of home use medical devices, lay users constitute another group of actors influencing MDDD. Considering the fact that home use medical devices are expected to be used by nonprofessional people such as patients, next-of-kin, and caregivers, the role of lay users change from being end users into operators of these devices. Thus, product development teams are in need for a revision of their perspective regarding use environment, and user typologies.

3.2 Turkish medical industry

In this topic, Turkish medical industry will be explored in terms of influential factors. Due to the lack of in depth resources about product development in Turkish industry, the topic is supported with interviews carried out with two industrial designers specialized in medical device design.

According to sectorial reports, medical industry is mostly composed of SMEs (TOBB, 2009). Firms operating in the industry can be divided into two groups as manufacturing firms and suppliers. In fact, large scale companies' workforces mostly consist of sales departments and distribution channels. R&D departments and product development teams of these companies cannot be regarded bigger than a medium sized furniture company's capabilities. The product range manufactured in

Turkey can be described as diverse. However, majority of the manufacturing is dealing with low-tech medical devices such as patient beds, oxygen tanks, nebulizers, disposable products, etc. In terms of funding, most companies are aware of support programs carried out by TUBİTAK and KOSGEB. In fact, share of medical projects in sum of TEYDEB innovation supports respectably increased between 2007 and 2011 (Bayhan, Karaca, Altay, & Kayalıgil, 2013). Reimbursement is mainly carried out by Social Security Institutions (SGK) in Turkey. Although complementary and private health insurances are increasing in healthcare economy, 78% of healthcare expenditures have been reimbursed by government budget in 2019 (TUİK, 2020).

In addition to data and information presented in sector reports, interviews also give clues about the Turkish medical industry. To get more in-depth information about Turkish medical product manufacturing industries, two interviews were carried out with senior product designers with expertise in medical device design with more than 10 years of experience of each. The first candidate has worked as an in-house designer in a global leading company in healthcare industry and at the time of interview was working as a freelance designer cooperating with national scale medical device manufacturers. The other designer has started and continues to cooperate with the manufacturers as freelance designer since the beginning of his career. The interviews were carried out in their offices and the questions mainly focused on their design processes. At the beginning of the interviews participants were asked to explain their career briefly. The interviews followed on with the exploration of their design processes. The designers were asked how they begin their design projects, how they acquire information about devices and manage their projects. The last part was mainly about the evaluation of the medical device manufacturing industry from their perspectives as a designer.

Firstly, both participants mentioned motivation for new product development as a counter strategy for dealing with issues related to intellectual properties. They argue that manufacturers are mostly followers who define their strategies according to new devices introduced by leading competitors. Participants express that companies

mostly deal with software development during the new product development process, because software development is more available and agile compared to engineering design. Thus, engineering design is mostly outsourced from foreign consultancies specialized in medical industry. Concerning requirement elicitation, participants mention that no fieldwork study or research are carried out in the briefing process. All ideas and suggestions for product improvements are gathered by informal meetings with healthcare professionals or companies' sale departments. Moreover, involving users in the design research phase is considered as requiring too much time for medical device design projects, which are expected to be completed between 2 and 3 months' time.

Both participants mentioned they begin their projects with a startup phase of understanding the illness and the device. Designers start their projects by transferring all required technical information to themselves. These technical information are mostly related with technical features of the devices, regulations related with approval of the device, and clinical needs mentioned by healthcare professionals. The reason for mentioning healthcare professionals is the fact that the designers are studying over development of medical equipment which are used by professional users. As mentioned earlier, intellectual properties play an important role in the process. Thus, designers carry out a market analysis that is generally structured on intellectual properties. During ideation phase one designer mentioned that he makes observations in clinical practices (e.g. surgeries). Designers continues their design process with improvements and revisions until the firm is satisfied with the new device design. Once the design process is detailed, firm continues with the approval stages in order to manufacture the product.

In addition to their design processes, one of the participants mentioned problems in the Turkish medical industry in terms of absence of long term strategies and its effect on the companies. Participant mentioned that manufacturers do not plan on long term goals and are not committed to the market. In other words, companies can shift to other markets very rapidly if they believe a better opportunity emerges. This

approach result with the lack of investments in means of production both in employment and manufacturing equipment.

3.3 Models of MDDD

Owing to product development being a highly case-specific process confronting unique obstacles and limitations, it is not possible to find a model of new product development that is capable of dealing with every possible scenario. All the same, engineering design discipline studies on developing models for product development is also valid for MDDD. Unfortunately, no study aiming to illustrate MDDD process in the case of Turkey could be found. Thus, studies carried out in foreign countries will be mentioned. Just as studies issuing other topics in healthcare, this subject is also explored mostly in Northern European Countries and US. As seen in Table 3-1, MDDD models aim to formulate the process in a structured sequence of steps including all necessary topics worth consideration. All these studies include main product development stages (i.e. concept generation, design detailing, design transfer, etc.) as well as specific topics that should be considered in MDDD (e.g. sterilization, regulatory approval, physician training, etc.). Alexander & Clarkson (2002) studied structuring MDDD process in terms of assuring continuous verification and validation in every step. Design verification and validation are frequently used terms in MDDD. Design verification means checking whether the design output (last detailed form of design prior to manufacturing) matches product features which are refined from the requirements elicitation process. Design validation means checking whether the design actually meets with needs in real life conditions. It is unfortunate to say that, MDDD teams are supposed to complete their verification stage in order to validate their design. In other words, product developers complete their design process in ambiguity related to whether they can apply for regulatory approvals or shift to manufacturing issues. In fact, this was the main motivation of Alexander and Clarkson.

As another point worth mentioning, Panescu (2009) refers to foundation as the initial barrier or issue which should be resolved prior to other activities carried out in the early stages of the process. The claim is also supported by other studies which mention budget as a major barrier against innovation in MDDD (Brown, Meenan, Dixon, Young, & Brennan, 2008; Pietzsch & Paté-Cornell, 2008 Medina, Jankovic, Yannou, & Okudan Kremer, 2013). In addition to investment barrier, intellectual property rights are another issue that influences companies' decisions over MDDD. On the one hand, companies have reluctance in decision making for the development of a new technology or product in sectors where intellectual properties have covered most of the possible options (Gold, Kaplan, Orbinski, Harland-Logan, & N-Marandi, 2009). On the other hand, existing patents referring to a particular medical product draw the attention of other companies to develop a different technology which would allow treatment in a better cost-benefit performance.

Table 3-1: Stages of selected MDDD models

	(Alexander & Clarkson, 2002)	(Aitchison et al., 2009)	(Panescu, 2009)
MDDD stages	Device User needs / Developing verification requirements for device validation	Feasibility: - Design input - Commercial Aspects - Planning - Regulatory Requirements	Founding Phase: - İntellectual property survey - identification clinical needs - regulatory approval & reimbursement strategy
	Device design / Developing design inputs for final device verification	Design Review: - evaluate design requirements - assess capability of the design - identify problems	Concept Phase: - product features & requirements specification - identification of potential risks
	Processing user needs / Developing verification requirements for process validation	Design: - Concept Design - Detail Design Design Verification: - Finite Element Analysis - Risk Analysis - Rapid Prototyping	Development Phase: - Product requirements elicitation - identification of potential risks for verification & validation - Developing prototypes
	Process Design/ developing verification requirements for design output/ verification of final processes	Manufacture: - Quantities - Surface finish - Cleaning - Sterilization	Verification and Validation Phase: - Testing lower & higher level requirements - Design revisions - Submission to agencies (clinical trials) & getting approvals
	Product development/ Design verification/ Qualification of final processes	Design Validation: - Mechanical testing - Clinical Investigation - Sterilization Validation Design Transfer: - Documentation - Surgical technique - Training - Packaging & Labeling - Master device record	Production Phase: - Scaling up & protecting requirement compatibility - Training of manufacturing employee - Verification of business requirements
	Medical device/ Design output	Design Changes: - Post-market surveillance - Documentation - Risk review	Market Release Phase: - Selection of appropriate countries - Training of users - Preparation of marketing materials - Development od post-market services

Table 3-2: Stages of MDDD models (continued)

	(Zenios, Makower, & Yock, 2010)	(Santos, Gazelle, Rocha, & Tavares, 2012)	(L. A. Medina, Kremer, & Wysk, 2013)
MDDD stages	Needs Finding: - Strategic Focus - Observation and Problem Identification - Need Statement Development	Idea creation: - Recognizing market opportunity - Assessment of the opportunity - Selection of countries to be commercialized	Product definition: - Clinical needs identification - Competencies analysis - Customer analysis - Market analysis - Technology analysis - Competitive analysis - Regulatory analysis - Intellectual property - Reimbursement strategy - Financial analysis - Product life cycle
	Needs Screening: - Disease State Fundamentals - Treatment Options - Stakeholder Analysis - Market Analysis - Needs Filtering	Concept development: - identifying customer's needs - competitive products & intellectual property analysis - financial feasibility - risk analysis	
	Concept Generation: - Ideation and Brainstorming - Concept Screening	Product design: - Concept generation - Setting final specifications - Design refinement - Material selection - Prototyping - Risk analyses - Design verification & validation	Design: - Design/development plan - Design inputs - Design outputs - Prototype developments & design analysis - Design review - Design verification - Design validation
	Concept Selection: - Intellectual Property Basics - Regulatory Basics - Reimbursement Basics - Business Models - Prototyping - Final Concept Selection	Manufacturing design: - Design transfer - Selection of manufacturing methods - Identifying suppliers - Designing supply chain - Production training	Risk management: - Risk identification - Risk analysis - Risk control - Risk monitoring
	Development Strategy and Planning: - Intellectual Property Strategy - Research and Development Strategy - Clinical Strategy - Regulatory Strategy - Quality and Process management - Reimbursement Strategy - Marketing and Stakeholder Strategy - Sales and Distribution Strategy - Competitive Advantage and Business Strategy	Regulatory approval and clearance	Production planning: - Design transfer - Process validation
	Integration: - Operating Plan, Financial Model - Business Plan Development - Funding Sources - Licensing and Alternate Pathways	Post- market activities - Post-market surveillance - Vigilance	Market introduction & post-launch: - Physician training - Post-market surveillance - Quality audits - Clinical validation - Product continuous improvement - Process continuous improvement

CHAPTER 4

METHODOLOGY

In the light of the literature review about medical device industry and MDDD process in terms of influential factors and stakeholders in the process, a field study is prepared to be made with lay users. The main research question of the study is what key points designers should take into account in the MDDD processes of home use medical devices. In order to understand the components of this question, the literature review is structured on the MDDD models and actors influential in this process along with related fields of studies and terminology used in these disciplines which designers should know in order to have a grasp on the issue.

In this section, methodological approaches applied in the process of the thesis are summarized. With this in mind, the stages are correlated with research questions mentioned in the introduction chapter. Following that, selection of the medical device with factors to be considered are briefly mentioned. The selection of the device is important due to its effect over availability of both experts and lay users in the first two studies of the research. Lastly, detailed information over sampling, data collection methods, study procedure and data analysis are explained.

4.1 Selection of home use medical device

In order to select a medical product which will shape the health conditions of participants and their availability, it is necessary to scan homecare products used for chronic conditions. Prior to scanning these products, a brief introduction to the classification of medical devices is also required in order to understand how to find information in terms of regulations and reimbursement, related to the selected product.

4.1.1 Classification of medical devices

Medical devices are classified in two perspectives in the medical industry. The first dimension of classification is the risk assessment of the product (Munzner, 2004). In this perspective medical devices are classified under either three groups in USA or four groups in EU according to their level of risk factors. The classification principles of FDA are illustrated in Table 4-1 providing clearer instructions of risk levels. This approach in classification is important due to changes in user testing requirements concerning safety regulations in the approval process of the devices. The second classification deals with the task-oriented grouping of devices. It is not helpful to illustrate a full list of UNSPSC (United Nations Services and Products Standard Codes) in this survey. Thus, the classification of a specific product is illustrated as an example in Table 4-2. As well as being useful for understanding the comprehensiveness of medical products, this classification is mostly used for contracting in wholesales and bidding. In Turkey, a derived version of this list which is called SUT (Sağlık Uygulama Tebliği) is used for almost the same purpose. In addition to mentioning the classification of medical products, it also gives information about requirements expected from each medical device and procedure of reimbursement.

Table 4-1: Classification of medical devices in FDA

Class I	**Class II**	**Class III**
General purpose medical devices with low-level risk. (tested for labeling, sterilization, manufacturing requirements)	Medical devices with medium-level risk requiring specific controls. (tested for safety and effectiveness in use context in addition to class I tests)	Medical devices with high-level risk requiring premarket approval. (tested in clinical trials and approved by an advisory panel)

Table 4-2: Classification of medical devices in UNSPSC

UNSPSC 42000000	**UNSPSC 42210000**	**UNSPSC 42212100**	**UNSPSC 42212105**
Medical Equipment and Accessories and Supplies	Independent living aids for the physically challenged	Leisure and recreational aids for the physically challenged	Camping equipment for the physically challenged

4.1.2 A suggestion of classification in user-environment perspective

As mentioned in the previous section, the existing classification methods are useful for regulatory approvals and purchases. In order to explore product specific dimensions, which can be helpful for product designers during product development, a new classification is attempted in this section. As seen in Figure 4-1, the dimensions for classification are use environment, type of user, and period of use. In the matrix no specific product example could be found to be used by nonprofessional users in healthcare facilities due to the fact that no nonprofessional person, be it patient or patient relative, is encouraged to interact with medical devices. Mostly by means of enabling technologies, products are simultaneously positioned in different clusters in this classification.

Figure 4-1: Clusters of new classification suggestion with product examples

To illustrate, hemodialysis is one of the candidates for home use medical devices which is helpful for emphasizing the change in the use environment. Although serious accidents are documented in FDA records, manufacturers and patients are supporting the development of new products targeting home use. While hemodialysis was a specialist medical technology in the mid-20th century, now patients with kidney failure can afford purchasing their private devices. As seen in Figure 4-2, home hemodialysis is a medical device expected to be used in bedrooms due to long periods of use and required comfort and posture of the patient. It is obvious that the product is not blended in domestic context and moreover, the components of the product are not different from those used in healthcare facilities. To sum up, product designers have many issues to deal with for this kind of medical devices.

Figure 4-2: Home hemodialysis developed by NxStage
(downloaded from:
http://upload.wikimedia.org/wikipedia/en/f/ff/HomeDialysisNxStage.jpg)

Another example for emphasizing the change in user typologies is wheelchairs. Specific types of wheelchairs show us that predefined user typologies have impact on product design (see Figure4-3). In healthcare facilities, wheelchairs are expected to be used by caregivers or nurses rather than patients. If we exclude these use environments, wheelchairs can be used by all user groups. To illustrate, active wheelchairs, which are designed considering environmental conditions and activities carried out by more active users in outdoor conditions, are apparently different from ordinary manual wheelchairs in the market. They have no handle to be pushed or the balance of the wheelchair is improved with angled positioning of the wheels. In addition, material choices in active wheelchairs emphasize the importance of lightness more frequently compared to other kinds of wheelchairs. Introduction of new technologies also have influence over the capabilities of patients. For instance, powered wheelchairs help patients to use their products in different environmental conditions and introduction of new controls in these products allow paralyzed patients to use wheelchairs with their mouth without the help of a relative or a healthcare professional.

Figure 4-3: Different types of wheelchairs
(From left to right downloaded from: https://www.mobilitysmart.co.uk/folding-heavy-duty-extra-wide-steel-wheelchair-with-attendant-brakes-20-seat.html, https://wheelchairassistance.com/manual-wheelchair/mobility-scooter-vs-manual-wheelchair.php, https://wheelchairassistance.com/power-wheelchair/power-wheel-chair-battery-charger.php)

Another product group in this classification is non-medical products which are also servicing healthcare issues. Most of these products can be defined as consumer electronic products that are used for health monitoring or preventive health in addition to their main tasks. These products are helpful cases for product designers to figure out the role of engagement in medical devices. Although the main aim of these products is not structured on medical purposes, these products can be regarded as more successful than home use medical devices in terms of adaptation to home use context and domestic life. Two of the successful cases in this concept are entertainment consoles and training monitoring products. The first example is Nintendo Wii, which is a game console that has introduced new ways of interaction in console games. Now Wii Fit (see Figure 4-4) defines a new market for Nintendo users, enabling them to use the product for healthcare objectives, such as body mass analysis, balance trainings, and cardio exercises. Wii Fit proves that gamification theory can help designers to develop more engaging medical products. The second example is Nike Plus, an application developed by Nike for increasing motivation, and monitoring of training sessions. In addition to monitoring users' training performances, the application also allows sharing their data and experiences in social networks. The sharing feature of the app is an excellent example for social/interpersonal technologies mentioned in positive technology studies.

Figure 4-4: Nintendo Wii Fit
(downloaded from: http://www.nintendofeed.com/2013/11/news-shed-pounds-with-other-nintendo.html)

4.1.3 Exploration of medical devices used in homecare context

The research subject is structured on the concept of home use medical devices which are intended to be used by lay users (i.e. patients, next of kin and caregivers) in homecare. Therefore, home use medical products (including both devices and disposables) are sorted according to their use context as illustrated in Appendix A. According to this, home use medical products are found to mainly focus on patient needs such as bedding, respiratory ventilation, mobility, hygiene and monitoring. After an analysis of these home use medical products, medical device manufacturers located in Ankara region are listed and narrowed down into companies manufacturing any home use medical devices due to the requirement of selecting a medical device currently used in home context (see Appendix B). Due to the fact that absence of prototypes or product samples is mentioned as a barrier against user studies on healthcare (Money et al., 2011; NHS, 2010; Shah, Farrow, & Robinson, 2009), devices that are available for purchase in Turkey and reimbursed by SGK are prioritized.

As well as the availability of the selected device, maintenance and companies with adequate technical knowledge are also necessary for the practicality of the fieldwork. Thus, companies' product ranges are re-evaluated. Parallel with prior analysis of

home use medical devices in Appendix B, respiratory assistive devices (i.e. CPAP, BPAP, nebulizers, ventilators) also constitute a common product family for manufacturers and services in Ankara region. As a result, respiratory assistance devices are selected for the case study.

4.1.3.1 Home use respiratory therapy devices

Respiratory assistance devices compose a major product line for medical device manufacturers. These devices aim for both home (personal) use and hospital (professional and shared) use, and should answer requirements of these different profiles and environments. Devices used in respiration therapies are illustrated with their description in Table 4-3.

The experience of patients receiving home mechanical ventilation therapy is mostly emphasized in nursing, respiratory and compliance literatures. Among the patient profiles, children and infants draw a specific attention in terms of stressors for transition from nursing homes to homecare context (Kingston, 2007), the responsibilities and relations between family members (Lindahl & Lindblad, 2011; Manhas & Mitchell, 2012) and children's own experiences about being dependent on a medical device (Sarvey, 2008). Additionally, other studies in nursing literature also analyze relationships between professional (nurses and caregivers) and non-professional actors (parents, siblings and other family members) in terms of transition to home context (Huang & Peng, 2010; Kingston, 2007), and emergencies (Costello & Almodovar, 2007; Noah & Budek, 2007).

Table 4-3: Home use medical devices for respiratory therapy

Product name		Product description	Renewal period
Aspirators		A suction machine used for removing fluids preventing respiration comfort.	Once
Nebulizers		A device for transforming liquid drugs into mist form for respiratory therapy.	Once
Oxygen concentrators		A device generating purified oxygen for therapy which is a replacement for oxygen tubes.	Once
Pulse oximeter		A device for monitoring oxygen concentration in patients' blood.	Once
Non-invasive mechanical ventilation devices	CPAP	A device which keeps airway open with continuous positive air pressure for breathing problems.	10 years
	Auto CPAP	CPAP device with an adjusted pressure according to patients' respiration level.	10 years
	BPAP	Using two levels of pressure and continuously changing according to patients' respiration pattern.	10 years
	BPAP ST	A device which also probes patients to breathe in a pre-set amount of time.	10 years
	ASV	A device, which is used for treatment of central sleep apnea and congestive heart failure, calculating advanced air pressure algorithms.	10 years
Invasive mechanical ventilators		A device used for permanent respiration failure with a tracheostomy tube.	5 years

However, in these studies, non-invasive mechanical ventilators are not mentioned as an actor in this network and no problems or side effects resulting from the device are included. Additionally, none of these studies starts with an in-depth analysis of daily practices or routines while most of them have direct relation with patients' adherences. Therefore, none of these studies has a clear answer as to the differences occurring due to the material features of these devices. In other words, the impact of these devices on the lives of patients and related actors is absent in these case studies. Among these devices, CPAP and Auto CPAP are selected as the subject for the study due to more frequent use resulting from increased rate of people diagnosed with obstructive sleep apnea.

4.1.4 Conditions of patients using CPAP devices

CPAP devices are commonly used by obstructive sleep apnea (OSA) patients. OSA can be defined as difficulties experienced during breathing due to physical blockade in upper airway. OSA can result from various reasons, such as obesity and anatomic factors narrowing upper airway (McNicholas, 2008).

In addition to poor quality of sleep, patients experience physical health problems such as increased risk of heart failure, cardiovascular problems, and hypertension. As well as these physical problems, physical conditions resulting from OSA such as increased fatigue, daytime sleepiness, and lack of alertness lead to other health problems beyond physical conditions of the patients. For instance, OSA affects the mood of the patients resulting with changes in patients' daily lives and behaviors. According to Aloia & Bruce (2007), depression and anxiety are widely encountered as a mood disorder among male OSA patients which leads to problems in social relations, work life, cognition and quality of life.

In addition to mood disorders, neurological results of OSA also effects patients' daily lives in terms of neurobehaviors which means behaviors that are directly related with neurological capabilities of people such as speech, motor skills, cognitive functioning. In terms of these behaviors, researchers focus on high risk activities due to lack of alertness and problems with motor skills. Especially probability of accidents at high risk working activities and driving is found to be two times more common among OSA patients (Garbarino, Guglielmi, Sanna, Mancardi, & Magnavita, 2016). Besides accidents, cognitive impairment resulting from dysfunction of frontal cortex of the brain, has negative effect on patients' memory related tasks, speech fluency and goal oriented activities, which can greatly affect patients' work lives and performances (Aloia & Bruce, 2007).

Lastly, knowledge and awareness of OSA patients about sleep apnea is another factor which shapes CPAP treatment. In spite of increasing number of people using CPAP devices and healthcare facilities specialized in sleep medicine, the misjudgment over

symptoms of OSA results with low ratio of diagnosed patients. To illustrate, snoring is widely encountered in the public and still considered as a joking matter. Besides, other symptoms such as fatigue and lack of sleep, are mostly connected with stress and intense business schedule rather than a health problem. Along with symptoms, patients' lack of knowledge about OSA also affects their adherence to treatment. Degrading the treatment and monitoring procedure into sleep time, and quality, misses the effect of mood disorder, particularly depression and anxiety over CPAP adherence. However, dealing with CPAP treatment as an interactive process between a medical product and a user with adequate feedback and a stimulating activity would shape the treatment into an enriched experience rather than an obligatory daily task.

4.2 Stages of the study

With the aim of proposing strategies for design research with end users in MDDD, the research is proposed to be carried out in five stages as illustrated in Table 4-4.

In Stage 2, research methods used in MDDD projects are explored and compared with potential design research methods applied in both professional and educational projects as aforementioned. Design research methods are also evaluated in terms of their practical and ethical barriers.

In Stage 3, companies manufacturing medical devices are analyzed and selected according to their product lines. Following, home medical devices manufactured in Ankara region are classified (see Appendix B) and companies are interviewed about their project processes and problems.

In Stage 4, a pre-sampling step is carried out with a short phone interviewing about the availability of the participants. This stage is necessary for understanding if any barrier exists against conducting a fieldwork with end users. Once the sampling criteria are set and participants are defined, a pilot research was necessary for testing feasibility of the fieldwork in terms of clarity of questions and scales.

In the final stage, the findings extracted from the fieldwork are analyzed in terms of their quality of content and main features of these materials. This analysis is transformed into a guideline including tips and comments about the key points in development of home use medical devices.

Table 4-4: Stages of the research with research questions

RESEARCH STAGES		RESEARCH QUESTIONS		
LITERATURE REVIEW	**Analysis of current situation in healthcare**	- Which stakeholders affect requirements elicitation of home use medical devices? - What is the role of end users in the MDDD process?	Biomedical Engineering & design literature	**RELATED LITERATURES**
	Understanding tools and methods employed for user research in the MDDD process	- Which design methods are already adopted in MDDD? - What kind of user information is sought by industrial designers in MDDD projects? - What are the barriers for industrial designers in terms of user research in MDDD?	Human factors & assistive technology literatures	
	Exploration of ways for integrating design research methods in the MDDD process	- Which characteristics of end users would affect selection of design research methods? - How do requirements of design research methods affect their viability in the MDDD process?	Healthcare research & design research literatures	
FIELD STUDY	**Study 1**	- What are the characteristics of CPAP lay users? - What are the constraints with regard to medical therapy in CPAP design?	Semi-structured interviews	
		Data analysis method: Content analysis		
Discussion & conclusion	- Which strategies can be followed by designers for design and development of home use medical devices?			

4.3 Literature review

During the literature survey of the thesis, various disciplines, which can present useful sources for structuring a brief bridge between industrial design, healthcare research and MDDD, were explored. Among research fields illustrated in Figure 2-1, human factors studies, healthcare research, design research and biomedical engineering have been found to be the most prominent research fields providing both required case studies and theoretical frameworks. Along with that, keywords were selected under main categories and searched in various online databases, as presented in Table 4-5. In addition to sources reached via online databases, sources in their references and later studies with cited selected publications are explored in Google Scholar search engine.

Table 4-5: Keywords and databeses used in literature review

Utilized keywords during literature search	
"medical device development / design" +methods, +regulations, +home, +user testing "homecare" "home use medical device" "CPAP" "user experience" "patient experience" "patient adherence / compliance" "design research" "user studies/research in healthcare/medicine" "healthcare research" "assistive technologies"	
Electronic online databases used through literature survey	
IEEE Xplore Digital library	ScienceDirect
EBSCOhost Databases	Medline
JSTOR	Springer Link
Wiley Online Library	BioMed

4.3.1 Analysis of current situation in healthcare

In order to illustrate the real life conditions of MDDD, previous studies focusing on the MDDD process models (Aitchison et al., 2009; Alexander & Clarkson, 2002; L. A. Medina et al., 2013; Panescu, 2009; Santos et al., 2012; Zenios et al., 2010) are explored. Studies over capabilities and features of Turkish medical companies are focusing on their innovation capabilities (Eren, 2010), and sectorial reports.

Unfortunately, none of these studies aim at illustrating the MDDD process within Turkish companies. Aforementioned process models mainly focus on practical issues to be addressed during engineering design of the medical devices. Stages of the MDDD process can be divided into two groups. The first group includes product development stages (i.e. concept development, design detailing, process design, etc.), which are also commonly carried out in other manufacturing sectors. The second group is composed of more specific and mandatory stages in MDDD (e.g. sterilization, regulatory approval, physician training, clinical testing). Although these models are helpful for companies to state a structural MDDD process, they are not useful for design researchers about integrating user studies in MDDD as design inputs.

4.3.2 Understanding tools and methods employed for user research in the MDDD process

Human factors studies and healthcare research literature are more appropriate for exploring user studies in MDDD compared to biomedical engineering case studies mentioned in the previous section. However, studies in these areas are dominated by a consensus over a number of research methods as illustrated in Table 2-4. These methods are also used in various research areas, the output of these studies result with stereotypical materials for product development teams as themes to be considered in the design of healthcare services.

As mentioned in the background of the proposed research, these stereotypical materials are composed of design guidelines and checklists. However, these materials are useful in problem-driven design approaches that focus on definition of unmet problems, and they depend on users' insights. Moreover, these themes are problems mentioned by participants which still need to be verified by participants repeatedly in iterative design ideas developed by MDDD teams. Therefore inspirational materials as images and 3D mock-ups directly generated by end users

as design inputs to be utilized in early iterative design ideas by industrial designers can be stated as missing for a possibility-driven design approach.

In addition, this kind of information is not emphasized in previous case studies in MDDD. In this perspective, direct intervention of end users receiving homecare in MDDD can be compared with collaborative design case studies in assistive technology literature. All the same, the participation of this user group is absent due to the lack of activist members among homecare patients.

4.3.3 Exploration of ways for integrating design research methods in the MDDD process

Although data collection methods are evaluated in terms of their expected outcomes, it should be considered that these case studies are mostly carried out from a heuristic evaluation perspective before clinical trials. Thus, specific conditions of end users should be analyzed in both physical and psychological contexts. These conditions will be mentioned in more detail, in participant selection for the research. Additionally, requirements for specific design research methods should also be addressed in the selection of the data collection method. To illustrate, some of the remote monitoring methods illustrated in Appendix A (i.e. Wizard of Oz) mainly depend on the use of technologies enabling remote access such as the Internet.

4.4 Pilot study

Before executing the main study, a preliminary study is required for better understanding the barriers and potentials for industrial designers in terms of *medical barriers* (the boundaries in medical treatment of Obstructive Sleep Apnea), *information infrastructure* (how actors interact with products), *user experience* (how users express their experiences with their CPAP devices), *comparison between hospital and home use contexts* (the similarities and differences between hospital and home use), and *priorities of development* (how stakeholders' priorities and

expectations differ or overlap on future CPAP devices). This information was helpful in the construction of a frame for designers to map potential design contribution fields and their relations. In the pilot study, the items in SEMSA scale about the private life of the participants are excluded for avoiding the possibility of participants getting uncomfortable.

CHAPTER 5

FIELD STUDY

In this chapter the field study is explained which is carried out with CPAP users with different experience levels. Age, education and technological literacy give important clues about the differences between participants' reactions against CPAP treatment. This chapter includes development process of the field study in terms of aim of the study, participant selection, data collection method and design of the survey as questions and scales used in the study.

5.1 Aim of the study

Main aim of the study is exploring patients' experiences in CPAP treatment and defining key points for designers to address in MDDD processes of home use medical devices. In order to achieve this aim, the study focuses on patients experiences in the early use phase of use, problems they encountered and changes happened in their lives. The survey is composed of both qualitative and quantitative data for enabling measuring the problems in patients' lives and underlying factors contributing to these problems.

5.2 Participant selection

The participant selection in the field study is composed by CPAP users from various ages, education levels and backgrounds. The majority of the participants are male due to two reasons. First reason is the fact that OSA is chronic condition that is shared more common among men. The second reason is the problems regarding the availability of female users mentioned in the limitations of the study.

The experience levels of the participants varies from ones in very early use phase (less than six months) to users who have achieved adherence process (longer than 5 years). The reasons for selecting participants with different experience levels in terms of use time can be explained in two issues. The first issue is users with different experience levels enables to make comparisons between the perception and users reaction against the treatment. The second issue long term users can make comparisons between devices and components with the help of their experiences with other products and can mention the problems resulted from long term use of products such as maintenance and cleaning.

5.3 Data collection method

The study is mainly designed as a semi structured interview. In majority of the study, questions are shaped in multiple choice forms with fill in the blanks sections that enable participants to refer to additional actors or factors not mentioned in the format. In addition to multiple choice questions, yes / no questions are followed by open-ended questions that seek in depth information about the underlying reasons. Questions, especially those referring to social context of CPAP treatment, are formed in open-ended format.

In addition to the aforementioned methods, four existing scales about user experience of CPAP use and users perceptions regarding CPAP treatment (UEQ, SEMSA, ACTI, and CHI-5) are utilized in the study which are explained in section 5.4.

5.3.1 Scales developed for user studies in sleep medicine

Before execution of the pilot study aiming to understand the relationship between actors during diagnosis, use of CPAP, maintenance, and effects of CPAP treatment on patients' and their relatives' lives, it is necessary to scan existing scales developed in sleep medicine. Due to the extensive range of scales developed and used in sleep medicine being explained in Shahid, Wilkinson, Marcu & Shapiro (2012), the book

is used as a guide for studying methods, target groups, and aims of the scales. The scales are not narrowed down into scales specific to sleep apnea because of the fact that most patients are without a diagnosis before their first visit to physicians. Before the diagnosis, all patients are asked about the symptoms and their complaints such as fatigue, daytime sleepiness, and lack of alertness in addition to their health conditions, such as the duration of sleep, sleeping hours, body mass index, and age; which are shared in most sleep disorder complaints.

In terms of target groups in sleep medicine, two major groups draw attention which are children (participants below 18 years old) and adults (participants older than 18 years old). This division results from both the ethical reasons and enabling ease of understanding for under age participants. In addition to division based on age ranges, diseases (i.e. sleep apnea, insomnia, restless leg syndrome, psychiatric disorders, cancer) and symptoms (i.e. sleepiness / alertness, fatigue, morningness / eveningness) are other factors shaping target groups into more specific populations (see figure 5-1). Although the scales ask questions about the shared symptoms in most sleep disorder conditions, some of these scales do not originate from sleep medicine. The inclusion of the questions or sections about sleeping habits and problems in the studies is for either learning about the effects of some diseases on sleeping habits or avoiding confusing sleep disorders with other health problems.

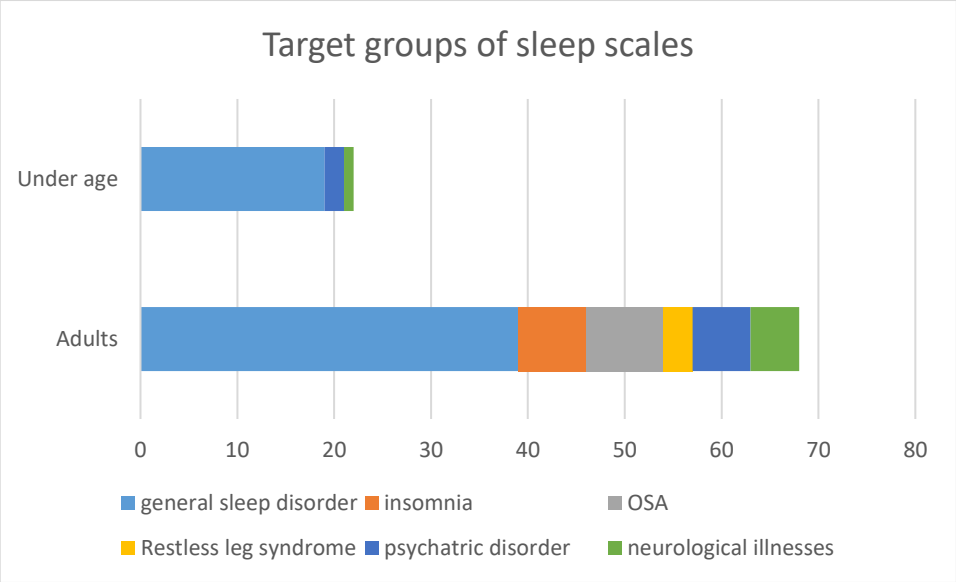

Figure 5-1: Target groups of sleep scales

In terms of the content of the scales most of the scales start with questions about patients' sleeping habits such as their sleeping hours, amount of daily sleep, daytime alertness, falling asleep, tendency to wake up and other sleep related complaints. These questions are mainly linked with participants' quality of sleep and are necessary for diagnosing sleep disorder problems.

Another content group is the effect of sleep disorder on daily functioning. In these studies, participants are mostly asked for these effects in a broad sense with brief questions. In a few of them, some of these daily activities are prioritized due to their high risk of falling asleep such as during driving and watching television, or their effect on their social life such as work life, sexual life, emotional state, and exercising.

Among these scales, that of Flemons & Reimer (1998) is more specialized in the exploration of daily life. In the scale, daily life is grouped into daily functioning, social interactions, emotional functioning, symptoms, treatment related symptoms and impact. In daily functioning, daily activities are divided into most important daily activities (e.g. work, school, housework, child care, etc.), secondary activities

(e.g. leisure activities, etc.), and general functioning (e.g. concentration, alertness, and memory). In social interactions, participants are asked how much they are interested in and how they feel when they are interacting with their family or close friends. In emotional functioning, participants are asked about how frequent they feel negative emotions such as depressed, angry, and frustrated; and how much they are concerned with weight and heart related health problems. In the symptoms section, widely known sleep disorder symptoms are listed. Lastly, side effects of CPAP treatment are listed and measured in terms of their tendency to cause a problem. Although the study is the most in-depth approach towards daily life, none of the scales aim to develop a scenario representing participants' daily lives.

In addition to content and target group of the scales, data collection methods are another factor worth mentioning. Almost all of the scales in the book are subjective measures meaning that patients are expressing the degree of their complaints and level of symptoms. Compared to objective measures that are carried out in sleep laboratories, subjective measures are useful for conducting studies with participant groups in higher numbers. Due to the nature of subjective measures not being solely dependable in clinical practice, researchers suggest the use of these scales as a former step before conducting sleep laboratory tests. Methods employed in the scales are mainly composed by various Likert scales (85 out of 102 scales). Other methods following these are yes / no questions (11 out of 102 scales), multiple choice questions (9 out of 102 scales), fill in the blanks forms (4 out of 102 scales) and visual analogue scales (4 out of 102 scales). Similar to multiple choice questions and Likert scales, fill in the blanks question templates are used for measuring and assessing participants' sleep duration and bed times which can be translated into numerical values. In order to reach a high number of participants and transforming research findings into statistical measures, open ended questions are very rarely used or even avoided.

5.4 Design of the survey

As explained in data collection section, the survey study is prepared as a semi-structured interview which makes use of both open ended questions, multiple choice questions and existing scales assessing CPAP use experiences.

In order to clarify CPAP users' experiences in the whole life cycle of the product, the survey is explained in six sections (see Appendix E).

5.4.1 Participant information

The survey starts with a brief information about the demographics of the participant. In addition to common demographic values such as age, gender, profession, and education level, the participant is asked about time period of their CPAP use, brand and life time of their current and if possible previous CPAP devices. At this stage, it is not possible for all participants to recall the brand or model of their devices. Thus, an extra catalog including visuals of all CPAP devices which are available in Ankara is prepared (see Appendix E).

5.4.2 Purchase of the device

After a brief greeting with the participant, the survey continues with their experiences during purchase of the device. At the beginning the participant is asked whether they purchased a brand new device or a refurbished one. Following that, actors and factors which helped or affected their decision stage are questioned.

5.4.3 Early learning stage of the device

In this section, participant is asked questions about how he/she managed to learn the device. Due to learning curve being an important topic for both safety and adherence of medical devices, it is important to learn how users deal with problems such as

confusion during use, maintenance, and device set up. In addition, the effect of CPAP use on participant's daily life is asked to mention.

5.4.4 Use experience of CPAP device

At this stage of the survey, users' overall experience regarding the CPAP device is assessed by using the User Experience Questionnaire (UEQ). UEQ is developed for assessing user experiences under six domains including not only traditional usability concerns titled as attractiveness, perspicuity, efficiency and dependability, but also hedonic qualities of the user experience mentioned as stimulation and novelty (Laugwitz, Held, & Schrepp, 2008). These six domains of user experience are measured by using seven point Likert scale for 26 items expressed by two opposite adjectives on extreme ends of the scale. According to the developers of the scale, the survey is applicable for 20 to 30 participants as long as internal consistency (Cronbach's Alpha) is high.

5.4.5 Effects of CPAP use in daily life

This section of the survey starts with two existing scales followed by open-ended questions. The scales used in this section are self-efficacy measure for sleep apnea (a.k.a. SEMSA) (Weaver et al., 2003) and the attitudes to CPAP treatment inventory (ACTI) (Broström, Ulander, Nilsen, Svanborg, & Arestedt, 2011). During the interview part of this section, participants are asked about how CPAP treatment changed their life concerning their social relations and privacy of their CPAP use.

SEMSA: Self efficacy measure for sleep apnea

The scale is developed as a self-administrated questionnaire for measuring factors which affect the adherence possibility of CPAP treatment. Rather than the barriers frequently mentioned with OSA, the scale divides the factors affecting the adoption of CPAP use behavior into three groups called risk perception, outcome expectancies

and treatment self-efficacy. In risk perception, participants are asked about the degree of likeliness of negative results of having OSA without CPAP treatment such as falling asleep while driving or difficulty in concentration. In the second group, participants evaluate the positive outcomes of having a CPAP treatment. In other words, how much CPAP treatment reduces the risks mentioned in the first group. Finally in the third group, participants are asked to what extent they can withstand barriers or side effects of CPAP use. The scale is formed in four point Likert scale ranging from 'very low' to 'very high' and 'false' to true'.

ACTI: Attitudes to CPAP inventory

The second scale used in this section of the survey is developed for understanding the likelihood of participants' adherence to CPAP treatment. Brostörm et al. (2011) developed this scale by conducting interviews with adherent and non-adherent patients along with a brief literature survey about adherence to CPAP treatment. Following that the findings are discussed with a group of medical experts composed of physicians and nurses experienced in CPAP treatment. As a result, the scale is formed under five items measured by 5 point Likert scale ranging from 1 point (completely agree) to 5 points (completely disagree) resulting with scores between 5 to 25 points, such that higher scores mean low possibility of long time adherence to CPAP treatment.

5.4.6 Daily use of CPAP and adherence to CPAP treatment

The section asks participants the frequency and duration of use of their CPAP devices. The frequency of use is important for understanding the level of adherence to CPAP treatment because there is no objective measure for the term 'regular use' of a device among patients. In other words, two patients can both describe their CPAP use as regular, while one uses every night and the other may use once every three days. In addition to use frequency, environment of use is another topic to mention during the interview because side effects of CPAP treatment can also affect

the daily use of the device. To illustrate, the noise problem resulting from the electric motor of the device can lead to separation of beds for couples. One last topic mentioned in the interview is how CPAP users store their devices, which can give designers an idea about patients' habits of use. In addition to the interview part, CPAP Habit Index-5 (Broström et al., 2014) is used in order to understand how much the habit of use is parallel with other measures of CPAP adherence.

The survey concludes with two questions. The first one asks participants whether they have any further recommendations or wishes from their CPAP devices. The last question asks participants to rank the most important features of the devices to focus on during the design of future products.

5.5 Data analysis

This section explains methods used for the analysis of the survey. Two separate analysis approaches are employed because both qualitative and quantitative question kinds are used during the survey. These two different data types are adopted in the survey because the quantitative data allows the separation and classification of participants while the qualitative data enables capturing enriched data which shows underlying threats against adherence and problems regarding the existing devices. Moreover, the quantitative data is not always helpful for acquiring unexpected feedback from participants while these new data can still be transformed into statistical measures.

In the qualitative data analysis, the interviews are evaluated by applying content analysis (Scott, 2006). The open ended questions are firstly transcribed and divided into meaningful phrases. After completion of the transcription phase, these phrases are transformed into excel sheet forms and then coded with keywords. The keywords are listed in a separate excel sheet and grouped under sub categories which are later grouped under main categories. These codes are helpful for assessing the frequency of their use which are connected with their quantitative analysis.

In the quantitative data analysis, Likert scale is the main question type employed along with fill in the blanks and multiple choice ones. At the beginning of the analysis, the survey answers are transformed into separate excel sheet as values for each participant. Likert scale questions are analyzed by calculating the mean and median values in order to understand common evaluations of the participants.

CHAPTER 6

FIELD STUDY FINDINGS

In this chapter, findings of the field study are first explained and discussed in the structure of the field study material. Following that, the findings are grouped under general themes that explain important topics for MDDD for home users' perspective. The quotations in this section are translated from Turkish surveys.

The findings are generated from 30 participants using different CPAP devices with different demographic backgrounds. In addition to different education levels and differences in the abilities regarding use of technological products and software, participants are in different stages of learning curve and period of use ranging from one month to 15 years, which affects their attitude and experiences.

6.1 Participant demographics

Participant demographics include age, gender, education levels, computer / internet use and period of CPAP use. Among these dimensions two of them can be regarded as more influential compared to the others, which are education level and period of CPAP use.

6.1.1 Gender

In terms of gender, 27 of 30 participants are male. The dominance of the male participants could have resulted from two reasons. The first reason can be traced to male researchers' barriers against having field studies with female participants. The second one is the more common male population among OSA patients. Lin et al. (2008) show that OSA is more common among males. In addition, Young et al. (1996) question whether evaluation of OSA is appropriate for both male and female

and results with the fact that predictors, and symptoms are parallel in both male and female users. However Young et al. (2008) claim that the symptoms and severity of OSA change accordingly among men and women. The severity of OSA among male patients results with symptoms of snoring and daytime sleepiness. However, the symptoms of female patients are described as insomnia, depression, restless legs, nightmares, hallucinations, and palpitations. Thus, female OSA patients can be diagnosed with different conditions such as depression or hormonal disorder.

6.1.2 Age

Participants' age range changes from 34 to 67. Seven of the participants are in their 30s, eleven of the participants are in their 40s, eight of them are aged in their 50s and the remaining four participants are in their 60s. It is fair to say that age ranges in OSA studies are mentioned as much older. However, it is also mentioned that male OSA patients above 40 constitutes a large portion of the patient population with mild-to-severe conditions. Moreover, OSA can even be seen in patient groups aged in their 20's.

6.1.3 Education

Majority of the participants in the study (23 out of 30) has an undergraduate degree education from various disciplines, and 5 participants have a high school degree and last 2 of the participants have graduate degree level education. Although it is easy to mention that participants with high education levels are more equipped with finding information sources regarding early learning curve, the abilities of the participants are caused by not only the education level but also can be linked with other capabilities that are gained during this stage of their life. Firstly, participants who know a foreign language (preferably English) can use original files of the manufacturers or international user forums as a source of information, while others are using information sources in Turkish. This difference does not only affect

experience in the early stages of use but also affects their habits and preferences in the later stages regarding the purchase of product accessories and consumables. The importance of knowledge of foreign language can be illustrated by P1's problem regarding the early training of the device. The participant mentioned that he could not acquire a user manual with the device and searched the internet for one in Turkish but could only find an English version that he could not read.

6.1.4 Period of use

Another important factor differentiating participants' attitudes and experiences is their period of use. At early stages of learning, users confront difficulties in terms of acquiring adequate knowledge on product adjustments and controls along with ergonomic problems concerning sleep comfort of both the user and their partners. In other words, once users adapt to use the device properly, their reflections against the device and treatment change accordingly. Seven participants are in their first year of use and six participants have been using their device between one to two years. Eight participants have use experience between two to five years. Five participants are using their devices for more than five years and remaining two participants have more than 10 years of experience in CPAP use. However, participants, who experience a dramatic change in their sleep quality and related issues due to the severity of their conditions, show positive attitude and gratitude towards the treatment.

In addition, participants who have used the device for longer than 10 years could compare their devices with their previous ones. Different from these two participants, P11 can also make comparisons because he has two different devices. He has purchased an extra device that is more portable to use during his trips. Although the remaining participants do not have another extra device they also made judgements about other devices in terms of the impressions they experienced in the product selection phase.

6.2 Product selection and purchase

Product selection and learning experiences are affected by reimbursement procedures of SGK. In the field study, 5 participants have purchased their CPAP devices among the returned ones to the SGK headquarters. The remaining 25 participants have purchased brand new devices. P11 mentioned that he waited especially for a week to avoid purchasing one of those because if there is any refurbished device available in SGK, patients are expected to use that device rather than purchasing a new one. Otherwise users cannot get their reimbursements from the social insurance fund that covers a considerable amount of product price. In terms of product selection, the reimbursement policy limits patients to buy their preferred devices unless they get a written notice that informs them there is no refurbished device available.

The reasons for purchasing a new device are mostly due to hygiene concerns (19 of 30 participants). Although users can purchase new masks and hose to use with their used devices, participants in general do not feel relaxed with using a pre-owned device. Moreover P17 mentioned that the office for refurbishing devices in SGK also gives a negative impression about the hygiene of the product. He stated that "the room is not different from an ordinary electronics workshop. There are no sanitizers or anything."

In addition to the hygiene concerns shared by the majority of the participants, P17 mentioned the negative impression of using a deceased person's device. The device may return to the SGK in two ways. The first scenario is the lack of use of the device by the patient. According to the regulations, patients are expected to use their products at least 1200 hours in a year. Although none of the participants mentioned a concern about this enforcement, it is possible for SGK to take devices back from patients who do not use their devices properly. The second scenario is the return of the devices which used to belong to departed people. Although it is rational to make use of these devices in good conditions, it is not very easy for users to adapt to this idea. P17 stated his concern about this issue as "I don't know how the previous user

used the product. Moreover, he may have had some infectious disease or anything. Sleep apnea is most probably not the reason."

6.2.1 Actors influential in product purchase

The source of knowledge is important in users' overall experience in terms of the early stage of device use and product purchase. Users seek information about the device and hints for selecting the most appropriate product for their treatment. Unfortunately, the findings point out some problems regarding guidance in the product selection process. Actors who have a role in this process are briefly explained in the following.

Doctors

Six participants mentioned doctors as a source of information in the product selection process. However, the doctors are not mentioned as the most influential actor in the product selection process due to various reasons. The most obvious reason is being too general. P4 mentioned his doctor's product suggestion related to product origin as "...doctor told me to avoid Chinese products and to choose one of the well-known brands." Although this is a valid suggestion, it still requires market research. Another problem in this suggestion is the fact that medical device manufacturers are very specific and not very well known except for a few large scale companies which also produce electronic goods used in daily life. P3 mentioned the lack of guidance by doctors as "...to tell the truth doctors' advice is important but they do not tell any brand. Thus I have searched on the internet sites and medical shops."

The following problem found during the study is the fact that doctors mentioned by participants with clearer suggestions are not the medical professionals who examined the participants. P4 and P18 mentioned their doctor friends as being informative. In other words, participants take advice from their close relatives and friends for additional information and guidance at this stage. Similarly, P2 mentioned his doctor relative's help during the purchase period as "my nephew is a doctor in İstanbul. He

has talked to someone and led me to some medical salesmen in Ankara. Thanks to them, I have purchased my product."

Salesmen

Except for five participants who use devices refurbished by SGK, all participants mentioned the salesman as an influential actor in the product selection phase. The role of a salesman is mentioned as both positive and negative. The majority of the comments are positive in terms of training and maintenance. The importance of the salesman for users can be understood in P8's words as "the fellow (salesman) showed me how to use the product and repeated it again if I could not understand…. The shop has closed, I do not know how to get reports for my controls." Beyond product purchase, salesmen show important roles in the latter stages such as examinations, maintenance and renewal of product components. Especially by means of messaging and communication applications (e.g. WhatsApp) and social networks (e.g. Facebook), users can get instant help from their sales representative even if they are in different cities or on holiday. Moreover, they are not simply referring to the help from the sales representative as another ordinary service from a technical service personnel. They usually express their gratitude to the positive changes as P8 "Thanks to the seller, it is possible to try different types of masks for a few days" and "the sellers were so helpful… they repeated some parts of the device controls if necessary." However, this is not valid for all participants. P5 and P22 mentioned the lack of testing products components due to hygiene reasons. P5 stated that problem as "I asked the seller whether I could get masks for trial but he did not accept. He told me that they cannot get the masks back once they are used". It shows that salesmen's different approaches shape participants' experiences.

In addition to their support in the product purchase and latter stages, participants also mentioned negative points. To illustrate P4 stated that "talking to salesmen is not very helpful. Everyone praises their own products. You understand the difference if you talk to different salesmen." If the patient adherence is fulfilled, the role of the salesmen becomes weaker. P12 mentioned customer loyalty to the brand as "I am

very pleased with the product. I have used P… before. (...) as a matter of fact, German brands and P... are available in this market. I have continued to use the same brand."

Relatives and friends

As mentioned in doctor's guidance, the role of relatives and friends is influential during the product purchase. Even if there are no doctors among the family or close friends, the relatives help participants by asking their kith and kin for any guidance. The difference between advice from doctors and kin is the fact that doctors cannot express themselves freely due to limitations of professionalism. Medical professionals cannot clearly mention any product or brand. They can only focus on product features in terms of features such as being AutoCPAP, CPAP or BiPAP. The features described in the prescription are available among all products but other important features in terms of monitoring, controls and build quality are absent.

6.2.2 Factors influential in product purchase

Along with the effect of the medical sales representatives, medical doctors also have an effect over the product selection of patients. Although medical doctors cannot clearly mention a brand or model they can guide patients about the general important key points in the decision process. The role of expert reviews are stated in the previous part as actors influential in the purchase period.

Product origin

Nineteen out of 30 participants mentioned that physicians told them to select internationally well-known brands which they can also check on the internet. In addition, origin is another important topic in purchase decisions. P10 mentions that devices manufactured in the EU and USA are better in build quality compared to Chinese products. Moreover, he states that local brands are not different from Far Eastern products because product components are mostly supplied from the same origin. Lastly, P5 mentioned that he was told that the product is a German brand,

whereas the device is originally manufactured in China. Thus the price was more affordable compared to other better quality perceived brands. At this point, it is clear that price along with the origin of the device is another point that patients consider during the purchase decision. Still, the price is not an issue that participants show an agreed stance upon.

Price

The price concern mentioned by twelve participants in various ways. Although participants mentioned the price issue as a secondary concern after the quality of the products, the availability is still important. P2 mentioned the issue as "I liked the Phillips product but I choose this one (Respirox) not to pay extra." The reimbursement and price range among the devices can result in the decision of the users. Users agree to used refurbished devices do not have to pay a price because they can get new components via reimbursement that are in contact with the user.

6.3 User experience questionnaire (UEQ) results

As mentioned earlier, UEQ is a tool developed for analyzing products UX features by means of 26 items in semantic differential approach. The items are evaluated in seven level Likert scale. These items are grouped under six different scales which are attractiveness, efficiency, perspicuity, dependability, stimulation and novelty. These domains form three groups as attractiveness, pragmatic quality and hedonic quality. The mean values are calculated for each item and their standard deviations are calculated with confidence intervals. In addition to that, the correlations of the items in each scale are measured for examining consistency of the answers of each participant. At the last part of the tool, the results are compared with results of previous studies for creating a benchmark evaluation in terms of each scale. The items used for each scale are listed in Table 6-1.

Table 6-1: Items used in UEQ scales

Scales	Items
Attractiveness	annoying/enjoyable, good/bad, unlikable/pleasing, Unpleasant/pleasant, attractive/unattractive, friendly/unfriendly
Perspicuity	Not understandable/understandable, easy to learn/difficult to learn, complicated/easy, clear/confusing
Efficiency	Fast/slow, inefficient/efficient, impractical/practical, organized/cluttered
Dependability	Unpredictable/predictable, obstructive/supportive, secure/not secure, meet expectations/ does not meet expectations
Stimulation	Valuable/inferior, boring/exciting, not interesting/interesting, motivating/demotivating,
Novelty	Creative/dull, inventive/conventional, usual/leading edge, conservative/innovative

Overall results of the items are illustrated in mean values in Figure 6-1. The values are illustrated between +2 and –2 range due to the fact that users mostly avoid giving extreme answers to the Likert scale. As seen in the results, perspicuity, efficiency and dependability scores are in the green area which can be considered as positive evaluation. In terms of attractiveness and stimulation the mean values are in the positive range that can be evaluated on moderate level. Although the novelty of the products is also in the same zone, it is the only scale which is positioned it the negative range.

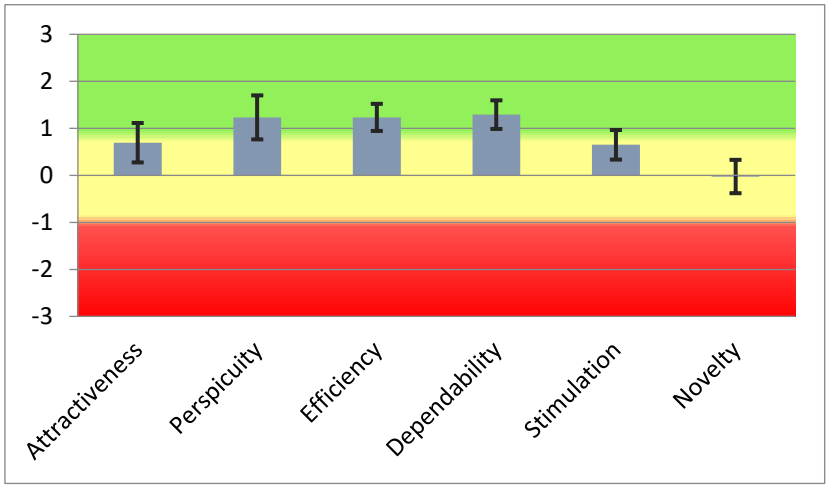

Figure 6-1: Overall mean values of the UEQ scales

6.3.1 Pragmatic and hedonic values

Products' qualities are measured under three groups that are attractiveness, pragmatic quality and hedonic quality. The pragmatic quality targets products features in terms of its practicality and usability. In other words, items that are related to product function are grouped under the topic. The group is formed by the items of perspicuity, efficiency and dependability. The hedonic quality focusses on product features independent from practicality and formed by the scales of stimulation and originality. The mean values of each quality aspects are illustrated in Figure 6-2. According to the results illustrated in the table below, product qualities are more oriented towards pragmatic features rather than the hedonic ones. It is understandable for a medical device aiming treatment of a chronic condition. However, the hedonic features of a product can play an important role in the adherence of a device especially in terms of creating a stimulation for use.

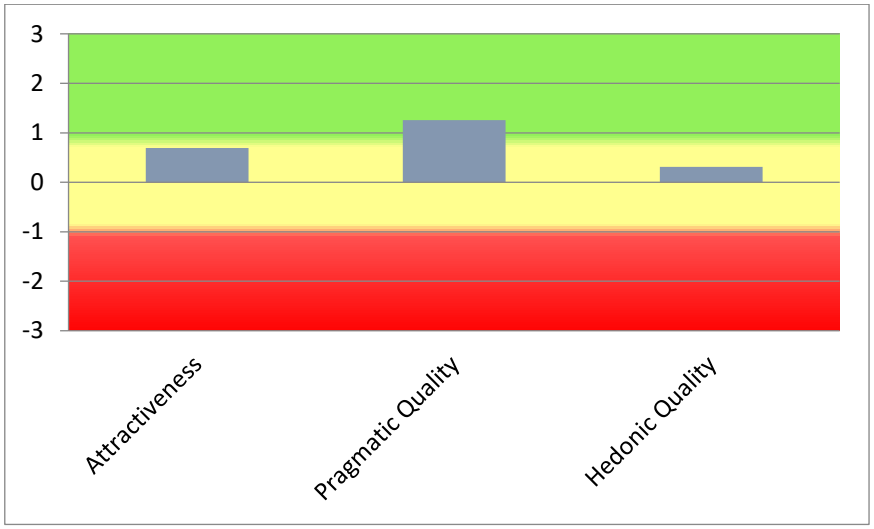

Figure 6-2: Mean values of pragmatic and hedonic quality of CPAP devices

6.3.2 Results of UEQ Scales

The results of the scales are explored in a deeper approach in this section. In addition to the overall mean values of the scales, the items in each scale can show differences and give clues about the features of the devices in users' perspective.

Attractiveness

The attractiveness of the product is measured with the items illustrated in Table 6.1. Among these items, good/bad has the highest mean value as +1.5 and it is the only item that can be considered as a positive evaluation. However being good or bad can be regarded as ambiguous and too general. Participants' evaluations of their CPAP devices is closely linked to the outcomes of the treatment and change in their lives. Therefore the evaluation can be affected by the gratitude resulting from the positive outcomes of the treatment rather than the functional features of the device. The mean values of all scales are illustrated in Table 6-2.

As seen in the results, the mean values show that other items are evaluated in a neutral zone which is between +0.8 and -0.8. However, the variance and standard deviation of the items show that the evaluations are formed by both positive and negative evaluations. In other words, it is not possible to say that users share a general opinion about the attractiveness of their devices by considering the mean value. But, it can still be argued that complaints and compliments of the users are positioned in the neutral zone. In other words, the complaints about the attractiveness of the devices are tolerable.

Table 6-2: Results of items in attractiveness scale

Items	Mean	Variance	Std. Dev.
Annoying/ enjoyable	0,4	2,0	1,4
Unpleasant/ pleasant	0,8	2,3	1,5
Unlikable / pleasing	0,3	1,9	1,4
Good / bad	1,5	1,6	1,3
Attractive / unattractive	0,6	1,7	1,3
Friendly / unfriendly	0,6	1,9	1,4

Perspicuity

Four items illustrated in Table 6-3 are evaluated in terms of perspicuity in the questionnaire. The mean values of the items are higher compared to attractiveness of the devices. In addition to that, the overall range of the evaluations regarding the perspicuity are mostly in the positive evaluation range. At this point, it is fair to say that CPAP devices perform better in terms of perspicuity compared to hedonic scales and attractiveness. The difference between participants' evaluations can be linked to the use period of their devices. Users who achieved adherence and use their products regularly show more positive evaluation compared to the ones with less experience in CPAP use. On the one hand, novice users at the early stage of product use with less than six months experience, evaluate their experiences in negative values due to the problems they encounter. On the other hand, users with more than five years of experience show an opposite attitude in terms of products' ease of use.

Table 6-3: Results of items in perspicuity scale

Items	Mean	Variance	Std. Dev.
not understandable / understandable	1,0	2,4	1,5
easy to learn /difficult to learn	1,4	2,2	1,5
complicated / easy	1,1	2,1	1,4
clear / confusing	1,5	2,2	1,5

Efficiency

Four items are evaluated on an efficiency scale. These items are being fast, efficient, practical and organized. The evaluations of these items are illustrated in Table 6-4. In general evaluation, efficiency has high mean scores similar to the other two scales (perspicuity and dependability) of pragmatic quality in the study. All items except being organized are evaluated in a positive way that are around 1.5. Considering the variance and standard deviation of these three items, it can be said that the majority of the participants evaluated their devices in a positive region. Only two participants P24 and P30 evaluated their devices' efficiencies in a negative way, which are -0.25 and -0.75 on means of the scale. Both participants are in the first year of use of their

products and between 40-50 years old. It can be said that these two participants showed negative evaluation due to the problems occurring in the adherence stage of use.

Table 6-4: Results of items in efficiency scale

Items	Mean	Variance	Std. Dev.
fast / slow	1,6	0,9	0,9
inefficient / efficient	1,4	1,0	1,0
impractical / practical	1,5	1,4	1,2
organized / cluttered	0,4	2,6	1,6

While three items of the scale show similarity in mean values, being organized or cluttered is different. Especially in terms of consistency, control of the tool shows that this item is evaluated with negative scores, while three remaining items in the scale are evaluated with positive scores. The scores of this item can show a difference higher than three points, which is considered as an inconsistency. However, the same critics also exist in other parts of the survey. Participants mention their problems with product components in terms of their storage, and positioning during sleep.

Dependability

Mean values and variances of four items composing the dependability scale are illustrated in Table 6-5. According to the results, being obstructive or supportive is evaluated with the highest scores. The variance of the item shows that almost all participants (except P5 and P30) evaluated their devices as being supportive. Considering the device is meant to give support against OSA with positive airway pressure, it is natural for participants to evaluate the device as supportive. As mentioned in the efficiency scale, participants can evaluate user experience in a negative way if they do not complete patient adherence during their early use phase. Although remaining participants evaluated their experience as positive in terms of devices' support, it is important to note the possibility that they can confuse the effects of CPAP treatment rather than their products' features which are much intertwined. Following being supportive, being secure and meeting expectations

have similar outcomes. Twenty two participants evaluated both items positively. Only one participant evaluated the score as different. P26 evaluated the device as being very secure while mentioning the success of the device negatively in terms of meeting his expectations. Being predictable or unpredictable has the lowest mean value among the items in the dependability scale. Although the mean value is in favor of the overall users' experiences, five participants criticized the product for being unpredictable.

Table 6-5: Results of the items in dependability scale

Items	Mean	Variance	Std. Dev.
unpredictable / predictable	0,9	1,4	1,2
obstructive / supportive	1,6	0,9	0,9
secure / not secure	1,3	1,5	1,2
meets expectations / does not meet expectations	1,4	1,6	1,2

Stimulation

As mentioned in the pragmatic and hedonic qualities of CPAP devices in participants' experiences, hedonic qualities are evaluated lower compared to the pragmatic ones. According to the results of the survey, items of stimulation show differences. While *being valuable* and motivating is evaluated in favor of the CPAP devices, other two items (being boring and interesting) are evaluated with lower scores. Although being valuable has a higher mean value compared to motivation, the range of evaluations of *being motivating* is higher compared to being valuable. In addition, only one participant evaluated *motivating / demotivating* in the negative region while four participants were not satisfied with the valuable / inferior item. Still, it can be said that participants' experiences regarding these two items are in the positive region. It should be noted that some participants referred to their devices and their treatment process interchangeably and expressed their happiness due to the positive outcomes of the treatment and gave extreme points especially to the valuable / inferior item.

Table 6-6: Results of the items in stimulation scale

Items	Mean	Variance	Std. Dev.
valuable / inferior	1,5	1,5	1,2
boring / exciting	-0,2	1,5	1,2
not interesting / interesting	-0,1	2,1	1,4
motivating / demotivating	1,4	0,9	0,9

Apart from being valuable and motivating, two remaining items in the scale show differences in users' experiences. Participants are divided into two groups in the evaluation of their experiences in terms of *boring* / *exciting*. Eight participants evaluated the item as being neither interesting, nor not interesting. Twelve participants evaluated the item in the negative region, while eight participants evaluated in the positive region of scale. The same separation also occurred for the not interesting / interesting item. Eighteen participants evaluated the item in the negative region, while eleven participants evaluated their experiences in the positive region. It should be noted that use motivation for products are generally linked with these two previously mentioned items and the results of the items are expected to match. However, as mentioned above, users' motivations for using their devices are mentioned with the changes that occurred in their lives. The opposing view of participants showed that use experience of CPAP devices should be studied deeply in terms of creating an excitement and interest for motivating users to use their products until the positive outcomes of CPAP treatment are achieved.

Novelty

Among the scales, novelty has the lowest scores in UEQ study. The overall mean value of the scale is calculated as -0,025. The scale is evaluated in the negative region by fourteen participants and thirteen participants evaluated the scale in the positive region. The overall evaluation of the remaining two participants is at the zero point. In all items of the scale, the mean values are slightly higher than zero as in Table 6-7. However the variance and standard deviation of the items show that participants are divided into two. Except for one participant for the *usual / leading edge* item, all

evaluations in the scale are between the -2 to +2 region, which means that the participants are not impressed by novelty features of their CPAP devices.

Considering the fact that medical devices are products that are not used in everyday life, devices are expected to be perceived as unfamiliar. However, the low tech features of CPAP devices in terms of interface and interaction compared to consumer electronics and mobile technologies used in daily life may affect participants to evaluate their devices as being dull or conservative. The benchmark of novelty scale of the device with previous UEQ studies will also show the weak side of the use experience of CPAP devices.

Table 6-7: Results of the items in novelty scale

Items	Mean	Variance	Std. Dev.
creative / dull	0,2	1,9	1,4
inventive / conventional	0,1	1,5	1,2
usual / leading edge	0	2,0	1,4
conservative / innovative	0,3	1,8	1,3

6.3.3 Benchmark of UEQ scale

In addition to the results of each scale and items, UEQ tool also illustrates a general benchmark of the results with previously made studies. These studies are not specific to medical devices or CPAP devices and include results of 163 studies with 4818 participants concerning different products and services in various sectors. Thus, the benchmark and results mentioned in this section should not be perceived as a benchmark of CPAP devices with other medical devices, treatments or healthcare services. Still, considering that homecare medical devices and technologies are becoming more consumer centric, future products should match other consumer goods and services in terms of user experience to achieve adherence and technology acceptance.

As seen in Figure 6-3, the regions of evaluation for each scale are different. To illustrate, the product/service is expected to have an overall mean value for being excellent is around 1.3 in novelty, while the same result can be achieved around 1.8 in perspicuity. In other words, product performance in terms of ease of use and clarity is higher compared to novelty. The evaluations of the studies are entitled as excellent, good, above average, below average and bad. Explanations for these regions are given in Table 6.8.

Table 6-8: Explanations of the definition of the ranges in UEQ benchmark

Results of the benchmark	Definition
Excellent	Positioned in the top 10 percent of the results
Good	Positioned between 10 percent and 25 percent of the best results
Above average	Positioned between 25 percent and 50 percent of the best results
Below average	Positioned between 50 percent and 75 percent of the best results
Bad	Positioned in the worst 25 percent of the results

According to the results of the CPAP devices, scales in the pragmatic quality are regarded as the border between good and above average, which means that incremental changes can make CPAP devices to be perceived as good products in terms of perspicuity, efficiency and dependability.

In terms of the hedonic qualities, the scores are positioned in the lower regions of the comparison. While the stimulation scale is regarded as below average, novelty of CPAP devices are evaluated as being bad. In other words, motivation for CPAP use is not evaluated as adequate and CPAP devices are perceived as not being new or innovative by a major portion of the study group. Compared with other products and services evaluated by UEQ, CPAP devices positioned in the worst 25 percent. Thus, it is important to enhance innovative features of CPAP devices to create a positive user experience among CPAP users.

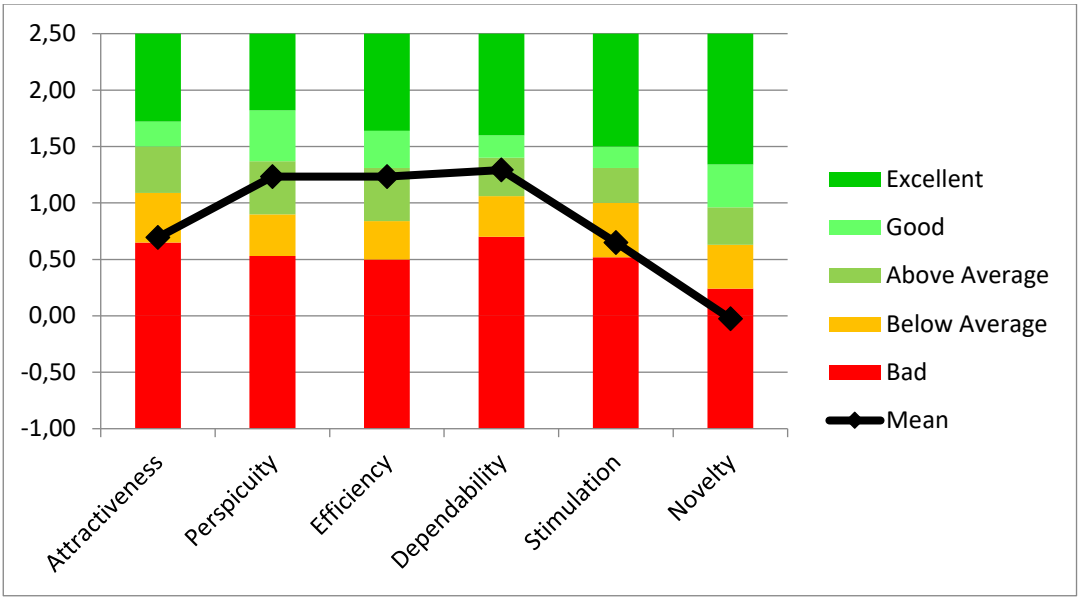

Figure 6-3: Benchmark of the study results with previous UEQ studies

6.4 Self – Efficacy Measure for Sleep Apnea (SEMSA) results

As mentioned in the fifth chapter, SEMSA is a questionnaire developed especially for newly diagnosed OSA patients in order to understand potential CPAP users' perceptions against CPAP treatment. The model is mainly structured on the social cognitive model and the health belief model that links behavior change in healthcare to three key concepts namely risk perception, outcome expectancy, and self-efficacy. It is crucial to point out that the scale is developed for early phase users but it is still useful to see the difference between the participants' reactions and change in the perception of CPAP use in terms of period of use. Due to use of four level Likert scale, participants cannot show a neutral stance against the items in the survey. During the pilot study, questions concerning sexual desire and performance are eliminated due to the possibility of disturbing the participants. Although it can be stated that people should feel themselves comfortable with sharing information, it is not possible for people to share their experiences and health problems with a reporter out of medical expertise.

In general terms, outcome expectancies are higher than two other clusters of the survey. It shows the high expectancy of the participants from CPAP treatment. Another factor of this result is the fact that some of the participants feel themselves relaxed against the severe risks of OSA and they are willing to pay extra and make changes in their daily lives.

Risk perception

In terms of the risk perception, *falling asleep during day (3.57/4)* is the highest among all risks of OSA. All participants in the survey have mentioned *falling asleep during day* as an existing risk and symptom in their lives. Twenty eight participants mentioned that they perceive the risk as high or very high in the study. *Falling asleep during day* is followed by *difficulty concentrating (3.13/4)* and *having high blood pressure (2.80/4).* Twenty six participants agree that their risk of difficulty concentrating is high or very high and 22 participants evaluated the risk of having high blood pressure as probable. In fact, some participants who are older than 50 years are diagnosed with high blood pressure and have medication in the background. However, the lack of concentration is not evaluated parallel with the risk of *falling asleep while driving (2.67/4)*. Ten participants evaluated their risk of falling asleep while driving as being low or very low. Still P12 mentioned the risk of traffic accidents, especially in long journeys, as a source of stress for which he always prepares coffee and has a good night's sleep that is a ritual that goes back prior to CPAP use. The same approach is also visible in terms of *having an accident* (2.63/4). Eleven participants evaluated the risk of *having an accident* as low or very low.

Surprisingly, the most severe risk of OSA, namely *having heart attack,* is measured with the lowest mean value (2.13/4) among the participants. Only 10 participants mentioned the risk of *having heart attack* as high or very high due to OSA. The reason for the unexpected result may be due to the stance of the younger participants and the denial of the serious risk of OSA. Another risk perception with low value is *being depressed (2.37/4). Being depressed* is not mentioned as serious risk among

the participants. Moreover, 19 participants do not perceive risk of being depressed as high or very high. Although they mention the positive change in their relationships among the outcome expectancies, they do not perceive themselves as being depressed prior to CPAP treatment. In addition to the mean value of the item, being depressed mentioned as the least perceived risk of OSA.

Table 6-9: Percentage of participants evaluating perceived risks of OSA

Perceived risks	Percentage of participants evaluated the perceived risk as being high or very high (evaluated as 3 or 4)
Falling asleep during day	93%
Having high blood pressure	73%
Having heart attack	66%
Difficulty concentrating	86%
Falling asleep driving	66%
Being depressed	40%
Having an accident	63%

Outcome expectancy

In terms of outcomes, the overall expectancy (2.90/4) of the participants are higher compared to risk perception (2.76/4) and self-efficacy (2.65/4). In other words, outcome expectations play a more important role in patients' perceptions in terms of CPAP treatment. In general, all items in the cluster (except traffic accidents) are mentioned above 2.5 that means participants expect positive change upon CPAP treatment. The highest mean value among the outcome expectancies is *feeling better (3.40/4)*. Twenty-eight participants mentioned that they are positive about feeling better. The factor is followed by *not snoring* and *being active*. Similar with *feeling better*, 27 participants agree upon the expecting positive change in terms of *not snoring.* Still the difference between mean values of the items show that *feeling better* (3.40/4) is higher than *not snoring* (3.17/4). In other words, participants expect the overall positive change in their lives in the first place. *Being more active* (3.10/4) is another expectancy which 26 participants mentioned their expectancy as a positive outcome.

Following three items in the survey, *better sleep for bed partner* (2.97/4) and *improved job performance* (2.93/4.00) are also evaluated as expected positive outcomes of the CPAP treatment. Although the mean values are close to three out of four points, participants who do not expect or perceived a positive change in their lives increase to 9 participants for *better sleep for bed partner* and 6 participants in terms of *improved job performance*. The polarization of the participants goes higher in the following two items which are 12 participants for *improving relationships* (2.60/4), and 11 participants for *being more alert* (2.63/4).

Among the items in the expected outcomes, *decreased chance of driving accidents* has the lowest mean value among the participants as 2.43/4. In addition to lowest mean value, 17 participants mentioned that they do not expect a positive outcome regarding the issue.

Table 6-10: Percentage of participants' expected outcomes of CPAP use

Expected outcomes	Percentage of participants evaluated as expecting positive outcomes (evaluated as 3 or 4)
Feeling better	93%
Not snoring	90%
Being more active	87%
Better sleep for bed partner	70%
Improved job performance	80%
Decreased chance of driving accident	43%
Improved relationships	60%
Being more alert	63%

Self-efficacy

In terms of self-efficacy the mean values and participants' reactions against the items show difference from a previous study made by Weaver et al. (2003). The mean values show that participants are more sensitive about the side effects of the CPAP treatment (see Table 6.11). The results also mention that participants can tolerate the preparation and requirements of CPAP treatment.

Preparation for CPAP use is defined as *taking longer to get ready for sleep* (3.37/4) and except one participant, 29 participants mentioned that they would tolerate spending extra time before sleep. In addition, participants who have been using the device for a longer period of time, mention that the preparation stage is almost automatic. In other words, users do not spend time preparing once they adhere to CPAP use. Surprisingly, the second item with the highest score is *having to pay for some of the cost* (3.27/4). Twenty-seven participants mentioned that they can pay for a portion of the cost for CPAP treatment. The issue is also discussed in the purchase section of the survey study. Although health insurance in Turkey is mainly covered by state insurance, participants still are in favor of paying a little extra for a better experience especially in terms of hygiene.

Following four items in the survey are positioned in the positive region of the survey that is above 2.50 in mean value. The third highest value among the items in self-efficacy is measured as *being a bother* (2.77/4). Twenty participants agreed that they would use their CPAP devices even if it were a bother. The following two items, *travelling* (2.63/4) and *disturbing bed partner's sleep* (2.57/4) are both mentioned by 18 participants as tolerable obstacles confronted during CPAP use. Mean value of travelling is measured in low values due to the fact that early users mentioned that they do not carry their CPAP devices during their short trips. Users with use experience for a longer period of time mentioned that they carry their devices with them especially during their summer vacations. Moreover, *feeling embarrassed* (2.60/4) is another item that participants evaluated as being tolerable. The item is associated with privacy by participants in the other parts of the survey. The difference between the participants' stances is closely related with the adherence and use period of the device. Participants are more open to share their health condition once they have experienced positive outcomes of the CPAP treatment.

The remaining three items in the survey are evaluated in the negative region and majority of the participants mentioned that these obstacles are serious against CPAP use. These items are related with the comfort of use, especially the ergonomics and getting used to wearing a mask. Among the negatively evaluated items, *having a*

stuffy nose (2.03/4) has the lowest mean value. Nineteen participants evaluated the item as an obstacle that can prevent them from using CPAP devices. The second most serious obstacle is *feeling claustrophobic* (2.13/4). Similar to stuffy nose, having difficulty in breathing during CPAP use before falling to sleep is mentioned as an obstacle to CPAP use by 18 participants. The third most serious obstacle against CPAP use is *having to wear a tight mask* (2.47/4). Sixteen participants mentioned the item as an obstacle that would prevent them from CPAP use.

Table 6-11: Obstacles to CPAP adherence

Obstacles to CPAP adherence	Percentage of participants who could wear CPAP even if confronted with the obstacle (evaluated as 3 or 4)
Took longer to get ready for bed (3.37/4)	97%
Had to pay for some of cost (3.27/4)	90%
It were a bother (2.77/4)	70%
I traveled (2.63/4)	60%
Disturbed my bed partner's sleep (2.57/4)	60%
Feel embarrassed (2.60/4)	57%
Had to wear tight mask (2.47/4)	47%
Made me feel claustrophobic (2.13/4)	40%
It made my nose stuffy (2.03/4)	37%

6.5 Attitudes to CPAP inventory

Attitudes to CPAP Inventory (ATCI) is a scale developed for understanding participants' perception and attitudes towards CPAP treatment. The evaluation scale range is between 1 (strongly disagree) and 5 (strongly agree). The most interesting outcome is the absence of opposing attitudes against CPAP treatment. In none of the items participants mentioned a negative attitude. In other words, all participants evaluated CPAP inventory between undecided to positive feedback.

The first three items in the scale are about the outcomes of CPAP treatment. The results of these three items show that participants agree upon the positive outcomes

of the treatment. In the first item 27 participants (90%) agreed on the fact that CPAP treatment reduced their problems caused by their sleep apnea. Remaining three participants evaluated the item as undecided, which means they do not experience a clear positive change via CPAP treatment. Twenty eight participants (93%) agreed that CPAP treatment improves their health. Two participants remained undecided about the item. The third item is about the CPAP treatment and quality of life. Similar to item 2, 28 participants (93%) agreed that the treatment improves their quality of life. Among the items, the undecided participants are the ones who were in the early use phase. In other words, participants who did not experience a radical change after using CPAP devices stated neutral against the treatment. Once the users experience positive changes in their daily lives, they tend to shift from a neutral stance to a supporting role for CPAP treatment.

The two remaining items are about participants' knowledge about CPAP treatment. The fourth item is about participants' knowledge about alternative treatment methods for sleep apnea. The last item evaluates whether participants use their devices as expected. Although there is no negative evaluation about the fourth item, it has the highest ratio of undecided users. Eight participants (26%) do not know whether CPAP is the best treatment for their sleep apnea. It is natural that patients follow their doctor's directions through their treatment. However, it also shows patients' passive position on their treatment procedures. The results of the last item shows that the majority of the participants, 27 participants (90%), agree that they are using their devices as expected of them. The remaining three participants have problems with the labelling on the devices and training of the user. The high ratio on this item can be linked to the fact that the use of the device is reduced to turning the device on and off and cleaning the device. Still, participants mentioned problems with calibrating the device and got help from sales people.

As a result of the scale, participant selection with a high percentage of adherence shows a very high agreement among the participants in terms of positive outcomes of the treatment and success. Thus participants who perform as an outlier draw more attention compared to the ones with common shared thought. To illustrate, P1 had a

problem with the training and manuals of the device due to using a refurbished device. The absence of a sales representative and trainer available in the learning phase creates problems in terms of source of knowledge and advice. Moreover, lack of communication at this stage creates an ambiguity which also affects the evaluation of the outcomes of the CPAP treatment. Even if the adherence occurs in different time periods, it is important for users to have some clues for checking their process.

6.6 Changes in the daily life of kith and kin

CPAP treatment may affect family members and close relatives in terms of emotional responses to users' health conditions and changes occur due to penetration of a new device to the sleep environment. The changes occurred due to the physical existence of the machine mostly affecting bed partners and house folk. In addition to the physical existence of a new device in the bedroom, CPAP treatment also has effects in terms of privacy.

Bed partners

All participants in the study mention that their sleep quality has improved compared to times before CPAP treatment. Along with that, 21 participants out of 30 mentioned that their partners have also witnessed positive changes by elimination of the snoring problem. Although they start with positive changes, the design of the device and sleep position of the user can also affect bed partners' sleep quality. To illustrate, P1 and P7 both mentioned that they are used to sleeping facing their partners and the air outlet on the mask that is necessary for avoiding high pressure disturbs the partners because it blows air to their partners' faces. However, once the noise problem is probed, they mentioned that the vibration and noise of the devices are still acceptable compared to the snoring problem.

> "(…) my wife told me that my snoring is gone … I am used to sleeping by lying on my side but air blown upon her face is a problem as she has told me.

(…) She did not complain about the noise. I guess it is nothing compared to the snoring (laughter)…“ (P1)

Although these two participants clearly mentioned that noise is not a problem, not all participants have agreed upon the subject because P5 and P8 mention noise as a problem. In fact, P8 mentions the problem in the purchase process as “(…) you cannot detect the noise in the showroom. Once you set the product in the bedroom you realize the real sound of the product.” In other words, the differences between the product showroom and use environment result with unexpected consequences. Additionally, P5 positions the device in a different way due to the noise problem that he addresses as “(…) new CPAP device is quite silent but I still put it under the bed because I am disturbed by the sound.”

In addition to the noise problem, another problem caused by the design of the product is due to the positioning of the interface. P9 mentions the importance of interface as “(…) the product is ok but the screen emits too much light. I cannot turn it on without using the screen. It causes problems.” P11 mentions the importance of the screen and the interaction in a different way as “it turns on once you put the mask on. It stops when you release your mask. I don’t know whether other products are the same but it is useful for people who visit the toilet frequently like me.” In addition to these two comments, P7 mentions the same problem as “(…) the screen is easy to read and it does not direct light on your face.” In the light of these comments, it should be noted that the device interface and controls do not only affect the user but also other people present in the use environment.

Lastly, change in the sleep routine of users also affects bed partners. The outcome can be both positive and negative. On the one hand, the sleep routine can be more accurate and result in desired outcomes as P2 states “I wake up around 6:30 and 7:00 am like an alarm clock.” On the other hand, users can still settle with limited sleep time which affects their night time as mentioned by P7 “I started to get better sleep but it ends at 4.00 a.m. I wake up with adequate sleep at that hour. It is hard to fall asleep again. I start to toss and turn. I don’t know what to do.” In addition, the

negative effects of the CPAP changes bed partners' sleep routines. P2 mentioned that his wife goes to sleep before he does in order not to get disturbed by the noise of the CPAP. In addition to these effects, CPAP use can also result in sleeping in separate rooms. Couples, who cannot tolerate the noise and disturbance of their sleep, can decide to sleep separately. Although this is not mentioned in this study, it is a noted effect of OSA in studies such as Flemons & Reimer (1998).

Children

Changes in daily life concerning children is another important issue to be addressed in device adherence. In this topic, the age of the children is important due to two reasons. If the children are very young, parents tend to hide the treatment from their children for two reasons, which are avoiding their anxiety, and the unfamiliar visual appearance of the device.

The problem is mentioned by 3 of the participants (P2, P6, and P12) who did not tell their children anything about the device in the first months. P2 mentions that his son felt worried about him in the first weeks and also told that their child had seen him with the mask while he was going to the toilet in the night, which scared him. Considering wearing a full face mask with a hose is quite like the appearance of villain characters in the movies, it is quite normal to hide it from very young children. But P2 also said that his son became used to the appearance of the mask and device in time. P6 mentions the problem with the product's form as "(…) product's appearance makes the problem seem worse. It is like an intensive care room." P12 mentioned that he and his wife did not inform their children about the CPAP treatment. The difference here is the fact that their children were older than the first two examples, they were in their twenties. Still, P12 and his wife tended to keep this as a secret in the first months to avoid making their children worried about his condition. In other words, children can be scared of the visual appearance of the CPAP device or worry about their parents' health and feel sad.

In addition P10 states the problem of children changing product's adjustments as "I do not leave the device out in the open in order not to allow guests' children to play

with it. It happened once and I could not understand why I could not use the device." In fact, the problem of change of product's controls is a more common problem that is pointed out in the following sections.

Close relatives and friends

Close relatives' reactions against CPAP treatment is closely related with users' adherence. At the early stages of adherence, patients tend to keep CPAP treatment private. However, patients who have been using the device for more than 10 years are very positive about sharing their experience and promoting their close friends and relatives to have a sleep test. P6, with 9 years of experience, states that "(…) If my friends talk about their sleepiness problem, I tell them about the sleep apnea problem. A few of my friends also started using the product after their sleep test." Similar to P6, P4 who has been using the device for nearly 15 years, also points out: "I am advising my friends to see a doctor. In fact, you have met P3. I told her to be checked. Now she is also using it." Different from P4 and P6, P2 is also very open about sharing his condition with not only close friends but also coworkers even though he has been using the device for only two months. It is fair to say, once the adherence is achieved, users feel encouraged to share their experiences even if they have not completed their first year of use.

In addition to patients sharing their conditions with their network, the opposite attitude is also valid. As mentioned in the previous section regarding children, patients can also keep their CPAP treatment as a secret from their relatives. P1 addresses this issue as "(…) I keep it as a secret only from my mother so as not to make her sad. (…) the device is positioned at a point that cannot be seen if you are looking from the doorway." In short, users are not sharing their health condition with their close relatives if they think it would make them sad or worried about the patient. Thus, it can be said that informing close relatives about users' health conditions and treatment is not only a matter of privacy, but it is also affected by relatives' reactions in terms of both emotions and attitudes.

Privacy of CPAP use

Privacy is an important issue in CPAP treatment. The issue is closely connected with the user's adherence process and outcomes of the treatment. Due to the fact that these two factors change individually, users' reactions over the privacy issue change accordingly. Twenty-three participants in the study mentioned that they share their OSA situation with others. Four of the remaining seven participants have not completed their first year of use. In other words, it can be stated that participants who do not fully complete their adherence process do not feel confident in sharing their condition with other people.

As mentioned earlier, the privacy concern of CPAP treatment can be caused by various reasons regarding the reactions of family members. Among the participants, the reasons for not sharing the condition with children is linked with two terms that can be stated as fear and anxiety. Fear is a specific reason for keeping the treatment private among parents because children are frightened by the visual appearance of CPAP. Anxiety is another reason for keeping CPAP use private from other family members. The anxiety is also mentioned with avoiding making the family members sad. P1 mentioned that he keeps his CPAP use as a secret from his mother due to the fact she would perceive the OSA as a very severe illness. This concern has also affected the use of the device in terms of storing and positioning in the bedroom.

While patients usually prefer not to share their CPAP treatment in the early stage of use, opposite cases also exist. P2 is a good example for creating high motivation for adherence. The severity of OSA was very high in terms of the number of stopped breathing. The change of sleep quality and alertness in daytime is more visible compared to other participants in the early use phase. As a result, the change has been realized by coworkers and their compliments created a positive reinforcement for the participant. Compared with other CPAP users who experience smaller changes that are not very visible, dramatic changes create a strong motivation. Thus, feedback can be expanded from just tracking purposes into creating positive

reinforcements for CPAP users as in other products aiming behavior change (i.e. diet apps, water intake, etc.).

CPAP use environment

Use environment is an important issue for the development of home use medical devices. FDA published a draft guidance about the development of these devices. The guidance is useful for R&D departments to have a broad layout for potential causes of accidents or malfunctions. To illustrate, conditions in the use environment such as temperature, humidity and contaminants are mentioned as issues to be considered. Although it is helpful for product development teams to have this checklist in terms of safety issues, an in-depth approach for reviewing use of different devices in non-professional spaces is more useful in terms of creating insights of use.

The first thing to consider about CPAP treatment is the place of use. As mentioned earlier, CPAP treatment disciplines users in terms of their sleep routines. Except participant 22, the remaining participants use their CPAP devices in their bedroom. Although some problems are encountered due to the CPAP use in the bedroom, they adapt to the new device use. P22 uses her device in various rooms due to differences in space use. Firstly, the participant is a single-adult user living in a villa. Thus, rooms have no shared use with any other roommates or family members. As a result, she can change her home environment according to her needs. For instance, the ground floor becomes the main living area in the summer season and she spends most of her time on this floor with an open plan. Thus, the device has been transferred from the bedroom to the living room and it stays on the coffee table close to the couch.

The second thing to consider is the placement of the device inside the room. Patients generally prefer to put their devices on the bedside table. Patients with privacy concerns prefer to store their devices in the drawer during daytime and put out their devices before sleep due to air ventilation. The rearrangement of the device on a daily basis requires longer time for preparation which is also asked in the Self

Efficacy Measure for Sleep Apnea (SEMSA). Fortunately, 97% of the participants mentioned that they would use their CPAP devices even if it takes longer to get ready for bed. In addition to the privacy issues, the height of the device also changes due to three reasons. The first reason is the noise of the device. P5 puts the device on the ground to avoid the sound of the device. Another reason for putting the device on the ground or turned against the wall is the light of the screen. To avoid the illumination, participants place their devices differently from the intended use scenario. Luckily, some users mentioned that their devices stop working if they remove their masks. The last reason for the requirement of height adjustment is due to the water droplets in the hose. CPAP machines with humidifiers enable patients to breathe moisturized air especially in dry seasons. However, the moisture in the hose turns into water droplets and accumulates in the hose and mask. Thus, patients make an S curve in the hose with positioning the machine lower than the bed.

The third thing to consider in the use environment is the use of devices outside home such as vacations and overnight visits. The use environment in these use scenarios show differences in terms of time. Users transport their devices into their secondary residences in vacations such as summer houses. The use in these secondary residences is similar to use in home environments because these spaces are rearranged and used for a longer period of time ranging between one week and several months. These long term vacations also affect the maintenance of the device. Considering summer vacations take place in urban rural places, especially long term users carry their extra product components with them in case of failure of the components they mainly use. P2 is a great example for this. He cleans and renews the air filter of his device before his summer vacation. Moreover he checks the straps of his masks and replaces them if necessary due to the negative effect of heat on the velcro and elastomer parts.

However, temporary environments that do not belong to the user can show differences. These environments include hotels, and relatives' homes. In terms of hotels, users have problems with positioning of the device. Although a bedside cabinet exists in these environments with an electric plug, these furniture does not

acquire enough space for devices. Considering these furniture are designed for smaller objects such as mobile phones, and watches, it is not easy to prepare the device and hoses similar to the users' bedroom set up. P11 purchased a secondary device that is smaller in size solely for his trips. Another problem in these temporary use environments is the position of electric plugs. Especially overnight visits are problematic in terms of privacy and electricity. Thus, users prefer spending their nights in their homes rather than staying over in their relatives and friends homes. It can be evaluated as a positive change that users adhere to the use of the product, it can also affect their relationships with others. Although few devices have batteries for use without an electric plug during travels, no participants in the study use these devices.

CHAPTER 7

DISCUSSION ON FINDINGS

In this chapter, findings of the field study are grouped under general themes which will emphasize important points to consider during the MDDD process. It is helpful to mention that these themes can be applied to personal medical devices which are expected to be used by patients in their daily lives. Although it will be mentioned among the themes, it should be noted that medical devices that show differences in terms of use scenario will require further study to define new dimensions for development and design.

7.1 User capabilities

The user profile is important for designers to have a better grasp of the capabilities of users. Although some demographics as age and sex are generally known by designers due to the definition of the illness and patient population in medicine, other important points are not generally drawn and have an effect on the use experience of the device.

The first group of characteristics of the patients are the physical features of the patients. Generally these characteristics are available in the medicine literature. Designers should first scan these features in order to understand the barriers of their future users that will jeopardize the use of the device. The most obvious barriers are the disabilities of the users such as movement, senses, etc. However the disabilities cannot be narrowed down to the physical and mental disabilities encountered in the literature.

The second group of characteristics of users are related to capabilities regarding education and technology. Users' characteristics especially in terms of language and

technology use, shape the way users cope with problems they encounter especially in the learning phase of use. Users' technological literacy shapes their communication capabilities with other actors in this stage because medical salespeople play an important role as a source for information or advice when users think they have a problem with their devices. In addition to that, education levels of the participants (especially in terms of knowledge of foreign language) create differences in finding information regarding the illness and treatment process. Users can benefit from technical reports or other information sources (e.g. manuals) written in other languages and participants familiar with medical terminology can benefit from a wider range of sources compared to others lacking these goods.

7.2 Product selection and purchase

Selection and purchase of the medical devices show some differences compared to consumer products used in daily life. In terms of the common issues, users pay attention to the features of products such as their brand and origin. These two features are also important for users during the purchase of durable goods that are expected to be used for long periods of time. Considering the devices are expected to be used for ten years, it is natural that users pay attention to the longevity of the devices.

Another important point to be addressed is the source of recommendations. Users mostly depend on two group of actors as healthcare professionals (doctors, nurses, etc.), and close relatives and friends. Users who can use internet and read in other languages make use of digital sources as well. However, patients express their need for an objective source of knowledge. Moreover, the specialized brands and products in healthcare makes it harder to make assumptions as in other consumer goods. Still, the general approach regarding the origin of the product/brand shows similarities. Users prefer Western brands that are manufactured in European countries rather than Far Eastern alternatives.

Another important factor in the selection phase is the definition of the product. If the product fails to match with the features mentioned by SGK in SUT, it will lose its chance to take part in the market as a medical device. If the product does not take part in this list, the designer or the firm cannot claim that their product is a medical device. It is necessary for ensuring that the device is compatible with the treatment procedures. Thus, the list of features in this document (SUT) can be defined as a mandatory list of things that the device must fulfill. That is one of the reasons why consumer digital technologies in healthcare and wellbeing clearly mention that the information and arguments in these apps and products are only suggestions for users and cannot be treated as diagnosis. They must consult with a medical doctor in order to get a professional opinion about their health condition. Moreover, the list of features are important for designers if they want their products to be purchased with reimbursement. Although healthcare products in consumer market are not reimbursed in the current situation, it would change once medical devices become more widespread especially for monitoring purposes.

7.3 Ease of use

Ease of use is an important point to be addressed in the MDDD process. Although there are helpful guides and terms for designers to use (i.e. heuristics) in the design phase, these materials are mostly generated in the HCI literature that ends up with suggestions and guides for digital interfaces. However, the devices do not only include digital interaction and require issues to be considered in terms of physical interaction.

7.3.1 Comfort of use

The comfort of use includes issues of compatibility of the device to the user. These are composed of anthropometric measures of the user and the qualities of the use environment. This issue has also been mentioned in the draft guidebook of FDA

(2012a). Different from the draft guidebook, the items mentioned in the following do not only refer to the safety and technical issues for devices' engineering design. It also addresses the points designers should take into account for meeting users' expectations. In addition to the physical interaction of the device, the digital components of the interaction also need to be studied by the designers.

7.3.2 Anthropometrics

The body measures and dimensions of reach are important points that designers should take into account. The components of the devices are frequently mentioned in the study for sleep comfort. The anthropometric measures and compatibility of the components and body mainly refer to two components namely hose and mask.

The length of the hose is the first thing participants mentioned in the study. The length of the hose affects the reach and movement range of the participants during sleep. If the length is not adequate, participants cannot sleep on their side. Although it may sound sleeping flat on your back is the healthiest option, users can experience difficulty in adapting to the new sleep habits in early use. Moreover, patients cannot control themselves during their sleep and can adjust to their past habits. In addition to the length of the hose, the moisture and water accumulating in the hose is another problem that requires attention to positioning the hose. Participants use third party improvised straps or clips to fasten the hose for avoiding the water leak into the mask. In short, the components should be designed in accordance with the product's and user's environment. It can be said that use environment changes in every case and it is not possible to make assumptions easily but designers should still include use environment in their field studies.

The mask is another component of the device that affects users' sleep comfort. The first frequently mentioned problem regarding masks is the *air leak.* Air leaks are mostly caused by gaps between the mask and the face. Although users can try masks available in the purchase points, the problem is caused by the fact that users mostly

buy their devices and masks together and available mask options are those that exist in the sale points. Thus, participants mentioned that they try different masks in the following years while renewing their masks. Due to the fact that, healthcare professionals do not take active participation in the purchase process, participants consult with sales people. Naturally, they encounter a subjective, even misleading, process because sales people do not judge the products objectively and aim to make sale.

The second issue mentioned by the patients is related with *materials* of the masks. The hardness and rigidity of the mask is closely related with the aforementioned air leak problem. However, there is no clear answer to the flexibility of the mask. While some users mentioned more flexible masks are better for covering users face, the opposite argument is also claimed.

The third issue mentioned by the participants was the *type of the mask*, which are mainly full-face and nasal masks. These two types of masks are used according to the breathing habit of the user. While nasal masks are more comfortable to use, the full-face ones are more suitable for users who breathe through their mouth.

Thus, the trial of the wearable product components and consumables, which can change for each user, can be done in healthcare facilities and patients can be guided more effectively. It can be opposed by mentioning that the required time for this trial is not available for every medical device. However, chronic conditions, for which home use medical devices are used for a long time, require repetitive and longer clinical visits and checkups that would help patients to get in touch with healthcare professionals more frequently. In other words, patients with these conditions can benefit from this kind of guidance.

7.3.3 Digital interaction

As well as physical interaction with the device and components, the interaction with the digital interface is another point worth studying by designers in MDDD process.

In addition to the fact that digital interfaces have almost become the main type of medium of interaction in daily life, the dematerialization of the products is another motivation for focusing on the interaction with digital interfaces. In this section, specific problems and needs mentioned in the field study are prioritized rather than general issues mentioned in HCI and interaction design. In other words, designers can develop new concepts if they include the following topics in their MDDD process.

7.3.3.1 Interface and feedback

The interaction with the controls and screen on the CPAP devices can be defined as a transformation of a professional device into an entry level product. While medical devices in professional facilities are used for multi purposes and have detailed adjustments, CPAP devices developed for home use are simplified products. The product controls consist of a few simple parameters such as pressure levels, mask types, ramp time, and clinical reports.

7.3.3.2 Labelling

The labelling of the device is important especially for users with limited knowledge about the device. The first thing to mention in labelling is the language barrier. If the language used in the device is not the user's native language, it creates problems in the learning stage. Due to the fact that medical devices are not very commonly used products, people tend to start using the device more cautiously. This is beneficial for cases of devices with higher risk levels. The main design strategy against the language barrier in using the devices is using icons in the user interface. Use of icons in healthcare is also frequently encountered in the facilities for guiding the patients. The icons used on the devices are easy to understand for users experienced with mobile digital products. The use of icons does not only ease the use of device but also enables the use of small screen on the device with compact information. Still,

product designers should take this problem into account for the user profiles with no experience with digital products.

The labelling on the device is also important for users who get a refurbished product. Considering the fact that users' most frequent source of information and help are sales people, the absence of this active group in the use scenario makes the language barrier more important especially in manuals. Considering the products are expected to be used by different users in product lifecycles, the durability of the device should also be long lasting.

7.3.3.3 Data management and connectedness

Data management is an important topic in health informatics in terms of data privacy and management of health history of the patients. In addition to privacy, the way of communicating use data and delivering feedback is important in MDDD. As mentioned in the previous section the use of small screens and simple interfaces challenges the capabilities of the designers. Although the choice of controls and screens is also an issue of production and cost management, designers can adapt to new design decisions.

The first design strategy encountered among the participants' devices is the *use of mobile apps* for tracking product use. Reporting use data and clinical information such as AHIs has transformed from the printed media into digital files. The digital files can be stored in memory cards as well as on mobile devices via wireless technologies. The transformation of the user data into digital form enables people to reach and track their health data remotely. The connectedness of the device does not only make cables obsolete, but it also enables to get healthcare professionals' opinions and share data with other actors easier. This trend has been studied in health informatics in terms of telemedicine, telehealth, telecare, etc.

Another design strategy available for designers is simplifying home use medical devices with the help of *connectedness*. Considering that wireless technologies

enables designers to use other mobile devices' capabilities, some product features can be transferred into other mobile devices. The most obvious stage is the removal of the interface and the controls. The cost management during MDDD and capabilities of NPD teams in medical device manufacturers, forces product development teams to use the most cost effective solution. This external factor affects user experience in terms of interaction. Thus, designers can benefit from the opportunities of connectedness in their designs. The issue will also be mentioned in the visual appearance section.

7.3.3.4 User profiles and misuse failures

The user profiles mentioned in this section are the user groups who exist in the use environment. The influential parameters in users' demographics that affect the use experience is mentioned earlier. Considering home use medical devices are not expected to be used only by patients in a controlled use environment, lay users and unexpected people in the use environment is another point to be addressed in the MDDD process. It is mentioned in the findings as failures that occur due to the change in parameters done by people other than device users.

Some existing products have button combinations for unlocking clinical set up similar to mobile phones. Although this reduces the chance of misuse or accidental change of adjustments, it is still possible for house folk to change the adjustments by mistake. Design strategy for eliminating this problem is *removing controls* on the device. It can be achieved by using wireless technology and using personal mobile phone apps. However this strategy requires use of these technologies by users. In other words, users who do not have experience and capability of using these software will have difficulties in adapting to this use scenario.

Another option for this strategy is creating an interface layout in a physical layered approach. The product can encounter the user with just a simple on/off button and the user can mainly use this control for daily use. If the controls for changing clinical

set up are positioned in a safe layer, this would limit other actors in the use environment to accidentally touch and change the settings. However, that kind of a physical interface will require more physical control buttons and parts that may result with increased costs. Still, this strategy can be used for other home use medical devices with higher risk levels. One last option for designers is using other security options that are being used in digital products as passwords and biometrics. Since these sensors and security measures are being used in our daily life products, this approach can also be transferred to home medical devices.

7.4 Attitude to device and health condition

Users' responses to a chronic illness and use of a new medical device is another factor that designers should be aware of in order to create motivation for device use. Otherwise patient adherence to the device will solely rely on the rational stance that patients are expected to follow their doctors' directions during the treatment. Patient emancipation movement is mainly focusing on this issue for enabling patients to have a role in the treatment process. However, the patient emancipation movement is different from other emancipation movements due to the fact that doctors are working for healing their patients (Williamson, 2019). In other words, these two groups should not be perceived as opposing forces and active participation of patients should be approached as an efficient communication between doctors and patients. Considering the device is a component of treatment and monitoring, the devices (especially smart technologies) could also have a supporting role in this issue.

7.4.1 Emotional response

Being diagnosed with a chronic condition has an effect on the patients' way of living, employment and ambitions (Turner & Kelly, 2000). The emotional state of the user in the first stage of the diagnosis is mentioned by participants as being saddening and distressing. The thought of using a medical device for the rest of their life does not

only affect the user but also others who are close as family members. In addition to distress, anxiety is also mentioned by the participants while mentioning the effects of CPAP use among house folk. Thus, the privacy of health condition and sharing patients' condition with others is closely related with this issue.

Along with the emotional state, the effects of the emotional response (especially distress) can also be seen as physical symptoms that are lack of energy, disturbed sleep, impaired appetite, which cannot be directly linked to the emotional state because these effects can result from the disease (Williamson, 2010). Still, designers can develop new design strategies for dealing with these negative emotions that disable the patient adherence and acceptance of the diagnosis.

The most obvious design strategy is using positive reinforcement methods that are being used in other products which also aim for behavior change. In order to create a positive reinforcement, the interaction between the device and the user should be studied and improved. Due to the fact that some medical devices such as CPAP can be manufactured as more conventional devices and use of low-tech components are reliable in terms of longevity and cost management, feedback and interaction of the devices end up with a one-sided approach. However, the use of mobile apps as a medium for interaction enables designers to develop new use scenarios. The capabilities of the mobile phones in terms of graphics and data management is far greater compared to medical devices that use modest components. In addition to the improved capabilities, use of apps in medical devices that are expected to be used all day long (e.g. insulin pumps) can also promise better privacy while being next to people with whom the user does not want to share his/her condition. For instance, an audio feedback created by the device would spoil the privacy of device use in a business meeting. In other words, the medium of feedback does not only affect the functional feature of the device but also the way the device is used in daily life. However, the use of mobile phones and other devices as a medium for product interaction also has problems in use scenario as the malfunction of the mobile phone or applications and battery life of the mobile devices.

7.4.2 Visual appearance

The visual appearance of the device is an issue that designers also should keep in mind. Medical devices are mostly manufactured as medical machines which are expected to fulfill a list of features and this creates a more conventional styling approach that does not keep up with today's consumer market. Participants in the study mentioned this issue as being *outdated.* This evaluation is resulted from various reasons. The first reason is the controls and technologies used in the CPAP devices. Considering some of the devices are being produced for a long time and product redesign is not undertaken as frequent as in other sectors, it is natural for devices to become outdated in a short time. Still, medical products which are very simple and have adapted a minimalist approach can deal with this problem and become classic. To illustrate, assistive devices such as canes, prostheses and wheelchairs have a better performance in terms of fashion and trends by allowing personalization that enables users to adapt their product according to their taste (see figure 7.1)

Figure 7-1: A personalized wheelchair
(downloaded from https://therehablab.wordpress.com/2011/05/20/personalization-and-multiculturalism/)

In addition to being outdated, the visual appearance of the device (especially in respiratory devices) can create negative emotions and moods, which has been mentioned earlier. Mask and hose of the CPAP devices create a resemblance to other respiratory medical devices that are used in more serious conditions even in intense care. This visual similarity creates a serious problem for house folk. Even if OSA is a serious health problem which should be treated, the device is not a high risk class medical device. Especially children and other house folk feel anxiety and sadness once they encounter a device which uses very similar components to ventilators.

In terms of design of the body of CPAP device, color, sturdiness, and material are important points designers should focus on. The colors of the devices are mostly selected in a monochromatic range from white to black. Using grayscale in medical devices is the first option that comes to mind and it is very natural considering the common use in professional hospital equipment. However, the color choice should be made by paying attention to the use environment. The grayscale is also being used in home electronics products but this also creates a comparison with electronic goods. To illustrate, a participant mentioned that his device resembles a radio from the 80s. Another important point to consider is the material and sturdiness of the device. Considering the device is expected to be used for ten years, users pay attention to choose a long lasting product. The fitting of the body parts and flexibility of these components are important points for convincing users about the longevity of the device.

The visual resemblance to other consumer products is another topic worth mentioning. The devices are usually designed as unibody products that use plastic or metal body parts which also function as a chassis holding inner components. The products mostly have few control keys and a screen for adjustment. The devices are usually positioned next to the bed on nightstands and some products resemble alarm clocks (see figure 7.2). This may help devices to blend in the use environment. However it cannot be claimed to be successful because the devices' components (hose and mask) are not included in this *invisibility* approach. As mentioned in the findings, the components of the device makes the product look cluttered. Thus, the

design of the device should be made in a holistic approach that includes all components existing in the use environment.

Figure 7-2: Visual similarity between an AutoCPAP (left) and an alarm clock (right)
(downloaded from https://therapysupply.com/product/dreamstation-cpap-with-humidifier/ (left), https://mirapolnext.pl/radio-kuchenne-hykker-biale-p-11765.html (right))

In addition, the form language of the devices changes in accordance with the approach taken in terms of the consumerization of medical products. While the CPAP devices are shaped in a minimalist approach, it can be stated that majority of the devices are still old fashioned electronic products that do not keep up with consumer goods used in daily life in terms of texture and form. However the approach shifts and becomes dominated by consumer goods once they take part among other consumer goods in sales channels. The difference between a CPAP device and a sleep tracker manufactured by the same firm can illustrate this issue. In terms of brand identity, the products are expected to bond a visual relation with each other in order to enable users to recognize their products. However the sleep tracker has been dominated by the form of mobile phones rather than the firm's other sleep medicine products due to the fact that the device is expected to be used with a mobile phone app and the device used to be sold as a health accessory product in sales channels (see figure 7.3). In other words, styling of the device is closely related with the way of goods put on the market. While products sold in medical sales channels are shaped in a 'device' manner, products put as a consumer good on the market are designed in a 'product' manner.

Figure 7-3: Comparison of forms of a CPAP device (left) and a sleep monitor (right)
(downloaded from https://www.resmed.com/en-us/healthcare-professional/products-and-support/devices/ (left), https://splus.resmed.com/ (right))

7.5 Use environment

Field study about the use environment of CPAP devices shows that the conditions of the environment have effect on the user experience on two broad groups which are location of the device and conditions in the use environment. The first group is mainly about the positioning of the device with regard to user and other elements in the use environment. The second one focusses on the features of the use environment that affect device performance and user experience.

In terms of location of the device, *visibility* is a factor that is mainly related with privacy of the device use. The privacy of the device use is also related with storing and positioning the device in the room. If users do not want house folk or others to see the CPAP, they tend to pack their devices every day and store them in a drawer or they position their devices in blind spots that disable others to see their device. If privacy is not a problem for the users, they do not need to pack their devices and even use their products in other rooms (e.g. sitting room) where they sleep.

Another issue of location of the device is related with reach in terms of electricity and sleep posture. If the device is not close to the plug, extension cables become a part of the experience. Mostly this scenario is mentioned in unpredictable use environments such as sleepover visits and vacations. If the use environment is temporary and unpredictable, the positioning of the device needs to be done again. Another problem with these temporary use environments is the change of conditions of user environment which are mentioned in the following paragraphs.

The conditions of the use environment generally affect the performance of the device. Some of these conditions can be controlled and manipulated by the user as dust and temperature, while others cannot be adjusted and the device should adapt to these conditions. The first environmental condition mentioned is the noise in the use environment. The noise mentioned in the study is the noise created by the device that can disturb sleep comfort of the user and bed partners. The noise can be perceived differently by the user because the noise can boost due to the vibration occurring and transmitted via the mask. The second condition is the temperature and humidity. These two conditions are closely connected in the CPAP case because the humidity of the air inhaled can result in side effects such as dry nose and bleeding. These conditions are manipulated by the device in order to avoid the side effects that may affect the patient adherence. However, it should be noted that these conditions are controlled by these devices because they are related with respiratory aid and treatments. In other words, devices are expected to adapt to the use environment conditions rather than changing them. The third condition is the illumination which is a change of condition created by the device. Due to the fact that CPAPs are used during sleep, light of the interface can create a problem for the user and the bed partner. Thus the brightness level, sleep mode and direction of the interface are designed in order not to disturb sleep. The last thing to consider in terms of features in CPAP is the air flow and particles in air. The use environment should be without contaminants and dust. Otherwise the filtering system would need more frequent maintenance. Adequate space around the device is required for a healthy air intake.

7.6 Checklist as a guide for MDDD of home use medical devices

A compact checklist for professional designers and students is developed with the purpose of mentioning important issues to address and guiding them through MDDD. Tips and suggestions as design strategies in the checklist are expected to help NPD teams to develop ideas which would improve user experience for increased adherence. Some of the items in the checklist do not require a field study and can be provided by manufacturers and healthcare professionals or can be found in the studies in the medical literature. In addition, the suggestions mentioned in the checklist are expected to be used by MDDD teams during their field studies and ideation of new products. The suggestions are listed as a short guidance in Appendix F for designers to check potential areas for improvements.

7.6.1 Who is the user?

Home use medical devices can be used by various actors with different roles. These groups can be listed as *patients*, *next of kin*, or *caregivers*. If patient has no barriers against the device use, designers can begin their field studies for need elicitation by studying the expectations of the patients. However the abilities of users are not always enough for assuming the patient will be the only user of the device. Medical devices with higher risk factors such as home hemodialysis devices that are listed as class 2 by FDA can require an additional user to be present during device use. Thus, definition of the user in MDDD process is not only related with the abilities of the user but also the requirements in the use scenario.

In addition to the definition of the user, the expectations of the users are important for achieving a successful adherence. These expectations cannot be narrowed down to the technical features and medical outputs of treatment. Although medical outputs are very important for professionals in measuring the success rate of the device, the experiences of non-professional users show differences from professionals in terms of integration to the daily life. To illustrate, negative outcomes such as depression

and anxiety can be encountered in caregiving activities carried out by next of kins. Due to these kinds of effects in caregiving that are resulted from the absence of professional approach to device and treatment process, designers should be aware of the effects of medical device use in daily lives.

7.6.2 What are characteristics of the users?

The characteristics of the users should be studied at the beginning of the MDDD process. Getting to know potential user groups is important for development of home use medical devices because it cannot be simply said that *patients* are the only users of these devices. As mentioned earlier *professional caregivers*, *family members*, or *relatives* can also use these devices in scenarios which the patients are disabled from using their devices properly. Thus, it should be revealed whether the device will be used by the patient or not. The strategies are briefly mentioned in Table 7.1.

Table 7-1: Design strategies concerning the characteristics of home use medical device users

What are the characteristics of the user?
• Physical characteristics related to chronic condition ***Symptoms*** *can affect the use even if the patient is not using the device.*
• Physical characteristics of the user demographics *Users' physical characteristics do not have to be related with the illness. Thus* ***user demograpics*** *should be included in profiling potential users.*
• Intellectual characteristics of the user Intellectual characteristics such as ***education level***, ***technology literacy***, and ***knowledge of foreign language*** are important for compatible design solutions.
• Daily routines and hobbies Users' daily practices should be included for better ***integration into daily life***. Otherwise it would be percieved as a disabler.

Physical characteristics related to chronic condition

The physical characteristics of patients mostly can be gathered from healthcare and medicine literature. Designers need to know the keywords and sources for these studies. However, the limited time of MDDD projects and difficulty of carrying out

a literature review make these sources partly unavailable for professional designers. Thus, professional designers gather these knowledge from their clients and healthcare professionals who take part in the MDDD projects as consultants. Designers mention this stage as transferring medical and technical knowledge regarding the medical device. The problem in this issue is the fact that patients cannot always use medical devices. Therefore lay users should be included in the MDDD studies.

Physical characteristics of the user demographics

Physical characteristics of the patients mentioned in the studies mostly describe the symptoms, demographics and specific characteristics of the patients resulting from illnesses. This information is very important for beginning of recognizing user needs. However, some key issues for product development cannot be always found in these studies. For instance, some physical characteristics which are not directly related with the illness are not mentioned but have an effect on the product design. To illustrate, a patient population which is mostly composed of elderly would also have problems with eyesight and this would not be mentioned in the healthcare research because it is not a condition directly resulting from the illness. However, this loss of ability should be included in the MDDD process especially in interaction and labelling.

Cognitive skills of the user

In addition to the physical characteristics of the users, cognitive skills of the users should also be included. It should be noted that home use medical devices are expected to be used by people from various backgrounds. Users will not have an experience or training in terms of using their medical devices. Thus, devices should be very easy to use and should not request high level skills. Otherwise problems occurring in the early use phase would jeopardize the adherence process. In order to deal with problems resulting from education level and literacy are mostly solved by using icons. Designers should be aware of the fact that selection of icons is important

because if these icons resemble others used in daily life with a different purpose, it can create problems again.

Daily routines and hobbies

Besides physical and intellectual characteristics of the users, there are other issues that designers should take into consideration and these user information is not very easy to find in other disciplines. These are key issues that can influence the user experience as a consumer product. Designers should evaluate the integration of the device into users' daily life. MDDD teams should seek information about the daily routines of the users and evaluate the effect of the device on these activities. Although it is not very easy to achieve an intuitive product which blends in daily life smoothly, MDDD teams should take these activities into consideration.

7.6.3 What is the frequency of device use?

The frequency of use plays an important role on the use environment and use scenario. If the device is expected to be used continuously all day long, it can be stated that the device is *mobile*. If the device is expected to be used repeatedly in different use environments, the device should be at least *portable*. Lastly, if the device and treatment require a specific set up and environment, the device may have to be *stationary*. The strategies are briefly mentioned in Table 7.2.

Table 7-2: Design strategies concerning the frequency of device use

What is the frequency of device use?
• All day long. (make it mobile!...) *You should check **wearable technologies**. It does not have to be a wristwatch.*
• Frequently in a day. (check for portability options) *First check the portability in **size and weight**.* *You should evaluate the **ease of set up**.* *Your design idea should **adapt to different use environments**. Try to lower your dependence and vulnerability on the qualities of the use environment.* *You should focus on the **maintenance and repair**. Concentrate on the capabilities of the user and available **third party components** to solve the problem.*
• Once a day. (check whether it has to be stationary) *You should rethink the reasons for being stationary. If the treatment **requires a specific set up** or your patient is **dependent to a certain use environment** (e.g. bedridden), stationary solutions can promise economic gains.*

All day long use

In terms of mobility, the devices can be used continuously for tracking or treatment. These devices would generate data and these data can turn into values or reports which enable patients to follow their treatment process and health status. The first design strategy is using *wearable technologies* and sensors for tracking purposes. Many healthcare products in consumer goods are developed by this perspective such as fitness and sleep trackers. These devices cannot be only defined as small or easy to carry objects. In fact, these devices have blended into other objects which are already used in daily life such as wristwatches and accessories. In other words, advancement in technology enabled us to integrate healthcare purposes into daily life products. In this perspective, designers should also focus on how to integrate their ideas into daily life by examining users' daily routines and belongings. Another point designers should take into account is the anatomic limitations. Designers should have a good understanding on the human anatomy and kinematics, and how these affect the integration of medical technologies into the human body.

Frequently in a day

In addition to the mobile devices, portability is another feature that designers can benefit from. Different from the mobility concept, portability is more focused on carrying products and setting them up quickly. In other words, the challenge for portable devices can be defined as adapting to different use environments. If the device does not include consumables, or the amount of consumables are small, as in insulin pens, it is suitable for developing a portable product. Although the mass and dimensions of the device is an important issue for portability, it cannot be claimed that all devices that can be carried around are successful portable devices. It can only be stated as a starting point for portability. The key issue in developing a portable product is *setting up* the device. The device should not require specific requirements in the use environment. Otherwise the device would fail in terms of the adaptation to use environments. Thus the required *space for use*, users' *comfort* and solutions to *prevent misuse and errors* should be examined.

A portable medical device should be ready to use in a short period of time because the time for preparation will restart over and over in each use. Thus, different from static ones, the controls on the device should be reevaluated and even can be reduced into a one-button control indicating 'ready to go'. Another issue to address is the change of use environment. The device should adapt to the features of different use environments in two terms as condition of the environment and the space of use. In terms of the environmental conditions, the device should perform successfully in different conditions, such as temperature, humidity, contaminants, electromagnetic interference and air flow, which are also mentioned by FDA (2012b) because the home environment is also an unpredictable use environment. The unpredictability of the use environment also affects the positioning of the device relative to the user. A portable device should be placed easily in the available space of use. To illustrate, a portable device should adapt to the use scenarios as grand tours, camping, vacations, etc. The change of use environment in these scenarios will affect the features of the device. Lastly, a portable device should allow users to solve problems that may occur during trips. The components of the device should be robust and easy to repair or

replace. Otherwise devices would fail easily due to the impacts or harsh use of the device that would easily occur in such a use scenario.

Once a day

It is not always possible to achieve or propose a mobile or portable medical device to the users. User characteristics and treatment processes would require a determined use environment. In terms of the user characteristics, health condition of the user would disable user to change location. To illustrate, use environment for a bedridden patient would be limited to home environment for majority of the time. Although patient would be transported or showed around, they will be more dependent on their living spaces and moving them would be tiring and undesirable in many cases. In this scenario, the use environment becomes more predictable and developing stationary design ideas would create opportunities in terms of financial and technical availability. In addition to the limitations of the user characteristics, requirements of the treatments can also limit the location of the devices. If the treatment process requires consumables that should be stored in specific conditions (e.g. temperature), the treatment process sticks to a predetermined use environment. As well as the consumables, the required time for a treatment session (i.e. operating time) also defines the use scenario and have effect on the locality of the device. To illustrate, home hemodialysis machines have been reduced to the size of almost portability, however the time period of a session and the consumables used in this treatment make the device stationary. Otherwise portability requires specific installations as in the case of mobile hemodialysis ambulances.

7.6.4 How can you improve the interaction of your device?

The interaction of devices play an important role in the adherence process of these technologies. Considering preventive healthcare technologies such as trackers and health information management apps have risen in consumer electronics market, most issues related to interaction of the devices are related with the performance and

usability of the digital interfaces and information systems. The strategies are briefly mentioned in Table 7.3.

Table 7-3: Design strategies concerning the improvement of interaction in home use medical devices

How can you improve the interaction of your device?
• Check the required information for your user. *Unnecessary information would only make it confusing.* ***Aim for lucid, clear feedback!***
• Reevaluate the **medium of interaction**. *You can* ***use other digital products*** *with apps.* *You do not have to include every control on device interface.* *You can even eliminate all controls on the device.*
• Consider **the chance of accidents**. *Use safety measures* ***as key locks or biometrics****. You can also hide the controls with* ***physical barriers****.*
• You can use apps for creating motivation with **increased connectedness**.
Warning! Some devices need an additional caregiver for safety. In these products **create continuous feedback** for monitoring or make the use sequence dependent on an additional actor in the use environment.

Check the required information for your user

Not all home use medical products have to offer digital technologies or a detailed feedback about the use. Some devices and products can have simple mechanical controls and adding these technologies would result as just making the product unnecessarily more complex and confusing. Thus the first question for the MDDD process in terms of interaction should be *what kind of information is necessary* for proper adherence to product use. A detailed feedback with lots of terminology would confuse an untrained user and create frustration.

Reevaluate the medium of interaction

Medium of feedback is important for determining the capabilities of reporting the use data and process of adherence. The components used on the devices cannot always promise a detailed information in the reporting. Thus *use of related electronic goods* is a design strategy that can be employed in the MDDD process. Although this

strategy is not desirable in the case of accidents and safety problems which may occur during use, this strategy can be used as an additional feature that does not limit intervention in emergency scenarios. With the help of this strategy, the interface of the device can be simpler and easier to understand enabling a smoother use scenario. Moreover the mobile apps can be used for *creating motivation* of use via means of connectedness. The use data and patients' treatment processes can be monitored and evaluated in the patients' accounts and applications can offer tips or targets for better habitation of device use.

Consider the chance of accidents

Another strategy is more related to the misuse and accidents that occur in the use scenario. The controls of the devices can be built in a *physical layered interface* that hides the controls which should not be available unless users need to adjust the clinical settings of the device. Another design strategy is using key locks for turning on these settings. However it has been mentioned that key locks are not secure enough for unexpected actors who also get in touch with the device. Thus *using biometrics* can limit the user to predetermined profiles and omit the accidental change of the settings.

In terms of accidents and malfunctions, one design strategy is related to the time period of use. If the device is expected to be used for a long session and the user is expected to be alert due to the risk factor of the treatment, requirement for *continuous input* can be another design strategy. This can be frustrating for some users but it is important for avoiding accidents as in line assistance of automobiles. In some cases, it is advised to have a partner to be present in the use environment but the design of the product does not direct their users to follow this rule. The input generated by the user does not have to be related with the treatment process. In order to avoid boredom and keeping the user connected to the user interface, games or other apps can be integrated to the device app. This design strategy can be useful especially for children, however this should not be perceived as an entertainment because this can also create a problem such as over use of the device.

7.6.5 How can you adapt your device to different user profiles?

The adaptation to the home users is another topic worth studying by designers. It should be noted that a product cannot always answer the whole patient population's expectations. This can result from the physical differences and requirements such as devices manufactured for children. Still, *customization* of the devices can be a design strategy to explore for adjusting to these needs. In most medical devices the customization of the settings are achieved by digital controls. However the physical features of the devices cannot be varied in the same level due to the barriers regarding scale of production and manufacturing capabilities of the companies. Home use medical devices' scale of production is not in high numbers as the quantities in the consumer market. In addition, the specification of the devices for different illnesses makes these products to be manufactured in small quantities. Thus many medical devices (especially ones manufactured for local markets) are produced within the limitations of the manufacturers and their sub-contractors. Thus, the physical adaptation of the devices to the user desires can be achieved by *personalization* which as a strategy makes use of the capabilities of user. The strategies are briefly mentioned in Table 7.4.

Table 7-4: Design strategies concerning the adaptation to different user profiles

How can you adapt your device to different user profiles?
• Think **customization** as a way of adaptation. *However it is highly **depended on the manufacturing capabilities** of the firm. If you cannot find a feasible way for this, you can think about personalization.*
• *If customization is not feasible, check the **capabilities of your users**. You can benefit from their skills for personalization of your devices.*
• *If **tailor made components** are feasible for your product, you can integrate the new ways of manufacturing as a personalization strategy.*
• *You can also benefit from new manufacturing approaches such as rapid manufacturing and open source approaches for increasing availability.*

In spite of the fact that, medical device manufacturers encounter limitations in customization of their devices, this strategy can be used for differentiating from their

competitors especially for medical products which should be manufactured as *tailor made* ones for their users. The most common example for these products can be implants and prostheses or orthoses which are expected to fit perfectly to the user body. While some of these products are designed as invisible products for blending into the body, designers can turn these product into aesthetic pieces as Canadian firm Alleles does (see figure 7.4).

In addition to the tailor made components, new ways of manufacturing can be used for adaptation to different user groups. Flexibility in additive manufacturing and prototyping can be employed not only for adapting to these user groups but also for the personalization of the products. The removal of some manufacturing tools and investments can empower end users to make interventions to the products for improvements. The boundaries of these interventions should be studied by designers in order not to contradict with safety and medical treatment requirements. Besides better integration to the user groups in terms of customization and personalization, new manufacturing technologies can be used for improving the availability of medical products. To illustrate, medical devices that are not available in some regions of the world due to economic, logistic or political problems can still be available for people if products' manufacturing processes are adapted to an open source approach.

Figure 7-4: Prosthetic leg design by Allelis
(downloaded from: https://alleles.ca/wp-content/uploads/2020/07/IMPERIALIST_black_14k-gold_BK.jpg)

7.6.6 How can you achieve privacy in your device?

Privacy is an important issue in the MDDD process. Participants mentioned this issue especially regarding reactions of their family members. Although using a medical device or having a chronic condition is nothing to be ashamed of, users may feel themselves uncomfortable sharing their health condition with others. Thus, providing privacy is necessary in development of medical devices which are designed to be used outside of healthcare facilities. The strategies are briefly mentioned in Table 7.5.

Table 7-5: Design strategies concerning privacy issues in home use medical devices

How can you achieve privacy in your device?
***Warning**: You should **check for the serious risks and emergencies** in the use scenario. The emergencies in some health problems can conflict with the idea of making product discreet.*
• *Make it invisible!* *You can **dematerialize and turn your device into a software**. Think how you can benefit from other smart wearable products' capabilities.* *You can **personalize or code the feedback** of your device in a way that only users would understand and follow their stats in privacy.* *Create **visual resemblance with a product in the use environment**. You should **be careful about confusions** and problems in the use scenario in case an unexpected actor should take part in the use scenario.* *Create a form language which **blends into the use environment**. Traditional medical devices can become a center of attention. **Choose your materials, colors and finishes wisely**.*
• *Privacy of the use data* *Check for issues in terms of **data privacy**. You can **consult with an expert** in the field of health informatics.*

Make it invisible!

As mentioned earlier, making the device *invisible* in the use environment is the first design strategy that can be used for privacy concerns. This strategy can be achieved by different methods such as *dematerializing the device*, *diffusion into other products*, and *visual similarity*. These methods can be employed in the NPD process

individually as well as in combination. While using these methods offer new opportunities in different devices, it can also create problems in use scenario. Therefore the results of the ideation process should also be discussed with healthcare professionals along with users in terms of strengths and weaknesses.

The first method is dematerialization that can be explained as transforming the device into a software that requires no physical hardware. This method can be used in monitoring devices which are used for tracking user statistics. Most of these technologies use sensors for generating data and a software for analyzing and turning these data into information. In addition to the software and sensors, creating smart environments for monitoring users can also be used in combination with visual similarity.

This method can easily be integrated with the second method as diffusion into other products. Today most healthcare technologies use this method such as health and wellbeing applications on mobile products. This allows users to benefit from the multi-functionality of their smart products. In addition to mobile phones and tablets, we have witnessed the emergence of smart wearables which targets the generation of user data and new opportunities for interaction in mobility. In terms of the smart watches, users can monitor their state of health and exercises that are a part of their treatments. Although smart watches come to mind when smart wearables are mentioned, the boundaries for using digital technologies on body goes beyond this approach. Designers can reevaluate the way of integrating human body and digital technologies by analyzing the way of acquiring necessary data to be used in patient monitoring. In other words, users do not have to put their smart wearable trackers on their wrists and devices can be positioned according to different cases. Turning the device into an accessory is helpful for this aim in two terms. The first benefit of turning the devices into accessories is the visual compatibility of the device into the impression desired to create. If the device blends into look and body, it will be easier to keep the device away from attention. Still, this strategy should be evaluated carefully because some chronic conditions involve serious risks and emergencies

therefore people who take part in these situations should be informed about users' chronic conditions.

The third method for invisibility is creating a visual resemblance in form. Turning medical devices into accessories and smart wearables can also be accepted as an example of this technique as well as diffusion into other products. However, an expanded approach in this technique is possible. The home use medical devices can blend into the home use context by creating a relationship with other products in the use environment. If the device takes form similar to other products which are expected to exist in the environment, the medical device would not draw attention and become invisible. The weak side of this method is being open to misuse by other actors in the use environment. As mentioned earlier, unexpected users such as family members, children and house cleaners could mistakenly change product parameters. Thus this method should be supported by additional safety measures disabling accidents and misuse.

Privacy of the use data

In addition to the form language of the device, privacy concerns are also related to digital use information and data. This problem is generally studied by informatics specialists. Designers can contribute to this issue with their expertise in interaction design in terms of the *way of interaction*, *understandability of feedback*, and the *coding of feedback*. Designers can find new opportunities in the way of interaction by using different senses and new technologies. Existing devices usually include old fashioned screens with numbers and icons. These screens are acceptable for devices manufactured by small scale companies due to limitations of their NPD teams and budget. However, devices manufactured by global companies also do not keep up with consumer products, even with the products their companies manufacture for different sectors. Still, designers can use technologies that are used in innovative sectors for enriching the pleasure of interaction.

The lucidity of feedback is another issue for both usability and privacy of device use. If the feedback is easy to understand and does not require time for tracking, users

can keep their device use more discreet. Feedback can be divided into different levels of detail as in mobile apps. Users can follow their condition with a few values and get detailed information in more suitable conditions later. This method can lead to the third method which is coding and personalizing feedback of the device. The graphic interface and icons can be altered to different options that do not reveal the device in public. This approach can also be adapted in other mediums of interaction such as sounds and lights.

CHAPTER 8

CONCLUSION

In this chapter, findings of the field study, the themes mentioned in the discussion part will be summarized and matched with the research questions.

8.1 Research questions revisited

Research questions which this study is trying to answer are mentioned in a brief way in this section. The first group of questions are answered through the findings of the field study and the literature reviews. Following that, the research questions of the field study and the discussion part are mentioned. Outcomes of the thesis for the research questions which are listed below are summarized in the following sub sections.

- *Analysis of current situation in healthcare:*
    - Which stakeholders affect requirements elicitation of home use medical devices? (Section 3.1)
    - What is the role of end users in the MDDD process? (section 3.3)
- *Understanding tools and methods employed for user research in the MDDD process*
    - Which design research methods are already adopted in MDDD? (section 2.3.1)
    - What kind of user information is sought by industrial designers in MDDD projects?
    - What are the barriers for industrial designers in terms of user research in MDDD?

- *Exploration of ways for integrating design research methods in the MDDD process*
    - Which characteristics of end users would affect selection of design research methods?
    - How do requirements of design research methods affect their viability in the MDDD process?
- *What are the characteristics of CPAP lay users?*
- *What are the constraints with regard to medical therapy in CPAP design?*
- *Which strategies can be followed by designers for design and development of home use medical devices?*

8.1.1 Analysis of current situation in healthcare

In terms of the current situation in healthcare, the actors participating in the MDDD process and role of users in this process are important for designers in order to develop a new design approach that enables them to better integrate user needs in addition to the medical requirements that the devices are expected to fulfill. However, designers should be aware of the fact that expectations of these user groups can conflict and designers would encounter dilemmas during their design decisions. Although user expectations in the needs elicitation play an important role in consumer goods, MDDD must also address the expectations of healthcare professionals in order to carry out a successful treatment process. Thus, designers should also be aware of the patient participation models in healthcare.

Which stakeholders affect requirements elicitation of home use medical devices?

The influential actors in needs elicitation during the MDDD process can be listed as patients, lay users, family members, healthcare professionals, and device manufacturers. These groups show differences in terms of their priorities. Thus their contributions to NPD processes of home use medical devices also differ and designers should include these actors in their project processes. The first two groups

(patients and lay users) mostly focus on the effects of device use on daily life. While their contributions can be perceived very similar, the effects of the device use can differ. To illustrate, CPAP devices have effects on the patients' lives in terms of the outcomes of the treatment such as being more alert and having better quality sleep. Along with that, the features of the device can affect the sleep quality of the bed partner due to the noise, light or air leaks. The effects of the device use is not only related with the technical features of the device. If the device is being used by patients' next of kin due to the disabilities of the patient, the responsibility and emotional state of caregivers also become important. Thus, the device should also comfort these users along with the patient.

In addition to the different user groups of home use devices, house folk is another group of actors who are affected by the new device in the home. The issue is mentioned as emotional states of the house folk in the findings. The house folk (especially children) should be included in the development process in order to manage their emotional states.

Healthcare professionals are important for meeting medical purposes of the devices. If requirements elicitation stage is carried out by only home users, the outcome of the process can lack or miss the medical features necessary for treatment.

Another actor influential in the MDDD process is the device manufacturers. The NPD teams are naturally affected by the expectations of this group because constraints, limitations of the manufacturers outline the potential design decisions in projects. These limitations can result from various reasons such as financial limits, lack of professionals, manufacturing limits of the firms and sub-contractors. The challenge for designers is seeking design solutions answering to the needs of these groups and making design decisions once conflicting requests are encountered. Another influential factor for manufacturers are the regulations for medical devices. These regulations generally aim for safety and success of treatments. Companies must follow these directions and manufacture products in the boundaries of these in order to take part in the healthcare market. Otherwise their products cannot be called

as medical device, they cannot be prescribed, and be reimbursed by insurance. Last limitation for the manufacturers is their competitors. Other devices in the market have effects on design opportunities. One limitation in this issue is property rights. Companies must have a complete survey about existing devices. NPD teams are well aware of this issue and MDDD processes start with a search for property rights and market analysis. In addition to that, the competition of pricing limits the potential design solutions.

What is the role of end users in the MDDD process?

The role of end users in the MDDD process is briefly explained in user studies and MDDD models in the literature review. Users take part in predetermined stages of the MDDD process namely needs elicitation and verification & validation stages. Users can take part in needs elicitation stage along with other actors as mentioned in the previous research question. The needs assessment stage is usually referred to as clinical needs which prioritize the position of the healthcare professionals. There is nothing wrong with this approach once it is understood that healthcare professionals do also want the health and wellbeing of the patients. In addition to that, healthcare professionals can be more objective due to their professional stance on the subject. Still, the clinical needs should be answered with the expectations of the users because the adherence process is heavily dependent on the psychology and perception of the end users. Along with the elicitation process, users commonly take part in the design verification and validation stages. The methodology of design verification and validation should be determined in the beginning of the MDDD process because all following stages should be examined with predetermined measures in order to continue and result with a successful device.

8.1.2 Understanding tools and methods employed for user research in the MDDD process

This group of research questions aim understanding user research in MDDD processes. Thus the questions are grouped under three topics which are methods used in healthcare, type of user information necessary for MDDD and barriers for industrial designers in user studies in the field.

Which design research methods are already adopted in MDDD?

The design research methods employed in MDDD processes are mentioned in Chapter 2. Traditional methods as interviewing and questionnaires are generally used in needs assessment studies. These methods are useful for carrying out field studies with high numbers of participants that enable to generate scales and turn these scales into statistically significant findings. These outcomes of the studies are objective and can be measured by other researchers with different research set ups for comparisons and follow up studies. In addition to the needs assessment studies, usability studies have adopted some design research methods that are frequently used in product design also (e.g. cognitive walkthrough, heuristic evaluation, think aloud protocol, behavioral mapping). These research methods promise a strong point along with a weak point in the MDDD process. The strong point in these methods is gaining in-depth information regarding the design of the device which is not possible with a questionnaire. However the weak point is the fact that implementation of these methods require time and professionals with experience which are not usually available in medical device manufacturers or design teams. The same problem also exists for methods used in longitudinal studies such as diary studies and design ethnography. Thus, the participant numbers are lower in these methods compared to the previous ones mentioned in needs assessment but the insights are more enriched and useful in terms of MDDD.

What kind of user information is sought by industrial designers in MDDD projects?

It can said that user information sought in MDDD projects mostly aim a definition of the user population of the device. The information related with this population is composed by demographics and symptoms. The reason behind this approach is the term of 'patient' is being preferred rather than user. In other words, the definition of users is structured on their illnesses. However the users are not solely composed of their illnesses. They have other qualities which compose their identities. Thus, these qualities should also be addressed in MDDD projects for a better adherence process of the medical device. Individual differences among the users like their beliefs and life styles can affect their reactions against treatment processes. To illustrate, users' daily routines or hobbies can have an important part in their social lives and limiting these activities due to use of a home use medical device would be problematic in terms of adherence because of the frustration caused by the changes in daily life. Thus, the approach taken in the user information should not be only related with the illnesses but be more comprehensive in order to better recognize the priorities of the users.

What are the barriers for industrial designers in terms of user research in MDDD?

As mentioned in the second question, the main barrier against industrial designers is the requirements of user research in terms of time and labor. With MDDD projects with short time schedules and limited budgets, it is not possible to carry out a field study with users (especially longitudinal studies). Thus, designers usually seek these user information ready from companies or healthcare professionals in the design briefing stage. In addition to the technical barriers against user research in MDDD, the availability of the users is another issue to be addressed. Users cannot always feel themselves as comfortable with designers or researchers as they do with doctors. Even the sex of the participant is important in this issue. NPD teams should be careful about the privacy of the study and be experienced in terms of communicating in a calming manner. Otherwise, participants would not be open to share their thoughts with a foreigner who is not a healthcare professional.

8.1.3 Exploration of ways for integrating design research methods in the MDDD process

Integration of design research methods into the MDDD process is mainly a topic that designers should pay attention to in terms of requirements of the research methods and characteristics of users. The compatibility between these two terms needs to be known by NPD teams. Otherwise, project teams cannot get satisfactory data from their participants during their field studies. Thus, research questions below should be evaluated together.

Which characteristics of end users would affect selection of design research methods?

How do requirements of design research methods affect their viability in the MDDD process?

As mentioned before user characteristics play an important role for usability and adherence of the device. These characteristics are also important for executing a fruitful user study in needs assessment. These characteristics can be defined in two terms which are physical and intellectual barriers.

Physical barriers are mainly related with the disabilities and limitations of the users which disable them from participating in field studies or expressing their ideas. First group of physical barrier that disable the users from research studies is disabilities in terms of mobility. Some health conditions can make patients or users dependent on certain locations such as their homes. In these conditions the researchers should design their research methodologies such that their research set up can be transferred to the location of the user. Fixed user study laboratory equipment is not an applicable choice. However some technologies on mobile devices can help designers to overcome this barrier such as eye tracking or usability applications on tablets. Designers can use these technologies for examining their project dummy interfaces or design ideas rather than fixed setups with cameras in the laboratories. Designers can also transfer their equipment and install them into the living area in users' homes.

However privacy concerns are the main barrier against this approach. Participants may not like to be monitored in their private lives. Thus the way of collecting data is an important issue to be discussed. Researchers can mount sensors in products and home environment for tracking the life in home and can compare these data with the data gathered from the users. This approach can help designers to check the accuracy of the expression of the users because all user research specialists know that participants may have a tendency to define the desired way of use rather than the existing one.

Another physical barrier against the application of field study is the time of the device use. In the CPAP case, the participants are expected to use their devices in sleep time which makes participatory observations out of choice. Healthcare research deals with this problem by using sleep laboratories where patients spend their nights and are monitored. In fact, this can be defined as simulating a use environment in a healthcare facility. The same approach is widely used in studies with children to make them comfortable during examinations as in Park (2009).

Physical barriers are not only related with time and location of the study method. Disabilities regarding communication is another issue for designers to consider. This barrier exists especially for children and elders due to their lack of skills or losing these skills in time. To illustrate, keeping diaries can be problematic for children due to being illiterate or for elderlies due to problems in motor skills necessary for writing that can be resulted from neurological illnesses. In addition to that, limitations due to lack of abilities in expressing ideas is another barrier for researchers. Children can use terms which are not very descriptive or in a different way. Thus, researchers should be aware of these issues.

Lastly, intellectual limitations can challenge designers during their research. These limitations can be related with some health conditions or a simple lack of skills related with using device. If users have a health condition such as mental illness or disability, designers encounter a difficult challenge because research methods generally depend on the communication skills of participants. Fortunately, in such

cases, devices are used by next of kin and they can participate in the studies. Other intellectual limitations are being illiterate or lack of technological literacy or experience with interaction. If users have no experience with interactive digital technologies, participants in the studies can feel uncomfortable and stressed. Thus, researchers should be comforting and acknowledge participants that their performance would not be evaluated as right or wrong, or success and fail.

8.1.4 What are the characteristics of CPAP lay users?

The definition of CPAP users can be stated based on two groups of characteristics, user properties related with the illness, demographics, and perceptions. The first group of characteristics focuses on the outcomes of the CPAP treatment, and the second group focuses on the general characteristics shared among user profiles, and the last one is users' reactions in terms of emotions and perceptions regarding devices.

In terms of the characteristics which are directly related with OSA, lay users share common characteristics that can be defined as the symptoms of the illness. The first common characteristic is related with lack of sleep. Due to inadequate sleep, users have problems with activities in daily life such as driving, work life and entertainment. Users generally experience difficulty in concentrating during activities that require alertness for long periods of time. The most common example for these kinds of activities is driving. Although it is not evaluated high in quantitative findings, participants mentioned the issue as changes in daily life during interviews. While one participant mentioned he had an accident due to being sleepy, another participant mentioned that he used to prepare for long journeys with coffees and 10 hours of sleep in order to avoid sleepiness during his trips. In terms of work life, participants have problems with concentration like driving especially during meetings due to being static for a long time. Office hours become napping hours especially for users who have an isolated space. Participants with more dynamic working conditions, do not complain about the issue. In short, the effects of lack of

sleep become clearer during static hours. To illustrate, OSA patients mention the sleepiness as a problem especially in their domestic life. Patients mention they tend to have naps especially after having dinners and during watching TV.

Other characteristics in the second group are health conditions resulting from shared illnesses among the patients. These health problems can be listed as heart failure, hypertension, and cardiovascular problems. These problems can be both linked to OSA or can be resulted independently from OSA. However, the increased chance of these conditions in the patient population is usually mentioned in medical studies and that make designers include these conditions as potential user characteristics. Patients can use medication and devices for tracking these chronic conditions as well. Thus, designers should be aware that device users are not composed of only one diagnosis and other frequent conditions should also be included in the ideation phase. The expansion of this user profiling can help designers combine ideas and offer multifunctional devices that ease tracking health conditions with fewer products.

The third group of characteristics are related with the psychological effects of OSA and CPAP treatment. The emotional state of the users is important for designers in order to build an effective communication and successful adherence process. In general OSA patients tend to have mood disorders such as anxiety and depression before CPAP treatment. Due to lack of sleep and hormonal disorders the psychological changes occur among the users which affect their daily lives both in private life and business. In addition to that, the early times of OSA diagnosis and CPAP treatment also create emotional effects such as anxiety, sadness, and depression. Being diagnosed with a chronic condition requires changes in lifestyles, and affects patients' moods due to the changes that need to be adopted. A constructive communication is necessary for these chronic conditions and comfort users. Risks of the illness can be used as a negative reinforcement as perceived risks in the health belief model. However, the emphasis on the negative sides of the illness affects patients' emotional state in a negative way. Although mentioning the risks is important, the expected outcomes by the treatment is more helpful for creating a motivation for use. The adherence is dependent on noticing the positive outcomes of

the treatment and patients who experience these improvements in their quality of life tend to accept and adapt to the new life style. Patients who are in more serious conditions experience these changes more prominently and tend to have a positive stance about CPAP treatment and also tend to share their experiences compared to users who do not perceive the outcomes clearly. Thus, the process of the treatment and positive changes should be emphasized to maintain a better mood during the treatment.

8.1.5 What are the constraints with regard to medical therapy in CPAP design?

Considering CPAP devices are simple and with low-risk, the constraints in CPAP design is lower compared to other home use medical devices with higher-risks like home hemodialysis machines. All CPAP devices should match the requirements mentioned by regulatory institutions in order to be licensed and take part in the market. These are mostly related with technical features of the devices in terms of dosing and parameters. In addition to that, the renewal of the licenses of devices mention that there should not be important differences in terms of design and purpose of use. This can make incremental redesign approach undesirable for companies and continue with their existing products.

In addition to that, CPAP devices should be easy to use and adapt to related product components in order to achieve a successful therapy. The devices mostly share standardized fixtures for product consumables such as hoses and masks. This design decision enables users to combine their CPAP devices with other companies' components, which increases the comfort of use in terms of anthropometrics and compatibility of the components to body parts. The design decision can alter to specific parts if the component promises improvements as elimination of side effects such as water droplets in the mask. Although these specific product components are proposed as additional features, the compatibility of the devices with standard parts

is still maintained. In short, manufacturers tend to use potential benefits which can be adapted from other companies' products.

8.1.6 Which strategies can be followed by designers for the design and development of home use medical devices?

Design strategies for designers to implement in MDDD processes of home use medical products include suggestions that enable them to explore potential design problems and generate solutions in the exploration and ideation phases. Design strategies regarding technical issues in MDDD such as testing and engineering design are excluded due to the fact that issues related with these terms are already adopted by manufacturers and can be found in engineering design studies in biomedical engineering and healthcare. The design strategies aim the areas of need assessment, use frequency and environment, interaction and adaptation to user expectations.

Design strategies for needs assessment:

Designers should explore the characteristics of user profiles. Among the design strategies the first suggestion is *consulting healthcare professionals* for recognizing the definition of the illness and patients characteristics mentioned in the literature. This would ease the time and labor necessary for understanding the target population. Another suggestion for designers is *exploring shared common conditions* among the target group. These conditions can be fruitful for revealing specific conditions of the users which are not listed in the symptoms and side effects of the treatments and illnesses. The third suggestion is *checking cognitive skills of users*. This is necessary for foreseeing the potential problems in terms of usability of the devices. If a device requires a specific set of intellectual competences, it would require training or else result in problems in the learning stage. Therefore the design solutions should match these capabilities rather than transferring the approach taken in the professional equipment. The last design suggestion for designers is *analyzing users' daily*

routines. The daily routines and activities which are important for users in terms of quality of life and entertainment are important because the limitations of these activities would create problems in the perception of the treatment.

Design strategies for use environment and frequency of use:

Use environments of the devices are closely related with their use frequency. If a device is expected to be used all day long, it turns into a mobile device. In the design of mobile devices, *turning the device into a wearable product* would be a first design strategy to be executed. There are several issues to focus on in this strategy while deciding on the placement of the device on users' body, among which are anthropometrics and kinematics. If the device should be used for a couple of times in a day, the device turns into a portable one. The first design strategy in terms of portability would be *reducing the size and weight* of the device. However reduction is not enough in achieving portability. Thus, designers should *make setting the device easier*. Time and space required before the use of device should be reduced compared to professional devices because this stage of use will be executed repeatedly. In this approach, another design strategy is the requirement of *adaptation to different use environments*. The change of use environment requires devices to be less dependent on the qualities of use environment because these devices can be used in unexpected environments such as hotels, offices, restaurants, automobiles and even outdoors. In order to achieve this goal, designers should *analyze the parameters of use environment* (e.g. temperature, humidity, contaminants, electromagnetic interference, etc.) that can limit usage. One last design strategy for portable devices would be *easing the maintenance and repair* with third party components due to the fact that variations in use environments and locations can limit the availability of components and access to maintenance.

Design strategies for interaction:

The first design suggestion in terms of interaction is *reevaluating the required information for users*. Detailed information illustrated as in professional devices would create confusion along with frustration for users. Thus, the feedback should

include required information and be presented in a lucid way. The way of interaction in terms of medium is another issue to address in MDDD. There are several options for designers to choose from in the development of a new device. The first option is eliminating physical controls on the device and *using other digital products for interaction*. This strategy enables designers to limit people who can make adjustments. Another option is *creating physical barriers on the controls*. This can be simple covers which make the buttons out of reach, or displacement or mapping controls for avoiding accidents. Last design strategy is *using safety measures* which are also used in other consumer goods such as biometrics, passwords or key locks. These safety measures are generally used for disabling change of settings of the devices but they can be inadequate if the design strategy is easy to override accidentally.

In addition to these, improvements exist in device design aiming for the safety of patients. Especially devices with higher risk levels require keeping a close eye during use and a second person for tracking the process of treatment. These actors are usually family members or caregivers sharing the use environment with the patient. In order to keep concentration during long treatment sessions, designers can *create continuous inputs*. However this strategy can result with boredom and annoyance if the input turns into a repetitive rhythm. Thus, third party applications (e.g. games) can be used rather than pushing a button repeatedly.

Design strategies for adaptation to users:

Adaptation to different user profiles can be achieved by *customization* and *personalization* strategies. In terms of customization designers should evaluate *manufacturing capabilities and barriers* during the MDDD process. The manufacturing issues such as scale of production and capabilities of manufacturers are important for designers because the medical manufacturing industry is heavily dependent on sub-contractors and manufacturers for outsourcing the production of their devices' components. Even large scale companies manufacturing in their own facilities design common parts and platforms for reducing manufacturing costs. If

the manufacturing limitations disable customization of the device designers can *benefit from users' capabilities* in terms of personalization. Users can adapt their devices according to their tastes and needs. In addition to that, designers can increase the adaptation level to higher levels if they can *use tailor made manufacturing* which is commonly used among prostheses and orthoses.

Design strategies for privacy:

Privacy of device use can be achieved by *dematerialization of the device*, *diffusion into other products*, and *creating visual resemblance* with other products in the use environment. These three strategies mainly aim for making the device invisible or discreet. Although these strategies can increase the privacy of device users, it can also create problems in health conditions with serious risks like crisis and strokes. In these conditions, first responders should be aware of the chronic conditions of users. Thanks to digital technologies, monitoring devices can integrate with other products and become software without a physical hardware. This strategy helps users to use their consumer goods for medical purposes. This trend can lead competitive companies of consumer goods to take part in the healthcare market. In this approach, personalization of feedback can also be used for privacy of device use. Users can personalize the feedback of their devices in a discreet way that only they would follow their stats. This adjustment of feedback can also reduce required time and make monitoring easier.

In addition to these strategies the form language of the device can be used as a design strategy by creating visual resemblance with other products in use environment. This strategy mainly aims matching the product appeal with use environment in order to avoid turning the device into a center of attention. The strategy can be applied in two ways which are *imitating other products* and *creating a bridge in form language*. The first strategy, imitating other products, can be criticized by designers as being kitsch and for losing the relationship between form and function. These critics are acceptable in case of creating confusions during use and these devices are expected to be used easily by a wide range of user profiles. However, this strategy can be

applied once this potential risk is managed. The second strategy is not simply making products similar to other objects but it is about creating a visual form which blends into the use environment. In the CPAP case, devices can be divided into two groups. The first group has the form language of professional devices which are used in healthcare facilities. Color and material use among these devices are very similar to or even the same (white bended metal sheets) as professional equipment. The other group is closer to home electronics by using grayscale tones and plastic bodies. It should be noted that this difference is mainly related with the production capabilities of the companies. This simple change in design greatly affects the harmony in the use environment. However, the invisibility of CPAP devices is mostly inhibited by masks and hoses that put a medical product in everyday life environment. In short, the material and color use along with form of the device can help designers to match their design ideas with a new use environment in terms of styling.

8.2 Contribution of the thesis

The contribution of this thesis can be discussed under two directions, in terms of literature survey and field study.

The dissertation is structured on a literature review including healthcare research, MDDD, and design research. The literature review enables design professionals to have a better understanding of the terminology used and make a comparison between the approaches taken among these disciplines. Although designers are expected to already have this knowledge, the differences of the terminology make it harder to grasp the topic especially for freelance designers, who do not carry out MDDD projects on a regular basis. To illustrate, the terminology used for user's adaptation to a new product or technology is referred to as technology acceptance models in product development, while the same issue is studied in the field of patient adherence in healthcare research because the latter discipline also studies the behavior change required for using pharmaceuticals properly. In addition, the differences of NPD approaches in consumer goods and healthcare are also mentioned. In other words,

design professionals should be aware of the priorities of healthcare research in order to answer the requirements expected from a device in the medical perspective.

The field study illustrates user expectations in terms of device design. The same issue has also been studied by Aydın & Börekçi (2016) with parallel findings addressing the importance of user characteristics, use environment, lay users, and device features. In addition to interviews, this study includes scales which are used in sleep sciences. The results of these scales are evaluated in quantitative values and compared with the findings obtained in the qualitative parts of the study. The qualitative results illustrate deeper insights regarding the use of the devices. In order to understand patients' experiences through their adherence processes, in depth reviews are helpful in terms of emotional stances and perceptions of using a medical device for a chronic condition. Moreover these insights enable discussions over important points in patient adherence.

This thesis proposes a design checklist for designers with possible design strategies for the development of home use medical devices. The importance of the design checklist is the fact that a compact tool illustrating potential design issues regarding the design of a device for a new use context is expected to be useful for designers to carry out a design project within a limited time. Otherwise, a detailed literature review and a list of readings would reduce the chances of using the findings of the study by practitioners.

8.3 Limitations of the study

The field study is carried out as face to face semi-structured interviews and this created a geographical limitation to the participants of the study. Although the participants are from various ages and periods of use, it should be noted that device users from other regions can have other priorities and inputs to the study. Along with the geographical limitation, the sex of the participants is mostly male (90%). As mentioned earlier, one reason of the high majority of the male participants in the

study can be traced to the fact that OSA is also more common among men especially older than 40 years of age. In addition, this may also have resulted from the fact that the field study is carried out by a male researcher therefore some female participants preferred to quit the study before the interview sessions without indicating an excuse or reason.

Another limitation of the study is reluctance in sharing a personal health condition with a researcher who is not a medical doctor. Considering that OSA is a chronic condition that effects the relationship between CPAP users and their partners, participants are not always very open to mention the effects of CPAP use on these issues. Due to the fact that participants may feel themselves uncomfortable, the topic is not included in the survey.

8.4 Recommendations for further study

MDDD is an area of study that is linked to various disciplines and requires knowledge for different cases. Thus, further research can be made for different medical devices and health conditions (i.e. diabetes, hypertension, heart disease, etc.). The changes necessary in life styles for success in patient adherence and treatment process can result in different key issues for these different illnesses.

The design research methods used in elicitation of user needs can be expanded to cases where generating user data is not very fruitful by traditional methods such as interviews and questionnaires. Especially studying with children would require use of graphics and visuals because children may have difficulties in expressing themselves in words and text. In addition to the use of different methods with specific user groups, longitudinal studies can be carried out for examining the changes occurring during the adherence stage as problems and barriers. Video or written diaries or sensors creating smart environments can be used for monitoring use behavior.

In addition to user studies with different research methods, focus group studies can be carried out for studying the effectiveness of the checklist. These focus group studies can be set as workshops composed of actors with different profiles. Experience levels of participants can differ among these with included control groups in order to study how senior designers' approaches differ from junior designers' and students' in terms of concept generation in order to understand how barriers in real life conditions affect designers' approaches. In addition to that, the backgrounds of group members can be selected from different professions for simulating dynamics of priorities in NPD teams through MDDD projects and their effect on ideation processes.

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APPENDICES

A. List of Home Use Medical Products

(Adapted from (Family Care America, 2013))

	Product name	Use context /Patients condition
1	Air cleaners:	Respiration
2	Air conditioners:	Respiration
3	Air-fluidized bed:	Bedridden
4	Alternating Pressure Pads and Mattresses, and Lamps Wool Pads:	Bedridden
5	Audible/visible signal pacemaker monitor:	Monitoring
6	Augmentative communication device:	Communication
7	Bathtub lifts:	Homecare / bath
8	Bathtub seats:	Homecare/ bath
9	Bead bed:	Bedridden
10	Bed baths:	Bedridden /hygiene
11	Bed lifter:	Bedridden
12	Bed boards:	Bedridden
13	Bed pans:	Bedridden
14	Bed side rails:	Bedridden
15	Beds—lounge:	Bedridden
16	Beds—oscillating:	Bedridden
17	Blood glucose analyser/reflectance colorimeter:	Monitoring
18	Blood glucose monitor:	Monitoring
19	Braille teaching texts:	Communication
20	Canes:	Mobility
21	Catheters:	Consumables/disposables
22	Commodes:	Bedridden
23	Communicator:	Communication
24	Continuous passive motion devices:	Physical therapy
25	Continuous positive airway pressure (cpap):	Respiratory ventilation
26	Crutches:	Mobility
27	Cushion lift power seat:	Homecare / mobility
28	Dehumidifiers:	Respiration
29	Diathermy machines:	Heating
30	Digital electronic pacemaker monitor:	Monitoring

31	Disposable Sheets and Bags:	Consumables/disposables
32	Elastic stockings:	Consumables/disposables
33	Electric air cleaners:	Respiration
34	Electric hospital beds:	Bedridden / bedding
35	Electrostatic machines:	
36	Elevators:	Bedridden
37	Emesis basins:	Bedridden
38	Esophageal dilator:	Operation tool
39	Exercise equipment:	Exercise
40	Fabric supports:	Bedding / posture
41	Face Masks (oxygen):	Consumables/disposables
42	Face Masks (surgical):	Consumables/disposables
43	Flowmeter:	Respiratory ventilation
44	Fluidic breathing assister:	Respiratory ventilation
45	Fomentation device:	Heat therapy
46	Gel Flotation Pads and Mattresses:	Bedridden
47	Grab bars:	Homecare /mobility
48	Heat and Massage Foam Cushion Pad:	Orthopaedic therapy / physical therapy
49	Heating and Cooling Plants:	
50	Heating pads/hot packs:	Heating therapy
51	Heat lamps:	Heating therapy
52	Hospital beds:	Bedding
53	Humidifiers (oxygen):	Respiratory ventilation
54	Humidifiers (room or central heating system types):	Respiratory ventilation
55	Hydraulic lift:	Mobility / bedridden
56	Incontinent Pads: (diapers)	Consumables/disposables
57	Infusion pumps:	Pharmaceutical
58	Injectors (hypodermic jet pressure powered devices for injection of insulin):	Pharmaceutical
59	Ippb machines:	Respiratory ventilation
60	Iron lungs:	Respiratory ventilation
61	Irrigating kit:	Post-operation
62	Lymphedema pumps:	Post-operation
63	Massage devices:	Massage
64	Mattress:	Bedding
65	Medical oxygen regulators:	Respiratory ventilation
66	Mobile geriatric chair:	Mobility
67	Motorized wheelchairs:	Mobility
68	Muscle stimulators:	Physical therapy
69	Nebulizers:	Respiratory ventilation
70	Oscillating Beds: (roto rest bed)	Bedridden

71	Overbed tables:	Homecare / feeding
72	Oxygen:	Respiratory ventilation
73	Oxygen humidifiers:	Respiratory ventilation
74	Oxygen tents:	Respiratory ventilation
75	Paraffin bath units (portable):	Physical therapy
76	Paraffin bath units (standard):	Physical therapy
77	Parallel bars:	Physical therapy
78	Patient lifts:	Bedridden
79	Percussors:	Physical therapy
80	Portable oxygen systems:	
81	Regulated (adjustable flow rate):	Respiratory ventilation
82	Preset (flow rate not adjustable):	Respiratory ventilation
83	Portable room heaters:	Homecare/installation
84	Portable whirlpool pumps:	Homecare/bath
85	Postural drainage boards:	Respiratory ventilation
86	Preset portable oxygen units:	First aid
87	Pressure leotards:	Consumables/disposables
88	Pulse tachometer:	Monitoring
89	Quad-canes:	Mobility
90	Raised toilet seats:	Homecare/bath
91	Reflectance colorimeters:	Diagnosis
92	Respirators:	Respiratory ventilation
93	Rolling chairs:	Mobility
94	Safety roller:	Mobility
95	Sauna baths:	Homecare/bath
96	Seat lift:	Mobility / homecare
97	Self-contained pacemaker monitor:	Monitoring
98	Sitz bath:	Post-operation
99	Speech teaching machine:	Communication
100	Stairway elevators:	Homecare/mobility
101	Standing table:	Homecare/mobility
102	Steam packs:	Heat therapy
103	Suction machine:	Respiratory ventilation
104	Support hose:	Consumables/disposables
105	Surgical leggings:	Consumables/disposables
106	Telephone alert systems:	Communication
107	Telephone arms:	Communication
108	Toilet seats:	Homecare/bath
109	Traction equipment:	Physical therapy
110	Trapeze bars:	Physical therapy
111	Treadmill exerciser:	Exercising
112	Ultraviolet cabinet:	Hygiene / treatment of skin
113	Urinals (autoclavable hospital type):	Bedridden

114	Vaporizers:	Respiratory ventilation
115	Ventilators:	Respiratory ventilation
116	Walkers:	Mobility
117	Water and Pressure Pads and Mattresses:	Bedridden
118	Wheelchairs:	Mobility
119	Wheelchairs (power operated):	Mobility
120	Whirlpool bath equipment:	Hygiene / therapy
121	Whirlpool pumps:	Therapy

Patients' Conditions	Number of devices
bedridden	20
respiratory ventilation	19
mobility	11
physical therapy	9
monitoring	6
communication	6
respiration	4
homecare/bath	7
homecare/mobility	5
homecare/feeding	1

B. Home Use Medical Products Manufactured in Ankara

Device	Manufacturing companies
Respiration & respiratory ventilation	
Air cleaners	Metisafe
CPAP	Foras, Elmaslar
Flowmeter	Ateşçi Medikal, Bates Medikal
Humidifier (oxygen)	UYS,
Humidifier (room)	Foras, Yavaş Medikal
nebulizers	Elmaslar, Ertunç Özcan
Postural Drainage Boards:	4a Medikal
Suction machine	4a Medikal,Üzümcü
Ventilators	UYS, Foras, Ertunç Özcan,Üzümcü
Bedridden	
Bedboards:	Teknikon,TMS Medikal
Hospital Beds:	UYS
Monitoring	
Audible/Visible Signal Pacemaker Monitor:	Ertunç Özcan
Heating/Heat Therapy	
Diathermy Machines:	Sümer AŞ
Fomentation Device:	Sümer AŞ
Heating Pads/Hot Packs:	Sümer AŞ
Pharmaceuticals	
Infusion Pumps:	UYS, Ertunç Özcan
Injectors (hypodermic jet pressure powered devices for injection of insulin):	UYS
Mobility	
Wheelchairs:	UYS, Sera Medikal, Kifas Medikal, KBB Tautman
Wheelchairs (power operated):	UYS
Physical Therapy	
Parallel Bars:	Sera Medikal
Traction Equipment:	Sera Medikal
Trapeze Bars:	Sera Medikal

C. Interview Sheet for Home Users (Turkish Version)

KATILIMCI BİLGİLERİ

Yaş:			Katılımcı kodu:		
Meslek:			Görüşme tarihi:		
Eğitim durumu:	o İlkokul	o Ortaokul	o Lise	o Üniversite	o Lisansüstü
Bilgisayar/internet kullanımı:	o Telefon	o İnternet	o E-posta	o Facebook vb	o Whatsapp vb
Toplam CPAP cihazı kullanım süresi:					
Şu anda kullandığınız CPAP cihazı markası:					
Şu anda kullandığınız CPAP cihazı kullanım süresi:					

CİHAZ TEDARİK SÜRECİ

1. Kullandığınız cihazı nasıl tedarik ettiniz?

o Yeni bir cihaz satın aldım.	o Sosyal Güvenlik Kurumuna iade edilen ürünlerden aldım.

2. Cihazınızı seçerken kimlerden tavsiye aldınız?

o Doktor	o Satış görevlisi (medikalci)	o Aile yakını
o Hemşire	o Üretici firma görevlisi	o Ürünü daha önce kullanmış biri
o Hasta bakıcı	o Sosyal Güvenlik Kurumu çalışanı	o Kimseden tavsiye almadım.
o _____	o _____	o _____

1. Cihazınızı seçmenizde neler etkili oldu?

o Fiyatı	o Uzman tavsiyesi	o Bakım onarım imkanları
o Ulaşılabilirlik	o	o
o	o	o
o	o	o

CİHAZI ÖĞRENME SÜRECİ

1. Cihazın kullanımı ile herhangi bir eğitim aldınız mı?

o Evet	o Hayır

2. Cihazın nasıl kullanılacağını size kim öğretti?

o Doktor	o Satış görevlisi (medikalci)	o Aile yakını
o Hemşire	o Üretici firma görevlisi	o Ürünü daha önce kullanmış biri
o Hasta bakıcı	o Sosyal Güvenlik Kurumu çalışanı	o Kendi başıma öğrendim.
o Kullanım kılavuzundan öğrendim.	o _____	o _____

3. Cihazı kullanmayı yeni öğrendiğiniz dönemde herhangi bir sorun yaşadınız mı?

o Evet (biraz açar mısınız?)	o Hayır

4. Yaşadığınız sorunu çözmek için kimden yardım aldınız?

o Doktor	o Satış görevlisi (medikalci)	o Aile yakını
o Hemşire	o Üretici firma görevlisi	o Ürünü daha önce kullanmış biri
o Hasta bakıcı	o Sosyal Güvenlik Kurumu çalışanı	o Kendi başıma öğrendim.
o _____	o _____	o _____

5. Cihazın bakımı ve yenilenen parçaları ile ilgili kimlerden yardım aldınız?

o Doktor	o Satış görevlisi (medikalci)	o Aile yakını
o Hemşire	o Üretici firma görevlisi	o Ürünü daha önce kullanmış biri
o Hasta bakıcı	o Sosyal Güvenlik Kurumu çalışanı	o Kendi başıma buldum.
o _____	o _____	o _____

6. Cihazı kullanmaya başladıktan sonra hayatınızda neler değişti?

CİHAZIN GENEL KULLANIM DENEYİMİ | **Katılımcı kodu:**

Anket, kullandığınız CPAP cihazı ile ilişkilendirilebilecek birbirine zıt özellikler (toplamda 26 çift) içermektedir. Bu özellikler arasındaki kareler, zıtlıklar arasındaki dereceleri temsil etmektedir. Ürüne dair izleniminizi, her özellik için karelerden yalnızca birini işaretleyerek göstermelisiniz.

Örnek:

Yararsız	o	o	o	o	o	o	o	Yararlı

Yukarıdaki gibi bir işaretleme, ürünü "yararsız" bulmaktan çok "yararlı" bulduğunuzu ifade edecektir.

Lütfen üzerinde çok düşünmeden karar verin ve ilk izleniminizi yansıtacak yanıtı vermeye çalışın.

Bazen verdiğiniz karardan tamamiyle emin olamayabilirsiniz veya seçtiğiniz yanıtın ürünle tam olarak ilişkili olamayacağını düşünebilirsiniz. Yine de, her satırdaki karelerden birini işaretleyerek mutlaka seçiminizi yapınız.
Önemli olan sizin kişisel fikriniz. Lütfen burada doğru veya yanlış yanıt olmadığını unutmayın!

Kullandığınız cihazın modeli:								
1. Lütfen kullandığınız cihazı aşağıda geçen özelliklere göre değerlendirin.								
Can sıkıcı	o	o	o	o	o	o	o	Eğlenceli
Anlaşılmaz	o	o	o	o	o	o	o	Anlaşılır
Yaratıcı	o	o	o	o	o	o	o	Yaratıcı değil
Kolay öğrenilir	o	o	o	o	o	o	o	Öğrenilmesi zor
Değerli	o	o	o	o	o	o	o	Adi
Sıkıcı	o	o	o	o	o	o	o	Heyecan verici
İlginç değil	o	o	o	o	o	o	o	İlginç
Önceden kestirilemez	o	o	o	o	o	o	o	Öngörülebilir
Hızlı	o	o	o	o	o	o	o	Yavaş
Özgün	o	o	o	o	o	o	o	Geleneksel
Engelleyici	o	o	o	o	o	o	o	Destekleyici
İyi	o	o	o	o	o	o	o	Kötü
Karmaşık	o	o	o	o	o	o	o	Yalın
Sevimsiz	o	o	o	o	o	o	o	Sevimli
Alışıldık	o	o	o	o	o	o	o	Çığır açıcı
Hoşa gitmeyen	o	o	o	o	o	o	o	Hoşa giden
Güvenli	o	o	o	o	o	o	o	Güvensiz
Teşvik edici	o	o	o	o	o	o	o	Şevk kırıcı
Beklentileri kaşlayan	o	o	o	o	o	o	o	Beklentileri karşılamayan
Verimsiz	o	o	o	o	o	o	o	Verimli
Açık	o	o	o	o	o	o	o	Akıl karıştıran
Pratik olmayan	o	o	o	o	o	o	o	Pratik
Derli toplu	o	o	o	o	o	o	o	Dağınık
Çekici	o	o	o	o	o	o	o	İtici
Sempatik	o	o	o	o	o	o	o	Antipatik
Tutucu	o	o	o	o	o	o	o	Yenilikçi

CİHAZ KULLANIMININ SOSYAL YAŞAMA ETKİLERİ	Katılımcı kodu:

UYKU APNESİ İÇİN KENDİNE YETERLİK ÖLÇEĞİ (SELF EFFICACY FOR SLEEP APNEA)

Risk Algısı

Kendi yaşım ve cinsiyetimdeki insanlarla karşılatırıldığında _____ İhtimalim:

	Çok düşük	Düşük	Yüksek	Çok yüksek
Gün içinde uykuya dalma				
Yüksek tansiyonumun olması				
Kalp krizi geçirme				
Konsantrasyon zorluğu çekme				
Araba kullanırken uyuklama				
Moralimin bozuk olması				
Kaza geçirme				

Sonuçlar - Beklentiler

CPAP kullanırsam _____

	Yanlış	Azda olsa doğru	Kısmen doğru	Tamamen Doğru
kendimi daha iyi hissederim				
horlamam				
daha aktif olurum				
yatakta eşim daha rahat uyur				
iş performansım artar				
trafik kazası geçirme ihtimalim düşer				
ilişkilerim gelişir				
daha tetikte olurum				

Kendi Kendine Yetebilme Durumu

_____ bile CPAP kullanırım.

	Yanlış	Azda olsa doğru	Kısmen doğru	Tamamen Doğru
uyumaya hazırlanmam daha uzun zaman alsa				
seyahate çıksam				
utanç hissetsem				
Sıkı bir maske takmak zorunda kalsam				
Zahmet / sıkıntı verse				
Belli bir miktar ödeme yapmam gerekse				
burnumu / genzimi tıkasa				
Klostrofobik / daralmış hissettirse				
Eşimi uykusunda rahatsız etse				

CPAP SAHİPLİĞİNE DAİR TAVIRLAR ÖLÇEĞİ (ATTITUDES TO CPAP INVENTORY)

1. CPAP tedavisi uyku apnesi kaynaklı problemleri azalttı.				
Kesinlikle katılıyorum	Katılıyorum	Karar veremedim	Katılmıyorum	Kesinlikle katılmıyorum.
2. CPAP tedavisi sağlığıma iyi geliyor.				
Kesinlikle katılıyorum	Katılıyorum	Karar veremedim	Katılmıyorum	Kesinlikle katılmıyorum.
3. CPAP tedavisi yaşam kalitemi yükseltiyor.				
Kesinlikle katılıyorum	Katılıyorum	Karar veremedim	Katılmıyorum	Kesinlikle katılmıyorum.
4. CPAP tedavisi uyku apnem için en iyi tedavi yöntemi.				
Kesinlikle katılıyorum	Katılıyorum	Karar veremedim	Katılmıyorum	Kesinlikle katılmıyorum.
5. CPAP cihazımı benden beklendiği şekilde kullanabiliyorum.				
Kesinlikle katılıyorum	Katılıyorum	Karar veremedim	Katılmıyorum	Kesinlikle katılmıyorum.

1. Cihazı kullanmaya başladıktan sonra sizin ya da yakınlarınızın hayatında neler değişti?

2. Cihazı kullandığınızı aileniz dışında çevrenizle paylaşıyor musunuz?

o Evet	o Hayır

3. Cihazı eviniz dışında başka yerlerde (tatilde, otelde, akraba ziyareti, vb) kullanıyor musunuz?

o Evet	o Hayır

4. Ev dışı kullanımda evde kullanımdan ne gibi farklılıklar olduğunu bizimle paylaşabilir misiniz?

5. Görüşme sürecinde değinmediğimiz ve eklemek istediğiniz bir şey var mı?

CİHAZIN GÜN İÇİNDE KULLANIMI VE KULLANIM ALIŞKANLIĞI KAZANIMI | **Katılımcı kodu:**

CPAP KULLANIM ALIŞKANLIĞI ENDEKSİ (CPAP HABIT INDEX 5)

1. Sıradan bir haftada geceleri CPAP kullanmak alışkanlıklarım arasındadır.

Kesinlikle katılıyorum	Katılıyorum	Karar veremedim	Katılmıyorum	Kesinlikle katılmıyorum

2. Sıradan bir gecede CPAP kullanmayacaksam özel bir neden gerekir.

Kesinlikle katılıyorum	Katılıyorum	Karar veremedim	Katılmıyorum	Kesinlikle katılmıyorum.

3. Uzun zamandır geceleri CPAP kullanıyorum.

Kesinlikle katılıyorum	Katılıyorum	Karar veremedim	Katılmıyorum	Kesinlikle katılmıyorum.

4. Sıradan bir gecede CPAP kullanmadığımda garip hissediyorum.

Kesinlikle katılıyorum	Katılıyorum	Karar veremedim	Katılmıyorum	Kesinlikle katılmıyorum.

5. Sıradan bir gecede CPAP cihazımı az çok otomatikman (kendiliğimden) kullanıyorum.

Kesinlikle katılıyorum	Katılıyorum	Karar veremedim	Katılmıyorum	Kesinlikle katılmıyorum.

1. Cihazı ne sıklıkta kullanıyorsunuz?

o Günde ..... defa	o Hergün	o ..... günde bir

2. Cihazı gün içerisinde ne kadar süre kullanıyorsunuz?

o Bir kullanımda yaklaşık: ..... saat ..... dakika	o Gün boyunca toplam: ..... saat ..... dakika

3. Cihazı günlük yaşantıda nerelerde kullanıyorsunuz?

o Yatak odasında	o Salonda	o Çalışma odasında
o Misafir odasında	o İş yerinde	o Otelde
o _____	o _____	o _____

4. Cihazı kullanmadığınız zamanlarda nasıl saklıyorsunuz?

ÜRÜN GELİŞTİRME ÖNERİLERİ

1. Bu cihaza yönelik geliştirilmesi veya değişmesini arzu ettiğiniz neler var?

2. Cihazın tasarımı ile ilgili dikkate alınması gereken hususları önem sırasına göre sıralayabilir misiniz? Size yardımcı olmak için bazı örnekler aşağıda verilmiştir. Verilen örnekler dışında istediğiniz gibi eklemelerde bulunabilirsiniz.
(ağırlık, boyutlar, ses, arayüz tasarımı (tuşlar, ekran büyüklüğü, vb.), bağlantı hortumları, maske, vb)

ÖNEMLİ KRİTERLER / HUSUSLAR	AÇIKLAMA
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

D. Interview Sheet for Home Users (English Version)

PARTICIPANT INFORMATION

Age:			Code of the participant:		
Occupation:			Date:		
Education:	○ Primary school	○ Middle school	○ High school	○ University	○ Graduate
Use of technology and internet:	○ Phone	○ Internet	○ E-mail	○ Facebook, etc.	○ Whatsapp, etc.
Total time of CPAP use:					
Brand of the CPAP device currently used:					
Time spent with current CPAP device:					

DEVICE PURCHASE PROCESS

1. How did you get your device?

○ I purchased a brand new one.	○ Got one refurbished product from insurance.

2. From whom did you take advice duing the selection process?

○ Doctor	○ Medical salesperson	○ Relatives
○ Nurse	○ Manufacturer personel	○ Another user of the device
○ Caregiver	○ Insurance (Social Security Institution)	○ Didnot get any advice.
○ _____	○ _____	○ _____

3. What are the factors affecting your selection process?

○ Price	○ Expert opinion	○ Maintenance
○ Availability	○	○
○	○	○
○	○	○

CİHAZI ÖĞRENME SÜRECİ

1. Did you get any training about how to use the device?

○ Yes	○ No

2. Who taught you how to use the device?

○ Doctor	○ Medical salesperson	○ Relatives
○ Nurse	○ Manufacturer personel	○ Ürünü daha önce kullanmış biri
○ Caregiver	○ Insurance (Social Security Institution)	○ Learned by myself.
○ Learned from user manual.	○ _____	○ _____

3. Have you ever encountered a problem during your early learning phase of use

○ Yes (please explain)	○ No

4. From whom did you get help to solve your problem?

○ Doctor	○ Medical salesperson	○ Relatives
○ Nurse	○ Manufacturer personel	○ Ürünü daha önce kullanmış biri
○ Caregiver	○ Insurance (Social Security Institution)	○ Solved by myself.
○ _____	○ _____	○ _____

5. From whom did you get help in terms of maintenance and renewable parts?

○ Doctor	○ Medical salesperson	○ Relatives
○ Nurse	○ Manufacturer personel	○ Ürünü daha önce kullanmış biri
○ Caregiver	○ Insurance (Social Security Institution)	○ Solved by myself.
○ _____	○ _____	○ _____

6. What kind of changes did you notice after begining to use you device?

USER EXPERIENCE QUESTIONNAIRE | **Participant code:**

The questionnaire includes 26 opposite items which you are expected to address your CPAP device. the level of your evaluation are represented as the gaps to be filled in the sheet. Please mention your impression by selecting only one gap in the squares.

Example:

Useless	○	○	○	○	○	○	○	Useful

The filled up example above express you evaluate the product useful rather than useless

Please do not overthink while deciding your answers and try to mention your first impression in your answers.

You may not be sure about your answers and the item is relevant to your device. Still, please select one of the gaps in every item.
Your personal thoughts are important in this study. Please keep in mind that there is no right or wrong answer.

Brand / Model of the device:								
1. Please evaluate your device in terms of the items listed below.								
Annoying	○	○	○	○	○	○	○	enjoyable
Not understandable	○	○	○	○	○	○	○	understandable
creative	○	○	○	○	○	○	○	dull
easy to learn	○	○	○	○	○	○	○	difficult to learn
valuable	○	○	○	○	○	○	○	inferior
boring	○	○	○	○	○	○	○	exciting
not interesting	○	○	○	○	○	○	○	interesting
unpredictable	○	○	○	○	○	○	○	predictable
fast	○	○	○	○	○	○	○	slow
inventive	○	○	○	○	○	○	○	conventional
obstructive	○	○	○	○	○	○	○	supportive
good	○	○	○	○	○	○	○	bad
complicated	○	○	○	○	○	○	○	easy
unlikable	○	○	○	○	○	○	○	pleasing
usual	○	○	○	○	○	○	○	leading edge
unpleasant	○	○	○	○	○	○	○	pleasant
secure	○	○	○	○	○	○	○	not secure
motivating	○	○	○	○	○	○	○	demotivating
meets expectations	○	○	○	○	○	○	○	does not meet expectations
inefficient	○	○	○	○	○	○	○	efficient
clear	○	○	○	○	○	○	○	confusing
impractical	○	○	○	○	○	○	○	practical
organized	○	○	○	○	○	○	○	cluttered
attractive	○	○	○	○	○	○	○	unattractive
friendly	○	○	○	○	○	○	○	unfriendly
conservative	○	○	○	○	○	○	○	innovative

SOCIAL EFFECTS OF CPAP USE | **Participant code:**

Self-Efficacy Measure for Sleep Apnea (SEMSA)

Risk Perception

Having OSA, my chances of _____

	Very low	Low	High	Very High
Falling asleep during day				
Having high blood pressure				
Having heart attack				
Difficulty concentrating				
Falling asleep driving				
Being depressed				
Having an accident				

Expected Outcomes

If I use CPAP _____

	Wrong	Slightly True	Somewhat true	Very True
I will feel better				
I will not snore				
I will be more active				
Bed partner will sleep better				
Improve job performance				
Decrease chance of driving accident				
Improve relationships				
Be more alert				

CPAP Self-Efficacy

I would use CPAP even if...

	Wrong	Slightly True	Somewhat true	Very True
Took longer to get ready for bed				
I traveled				
Feel embarrassed				
Had to wear tight mask				
It were a bother				
Had to pay for some of cost				
It made my nose stuffy				
Made me feel claustrophobic				
Disturbed my bed partner's sleep				

ATTITUDES TO CPAP INVENTORY (ACTI)

1. The CPAP treatment reduces the problems caused by my sleep apnea

Strongly agree	Agree	Undecided	Disagree	Strongly disagree

2. The CPAP treatment improves my health

Strongly agree	Agree	Undecided	Disagree	Strongly disagree

3. The CPAP treatment improves my quality of life

Strongly agree	Agree	Undecided	Disagree	Strongly disagree

4. The CPAP treatment is the best treatment for my sleep apnea

Strongly agree	Agree	Undecided	Disagree	Strongly disagree

5. I can use the CPAP as expected of me

Strongly agree	Agree	Undecided	Disagree	Strongly disagree

1. What changes have you witnesed in your and your familf's life after starting to use CPAP device?

2. Do you share that you use CPAP device beyond your family?

o Yes	o No

3. Do you use your device in other places (otels, relatives homes, etc.) except your home?

o Yes	o No

4. Would you explain the differences of using your device in places except your home?

5. Would youlike to add anything?

HABITATION OF CPAP USE	Participant code:

CPAP HABIT INDEX 5 (CHI-5)

1. Using the CPAP nightly is part of my routines a normal week

Strongly agree	Agree	Undecided	Disagree	Strongly disagree

2. A special reason is needed if I'm not going to use the CPAP during a normal night

Strongly agree	Agree	Undecided	Disagree	Strongly disagree

3. I have used the CPAP nightly for a long time

Strongly agree	Agree	Undecided	Disagree	Strongly disagree

4. It feels weird not to use the CPAP during a normal night

Strongly agree	Agree	Undecided	Disagree	Strongly disagree

5. I use the CPAP more or less automatically during a normal night

Strongly agree	Agree	Undecided	Disagree	Strongly disagree

1. How frequently do you use your device?

o ..... Times a day	o Everyday	o once in every ..... days

2. For how long do you use your device a day?

o In one time ..... hours ..... Minutes	o throughout the day: ..... hours ..... Minutes

3. Where do you use your device in a normal day?

o Bedroom	o Sitting room	o Study room
o Guest room	o Office	o Otel
o _____	o _____	o _____

4. How do you store your device when you are not using it?

SUGGESTIONS FOR IMPROVEMENTS

1. What points would you mention To be improved or changed in device design

2. Can you rank the important issues to consider in device design? Some examples are given below. You can add or change the items below as you wish.
Weight, size, noise, interface design buttons, size of the screen, etc.) hose, mask, etc.)

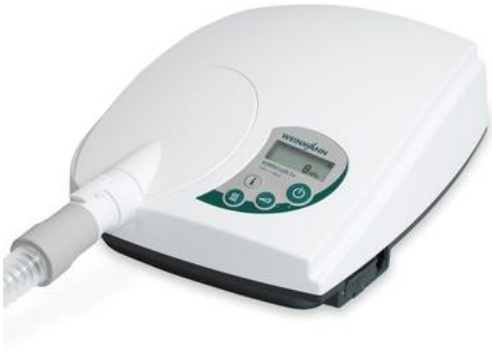
IMPORTANT KEY POINTS	EXPLANATION
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

E. Catalogue of CPAP devices available in Turkey

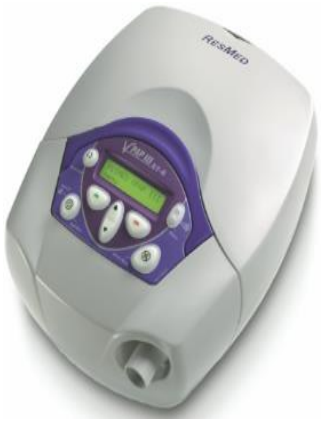
BREAS	DeVilbiss HEALTHCARE
	
BREAS Z1 CPAP	DeVilbiss Healthcare Blue
	
BREAS VIVO 40 CPAP	DeVilbiss Healthcare Sleep Cube
	
BREAS ISLEEP	DeVilbiss Healthcare 9000 & 8000

PHILIPS RESPIRONICS	PHILIPS RESPIRONICS
	
Respironics Dreamstation	Respironics System One
	
Respironics Dorma	
	
Respironics Sleepeasy	Respironics REMstar Pro

	
Respironics REMstar	Respironics Synchrony
plusmed health management	Fisher & Paykel HEALTHCARE
	
Plusmed CPAP	Fisher & Paykel Healthcare ICON
	
Plusmed Auto CPAP	Fisher & Paykel Sleep Style

WEINMANN medical technology	HOFFRICHTER Quality makes the Difference
	
Weinmann SOMNOsoft serisi	Hoffrichter Vector et. Serisi
	
Weinmann Prisma serisi	Hoffrichter Trend 2 Serisi
	
Weinmann SOMNOvent serisi	Hoffrichter Trend Serisi

	
	Hoffrichter Point Serisi
RESMED	RESMED
	
ResMed Airsense Serisi	Resmed Aircurve Serisi
	
ResMed S9 Serisi	

	
ResMed S8 Autoset Spirit Serisi	
	
ResMed S7 Lightweight	ResMed VPAP III ST-A
	
ResMed S5 & S6	ResMed Sullivan

	
SleepOne CPAP serisi	SleepAS CPAP Serisi

F. Checklist of design strategies for developing home use medical devices

DESIGN SUGGESTIONS FOR DESIGNERS IN THE DEVELOPMENT OF HOME USE MEDICAL DEVICES

1. Who is the lay user?

a) Patient
b) Next of kin
c) Caregiver

2. What are characteristics of the users?

a) Physical characteristics related with the chronic condition:

- *Symptoms should be included even if the device is not being used by the user because it will affect the interaction between care giver and recipient. (Consult with healthcare professionals on this issue to save time)*

b) Physical characteristics of the user demographics:

- *The symptoms are helpful for only checking the effects of the illness. However user can have other physical characteristics that can affect on the use experience of the device.(check for shared illnesses and health conditions that can be resulted from user demographics)*

c) Cognitive skills of the user:

- *You should check the intellectual capabilities of your user profiles. The technology literacy, knowing foreign language and education levels are important for achieving ease of use in your design.*

d) Check users' daily routines and hobbies:

- *Daily practices are important for achieving better integration to daily lives. If your design proposal conflicts with users' daily lives, it would be perceived as a disabler that would jeopardize the adherence.*

3. What is the frequency of device use?

a) <u>All day long (make it mobile!)</u>

- *You should check wearable technologies. It does not have to be a wristwatch. Think of possibilities with sensor technologies.*

b) <u>Frequently in a day (check for portability opportunities)</u>

- *First check the portability in size and weight. If you cannot carry easily during the day, you should explore for alternative solutions.*

- *You should evaluate the ease of set up. If the device is not ready to use in short time, the preparation stage can be a burden for your user.*

- *Your design idea should adapt to different use environments. Check for environmental factors (temperature, humidity, access to electricity, contaminants, etc.) which affects your device. Try to lower your dependence and vulnerability on the qualities of the use environment.*

- *You should focus on the maintenance and repair. Unexpected use environment and locations can make these services unavailable. Thus, concentrate on the capabilities of the user and available third party components to solve the problem.*

c) <u>Once a day (check whether it has to be stationary)</u>

- *You should rethink the reasons for stationary. If the treatment requires a specific set up or your patient is dependent to a certain use environment (e.g. bedridden), stationary solutions can promise economic gains.*

4. How can you improve the interaction of your device*?*

- *You should check the required information for your user. Unnecessary information would only make it confusing. Aim for lucid, clear feedback!*

- *Reevaluate the medium of interaction. You can use other digital products with apps. You do not have to include every control on device interface. You can eliminate all controls on the device.*

- *You should consider the chance of accidents. Use safety measures as key locks or biometrics. You can also hide the controls with physical barriers.*

- *You can use apps for creating motivation with increased connectedness.*

- ***Warnıng!*** *Some devices need an additional caregiver for safety. In these products create continuous feedback for monitoring or make the use sequence dependent on an additional actor in the use environment.*

5. How can you adapt your device to different user profiles?

- *You can think of customization as a way of adaptation. However it is highly depended on the manufacturing capabilities of the firm. If you cannot find a feasible way for this, you can think about personalization.*

- *If customization is not feasible, check the capabilities of your users. You can benefit from their skills for personalization of your devices.*

- *If tailor made components are feasible for your product, you can integrate the adaptation purposes to the manufacturing process.*

6. How can you achieve privacy in your device?

Warning: *You should check for the serious risks and emergencies in the use scenario. The emergencies in some health problems con conflict with the idea of making product discreet.*

a) Make it invisible!

- *You can dematerialize and turn your device into a software. Think how you can benefit from other smart wearable products' capabilities.*

- *You can personalize or code the feedback of your device in a way that only user would understand and follow their stats in privacy.*

- *Create visual resemblance with a product in the use environment. You should be careful about confusions and problems in the use scenario in case an unexpected actors should take part in the use scenario.*

- *Create a form language which blends into the use environment. Traditional medical devices can become a center of attention. Choose your materials, colors and finishes wisely.*

b) Privacy of the use data:

- *Check for issues in terms of data privacy. You can consult with an expert in the field of health informatics.*

CURRICULUM VITAE

PERSONAL INFORMATION

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EDUCATION

Degree	Institution	Year of Graduation
MS	METU Industrial Design	2012
BS	METU Industrial Design	2008

WORK EXPERIENCE

Year	Place	Enrollment
2019-Present	Selcuk University Dept. of Industrial Design	Instructor
2020-2021	TED University Dept. of Industrial Design	Part-time Instructor
2019	Atılım University Dept. of Industrial Design	Part-time Instructor
2009-2018	METU Dept. of Industrial Design	Research Assistant

FOREIGN LANGUAGES

Advanced English

PUBLICATIONS

1. OKURSOY, M. E., & PEDGLEY, O. (2019) Barriers and opportunities for integrating sustainable product design into Ankara small and medium-sized furniture enterprises In Soğütlü C. Döngel N. Çınar H. İmırzı H. Ö. Yılmaz K. Öztürk Y. Akkuş B (Eds.) *The XXIXTH International Conference Research for Furniture Industry 2019* (pp. 581-596)