CONTEXT OF USE OF HOME USE MEDICAL DEVICES: A STUDY ON THE IDENTIFICATION OF CONTEXTUAL FACTORS OF CPAP DEVICES

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CONTEXT OF USE OF HOME USE MEDICAL DEVICES:
A STUDY ON THE IDENTIFICATION OF CONTEXTUAL FACTORS OF CPAP DEVICES

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ABSTRACT

CONTEXT OF USE OF HOME USE MEDICAL DEVICES: A STUDY ON THE IDENTIFICATION OF CONTEXTUAL FACTORS OF CPAP DEVICES

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World population is getting older and technology is advancing rapidly over the last decades. At the intersection of these changes, there is a growing desire to provide more effective healthcare to the elder population with the help of improving technology. Medical devices have started to become miniaturized, simplified and affordable enough to find their way out of hospitals into homes. This situation has affected the design considerations on medical devices due to the change of the user groups and product environments. Therefore, there appears to be a need for design research on the context of use for such devices. This study explores the contextual factors of the home environment affecting the usage of home use medical devices. In-depth interviews are conducted with eight home use CPAP (Continuous Positive Airway Pressure) device users. The interviews questioned the habits and expectations of the users, the features of the devices, the tasks involved in their usage, and how the physical and social environments of the users are affecting the usage of the device. The findings indicate that there are eight major themes under which the factors are gathered. These are, factors related to user characteristics,

problems, motivating factors, tasks, storage and environment, assistance, factors affecting purchase decisions, and preferences.

Keywords: Home use medical devices, medical device usage, home environment, context of use, contextual factors, CPAP device.

ÖZ

EV TİPİ MEDİKAL CİHAZLARIN KULLANIM KOŞULLARI: CPAP CİHAZLARININ KULLANIM KOŞULLARINA YÖNELİK ETKENLERİNİN TESPİTİ ÜZERİNE BİR ÇALIŞMA

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Son yıllarda dünya nüfusu yaşlanırken, teknoloji hızlı bir şekilde gelişmektedir. Bu değişimlerin kesişiminde, gelişen teknolojinin yardımı ile yaşlı nüfusa daha etkili sağlık hizmetleri sağlanması arzu edilmektedir. Buna bağlı olarak, medikal cihazlar evlere girecek kadar küçülmüş, sadeleşmiş ve daha hesaplı hale gelmiştir. Bu durum, değişen kullanıcı grubu ve kullanım ortamı sonucu, medikal cihazların tasarımında göz önünde bulundurulan konuları da etkilemiştir. Bu sebeple, evlerde kullanılan medikal cihazların kullanım koşulları üzerine tasarım araştırmaları açısından bir ihtiyaç doğmuştur. Bu çalışma ev tipi medikal cihazların kullanımını etkileyen kullanım koşullarını konu almaktadır. Sekiz ev tipi CPAP (Sürekli Pozitif Hava Yolu Basıncı) cihazı kullanıcısıyla derinlemesine mülakatlar yapılmıştır. Sonrasında bu mülakatlar kullanıcıların alışkanlıkları ve beklentileri, cihazların özellikleri, cihazların kullanım adımları ve kullanıcıların fiziksel ve sosyal çevrelerinin cihaz kullanımını nasıl etkilediği açılarından incelenmiştir. Sonuçlar etkenlerin sekiz ana tema başlığında toplandığını göstermektedir. Bunlar, kullanıcı özelliklerine ilişkin etkenler, problemler, motive edici etkenler, kullanım adımları,

saklama ve çevre, destek, satın alma kararlarını etkileyen etkenler ve tercihler olarak belirlenmiştir.

Anahtar kelimeler: Ev tipi medikal cihazlar, medical cihaz kullanımı, ev ortamı, kullanım koşulları, kullanım koşullarını etkileyen etkenler, CPAP cihazı.

To my beloved family

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TABLE OF CONTENTS

LIST OF TABLES

TABLES

LIST OF FIGURES

FIGURES

LIST OF ABBREVIATIONS

AED: Automated external defibrillator

CDRH: Center for Devices and Radiological Health

CE: Conformité Européenne (French of European Conformity)

CPAP: Continuous positive airway pressure

EC: European Commission

EEC: European Economic Community

EN: European Norm (European Standard)

EU: European Union

FD&C: Federal Food, Drug, and Cosmetic Act

FDA: Food and Drug Administration

GDP: Gross domestic product

GHTF: Global Harmonization Task Force

GMP: Good Manufacturing Practices

HHCC: Home Health Care Committee

ISO: International Organization for Standardization

MDD: Medical Device Directive

METU: Middle East Technical University

OECD: Organisation for Economic Co-operation and Development

QSR: Quality System Regulation

PMA: Premarket Approval

UCD: User Centered Design

WHO: World Health Organization

CHAPTER 1

INTRODUCTION

1.1 Background of the Study

Medical device industry has changed drastically over the last decade as a result of developing information and communication technologies, new material studies and autonomous production methods, increasing processor power and shrinking electronic parts. The rapid increase of the world population and the growth in the aging population are among the driving factors affecting this change. While scientists are working on healthier aging and longer life expectancy, governmental health-care institutions are seeking long-term solutions to provide cost-effective and less stressed health care for their citizens. Consequently, with the help of advancing technology and due to changing needs of populations, health care started to shift from hospital to home.

Today, there is a wide range of home use medical devices that hopefully promise to provide care at home instead of hospital settings. It is expected that in the future, the trend in providing care at home with the help of home use medical devices will gain more importance mainly due to continuing changes in demographics, enabling technology and governmental health care decisions. That means medical devices will increasingly be used by patients and their caregivers instead of medical professionals, and also they will be used in diverse environments instead of relatively well equipped institutionalized settings. The growing segment of home use medical devices on the market will continue to enable people to treat, to manage

and to prevent their illnesses and disabilities in a more cost effective and less time consuming way within the comfort of their homes.

Home use medical devices are moving towards being produced as consumer products (Story, 2010). Recently, some home use medical devices are being sold in consumer electronics section of big stores. It is appealing that rapid advancement of technology enables migration of more and more medical devices from hospital to home but, potent challenges lie under how medical technology is delivered to the users. Sometimes this migration is a result of simply miniaturizing a hospital device to fit in home settings, or by directly transferring a complex medical device into the hands of lay users just because reduced costs of production. A smaller and colorful version of a hospital device may find its way over the counter and become available for lay users just because of commercial purposes.

Considering diversity of home use medical devices in terms of contextual factors, it is important to deliver medical technology safely and effectively. Latest trends may not be applicable for some medical devices. For instance, the trend of miniaturization of consumer products may pose a potential threat if it is implemented to a display feature of a home use medical device considering the possibility of visually impaired patients (Charness, 2010). Focusing solely on the implementation of technology or using technology extensively may result in serious problems, especially in terms of safety.

Medical device industry is one of the safety critical industries and minimizing the hazard potential is extremely important. Therefore, there are strong regulations and standards to minimize risks. Also, complying with these regulations is a prerequisite requirement for being commercialized on the market as a medical product. As a result, medical device manufacturers are mostly focusing on meeting with these regulatory requirements.

Existing medical device legislation dates back to the 1990s. Even though there are various revisions and amendments have been made since then, it is found that the

current one “has not kept pace with the enormous technological and scientific progress in the past 20 years” (European Commission, 2012a, p. 2) and even now there is not enough guidance available specifically addressing medical device design (Wiklund & Wilcox, 2005). Since home use medical devices are considered among medical devices, medical device regulations are also binding for home use medical devices. Considering that home use medical device sector has gained momentum over the last decade as a result of latest technological and scientific advancements, and current medical device legislations are dating back way before that; focusing merely on meeting with regulatory requirements will not provide enough guidance while designing home use medical devices. Especially concerning aforementioned differentiating contextual factors of home use medical devices from medical devices for hospital settings, regulations’ and standards’ main purpose of minimizing possible safety hazards may fail in the hands of primary users: medically untrained patients.

Usability of medical devices is in the focus of regulatory system as a risk management tool. But there is a lack of sufficient guidance in general, and home use medical devices are not addressed specifically, even though they distinguish from rest of the medical devices by their nature of different user group and use environment. There is a strong relationship between usability and context of use. Starting from the definition, usability is “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use” (ISO, 1998). Main context of use features of home use medical devices consist of the medical technology/device itself, user characteristic of patients as primary users, the physical and social environment of home, and what purpose this medical technology/device will be used for. These distinguishing factors require a special attention in terms of home use medical device usability. Since regulatory systems are aiming at device safety, these factors are gaining more importance considering factors such as; users’ capabilities and

disabilities, lack of medical intervention if there is an emergency case, and uncontrolled and ambiguous physical and social environment of the home.

Enhancing usability can be achieved by human factors studies in the product development phase with a user-centered design (UCD) approach. Given by the patient-centric nature of the health care (Carayon & Friesdorf, 2006), including the involvement of the end-user in the development of devices, which are used in this patient-centric field, is required. The activity of "understanding and specifying the context of use" (ISO, 1999) is identified among the main activities of UCD. But context of use is frequently ignored within usability activities and in conventional product development (Bevan, 1999; Maguire, 2001), and user involvement is mostly applied to the late phases of medical device development (Carayon & Friesdorf, 2006). In addition, since there is a trend of identifying home use medical devices as consumer products by time, being driven by technology instead of users' needs and demands is becoming a trend in the medical sector as well. In a regulatory and technically complex sector, which is mostly led by technology instead of by identified unmet needs (Martin, Norris, Murphy, & Crowe, 2008), the need and importance of studies and activities of UCD is becoming more clear.

In the light of given background of the situation of home use medical device sector, complexity of the regulatory system and changing dynamics of the market has put a strain on the manufacturers and designers. There is a lack of guidance on to how to enhance usability of medical devices and there is a tendency to ignore changing contextual factors of home use medical devices within the development of a conventional hospital medical device.

Recently, the regulatory and academic studies in the related field gained a momentum with an emphasis on the need for more user centered studies and on the need for more practical guidance for the manufacturers. Although the field of human factors is repeatedly called as a savior in overcoming existing challenges, considering that designers are the ones who struggle between complex regulations

(Fadier & De la Garza, 2006; Hale, Kirwan, & Kjellén, 2007; Kossack, Gellatly, & Jandrisits, 2007; Martin et al., 2008; Santos, Gazelle, Rocha, & Tavares, 2012), lack of practical guidance (Alexander & Clarkson, 2000a; Ward & Clarkson, 2004; Ward, Shefelbine, & Clarkson, 2003) and lack of studies on designing for the household for people with disabilities (Cheverst, Clarke, Dewsbury, Hughes, & Rouncefield, 2003; Lehoux, Saint-Arnaud, & Richard, 2004; Lehoux, 2004); there appears to be a need for design research from an context of use point of view.

1.2 Motivation for the Study

Continuous Positive Airway Pressure (CPAP) devices are used for preventing the collapse of upper airway during sleep by applying continuous flow of mild air pressure through the upper respiratory tract and are used by individuals who have breathing disorders. CPAP devices consist of a facial or nasal mask which is connected to main electronic device by a respiratory tube (hose). Users have to wear CPAP mask all through the sleeping, so the device has to be stored near the bed of the users. CPAP devices help to improve patients' complaints and symptoms such as snoring, restless sleep, waking up tired, daytime sleepiness, reduced concentration, and overall, reduced quality of life (Engleman et al., 1996; Sahebjami, 1998). The main reason behind the reduction in life quality and rise in the mortality risk due to sleep apnea is the decrease in oxygen saturation due to not being able to breathe sufficiently during sleep. In order to achieve improvements in sleep apnea patients' conditions, it is crucial to have a long-term (and sometimes life-long) adherence to CPAP usage. At this point, CPAP devices differ from other commonly used, over the counter home use medical devices due to absolute necessity of device adherence and fixed usage environment (e.g. bedroom).

In 2012, the author's father and later on several relatives were prescribed for CPAP therapy due to obstructive sleep apnea; therefore, the author witnessed how everyday life of CPAP users have been changed after the device arrived in their home, and she witnessed some problems that users encountered while using their

devices. During the same year, the author was working as an industrial designer on a medical device industry related local project which focused on industrial design activities in relation to medical device usability; this situation created an opportunity to gain insight into medical device manufacturers' rather limited knowledge about industrial design activities and user studies. As a consequence, she has found the motivation for this study to contribute to the field of medical device design by studying on CPAP devices and their users.

1.3 Scope of the Study

The aim of this study is to explore the field of medical device by elaborating on the changing contextual factors of medical devices as they migrate from hospitals to homes. The thesis explores the emergence of home use medical devices from the social and industrial perspectives, and then investigates the main challenges that affect the development of medical devices. The study then explores the contextual factors and their effects on the home use medical device users through a field study conducted with users of CPAP devices in their homes.

1.4 Research Questions

This study seeks to address the following questions in order to have a better understanding of the subject. The main research question is:

- What are the contextual factors that have effects on the use of home use medical devices?

The following sub-questions are also explored during the study:

- What are the driving factors that lie behind the current trend of home use medical devices?
- What are the unmet needs of home use medical device users?

- What are the attitudes and preferences that users have towards their home use medical device?

1.5 Structure of the Thesis

In Chapter One, background information on the thesis subject is introduced; the aim of the study and scope of the thesis are presented.

Chapter Two presents literature review with an introduction of home use medical devices and the reasons behind the shift of care from hospital to home. Afterwards the main challenge of the medical device industry, the medical device regulatory system, is explored. Lastly, this chapter is concludes with exploration of usability related contextual factors of home use medical devices.

Chapter Three presents the methodology, analysis and findings of the field study that is carried out with conducting interviews with users of Continuous Positive Airway Pressure (CPAP) devices.

Chapter Four summarizes the overall study with the discussions of the field study. This chapter is concluded with recommendations for further studies on the same field.

CHAPTER 2

LITERATURE REVIEW

This chapter consists of three sections and begins with the introduction of home use medical devices. The first section defines medical devices and home use medical devices initially, and then examines the motivations behind the emerging trend of home use medical devices, in order to set the scene of changing needs and demands of the societies and governments which affect the distribution of health care. During the literature review, it is observed that surrounding conditions of the emergence of home use medical devices is scattered in the literature. Therefore, the first section focuses on this subject along with the intention to provide most recent data. The second section explores the current state of the medical device industry in terms of regulatory challenges in order to understand the influencing factors on this sector that supplies previously mentioned changing health care needs and demands. Home use medical devices differ from medical devices by means of user group and usage environment. These two factors provide data for design decisions to understand users' needs and expectations from the product, and also have effect on the usage performance after the product meets its user. Therefore, the third section initially introduces usability and context of use, and as the home use medical devices are generally used in home environment by a diverse group of lay users, the related contextual factors are explored afterwards. Figure 2.1 illustrates the scope of the literature view.

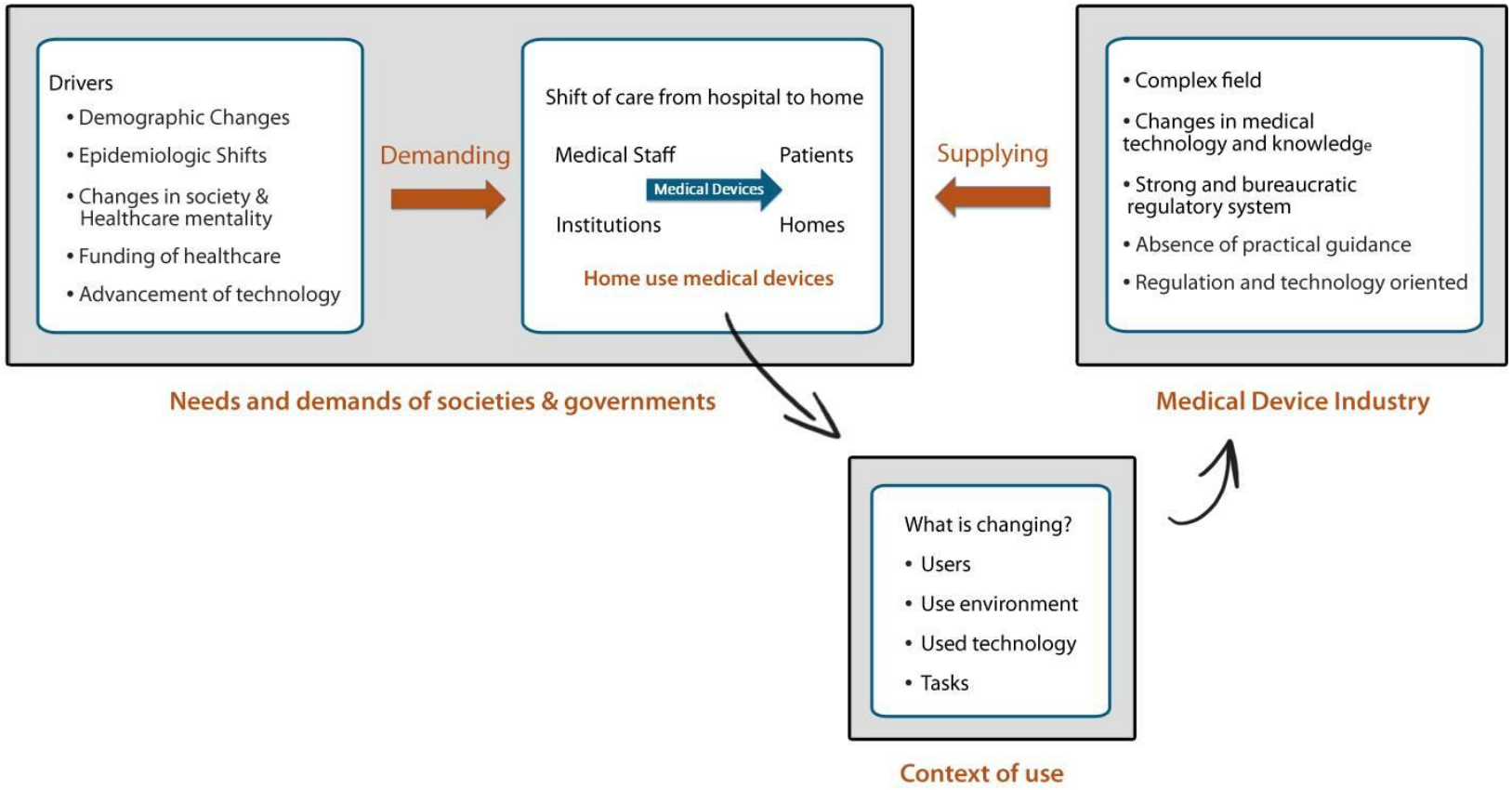

Figure 2.1 Scope of the Literature

Throughout the study a wide range of keywords such as; *homecare medical devices, home use medical devices, health technologies, medical device design, home use medical device design, medical device usability, medical device safety, medical device regulation, medical device standards, lay user, user requirements, user centered design, context of use, contextual factors, home environment, product environment* are scanned through METU Library, and various electronic databases including; EbscoHost, Springer, Elsevier, Wiley, Sage, Science Direct, Jstor, PubMed, BioMed, IEEE Explore and so on. Since home use medical devices are on the focus of recent literature and medical device industry is a rapidly changing field, related materials published between the period of 2000 and 2013 are selected to be explored. Also globally recognized data sources are consulted: Organisation for Economic Co-operation and Development (OECD), World Health Organization (WHO) and Eurostat (statistical office of the European Union). As Turkey is among OECD countries and European Union candidate members, data provided by OECD and Eurostat are valued during the study.

2.1 Home Use Medical Devices

This section provides background information on the definitions of medical devices and home use medical devices, types of home use medical devices and driving forces behind the emergence of home use medical devices.

2.1.1 Clarification of the Definitions

There are various definitions that coexist addressing medical devices. All of these definitions are provided within the studies of regulatory systems regarding medical devices and it is important to explore these definitions as home use medical devices are defined among medical devices. Currently, while the definition of *home use medical devices* is covered within the definition of *medical devices* provided by European Union's Directive in Europe, the United States has a separate branch studying on them that provides a more distinctive definition.

2.1.1.1 Medical device

In 1938, Food and Drug Administration (FDA) is assigned with the mission of regulating foods, drugs and cosmetics and this set of laws are entitled as "Federal Food, Drug & Cosmetic Act" (FD&C Act) in the United States. Then in 1976, FDA is amended to regulate medical devices with the same act (FDA, 2009; Junod, 2003; Santos et al., 2012). After several extensive amendments, medical devices are defined in Section 201(h) of final FD&C Act as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:
>
> (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
>
> (2) 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
>
> (3) 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. (p. 5)

In Europe, before the first regulation studies which started in the 1990s, each country had different legislations regarding medical devices (Santos et al., 2012). In 1993, European Union (EU) harmonized medical device definition by *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*, which is

collectively recognized as Medical Device Directive (MDD), and in this directive a medical device is defined as:

> any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by its 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,
>
> and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. (pp. 3-4)

On the other hand, according to Santos et al. (2012), even though there are attempts to form a uniformity among national regulatory systems, a consensus is not reached so far, thus, there are still multiple definitions that coexist regarding medical devices. On this subject, The Global Harmonization Task Force (GHTF) was formed in 1992 and their goal was the convergence of different medical device regulatory systems to promote unity of regulations on global scale. In 2005, The GHTF published a guidance addressing the definition of medical devices and entitled it as *GHTF/SG1/N29:2005 Definition of the Term 'Medical Device'*. The given definition in this guidance is modified several times by the organization, and their final definition is given in 2012 which is quite similar to the European Council Directive's (GHTF, 2012). It should be noted that, they also provided a working

draft on the subject in 2002 before the aforementioned final document (GHTF, 2002).

2.1.1.2 Home use medical device

In June 2001, Center for Devices and Radiological Health (CDRH) Home Health Care Committee (HHCC) was formed in the United States within FDA. HHCC's primary purpose is stated as to understand and study the usage of medical devices in the home environment by patients and lay caregivers and to make these devices more safe and effective. The following year HHCC published a report named *Report on Home Use Medical Device Meetings*, which defines home use medical devices as:

> Medical devices used in the home environment by persons who are ill or disabled and need, or whose providers of care need, education and/or other related health care services to use and maintain the devices safely and effectively. (FDA, 2002, p. 5)

In the same report, some problems are pointed out as: (1) the definition is not covering telemedicine and telemetry technologies, (2) the patients who are at the recovering phase are not addressed properly, (3) the usage of "home" is too limited considering the other places where these devices can be used (such as workplace, transportation vehicles, etc.) and there are some invasive and non-invasive devices which are attached to patient's body and travels with him/her, inside and outside (FDA, 2002).

In 2010, all the usage environments and all related technologies are addressed by FDA and CDRH with the last definition. According to the *Medical Device Home Use Initiative* (2010), a home use medical device is:

> A device intended for use in a non-clinical or transitory environment, is managed partly or wholly by the user, requires adequate labeling for the

> user, and may require training for the user by a health care professional in order to be used safely and effectively. (p. 3)

On the other hand, home use medical devices are not addressed separately by the aforementioned EU Medical Device Directive 93/42/EEC. As home use medical products and software applications became increasingly available, considering these devices are concerned by this directive too, there appeared to be a need for new adjustments. Therefore in 2007, a set of amendments was made by "Directive 2007/47/EC" and the boundaries of what constitutes software, within the scope of medical device, were added to the definition of medical device as (changes are emphasized in italic):

> any instrument, apparatus, appliance, *software*, material or other article, whether used alone or in combination, 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 . . . (pp. 23-24)

Also, it should be noted that, even though they are not covered in the definition, different user groups and usage environments are demanded to be included in *Annex I General Requirements Section 1* of MMD 93/42/EEC as:

> - reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
>
> - consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). (p. 43)

Considering the given home use medical device definition of FDA and CDRH, usage environment, addressed users, adequate labeling and required usage information of the device-related tasks are essential factors for safe and effective

device use. Also, it is noticeable that European Council Directive aims to cover home use medical devices by paying additional attention to intended usage environment and various types of users. Timeline of regulations and definitions addressing medical and home use medical devices are given in Figure 2.2.

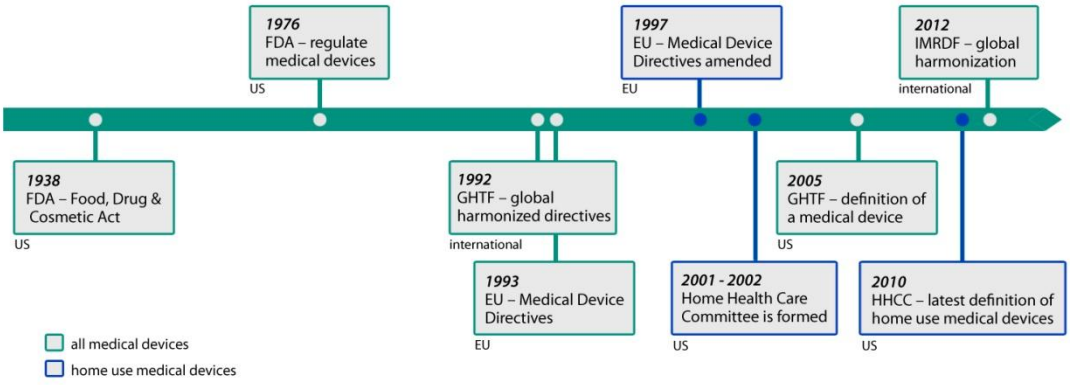

Figure 2.2 Timeline of regulations and definitions addressing medical and home use medical devices.

2.1.2 Types of Home Use Medical Devices

Home use medical devices vary in a wide range of products, such as monitoring devices, respiratory aspirators, medical thermometers, breast pumps, finger pulse oximeters, medicine reminders, needle-free home-use injection (insulin pen), hearing aids, interaction improvers, even heart re-starter (defibrillator), home dialysis, and so on.

Multidisciplinary committee of the National Research Council (NRC) of the US published a report of a workshop on the role of human factors in home health care in 2010 and a final report which is reviewed by NRC published in 2011. On these

reports, Story (2010), and thereby NRC (2011) categorize medical devices that are used in home under the following major titles and give examples of such devices as given on Table 2.1.

Table 2.1 Types of Health Care Devices Used in the Home (adapted from National Research Council, 2011; Story, 2010)

Medication Administration Equipment	Devices used to administer medications in tablet, liquid, or aerosol form, such as dosing equipments (cups, eyedroppers, etc.), inhaler, sprays, syringes, etc.
Test Kits	Kits used for detecting substances, chemicals and hormones such as HIV, hepatitis C, cholesterol, allergy, drug, alcohol, nicotine, pregnancy, etc. in urine or blood such as pregnancy test, allergy test, drug test, etc.
First Aid Equipment	Equipment used to care for injuries or temporary conditions, such as bandages, defibrillator, traction kit, etc.
Assistive Technology	Devices used to enhance personal capabilities, such as eyeglasses, prosthetic devices, hearing aid, wheelchair, walker, etc.
Durable Medical Equipment	Medical devices used to support performance of basic activities of daily living, such as hospital beds, lifts, mattress, etc.
Treatment Equipment	Equipment used to administer various medical therapies, such as dialysis device, IV equipment, infusion pump, etc.

Table 2.1 Types of Health Care Devices and Technologies Used in the Home (adapted from National Research Council, 2011; Story, 2010) (Continued)

Respiratory Equipment	Equipment used to treat respiratory conditions, such as ventilator, continuous positive airway pressure (CPAP), and, bi-level positive airway pressure (BPAP) devices, nebulizer, suction machine, oxygen cylinder, masks and canulas, etc.
Meters/Monitors	Devices for determining health status or managing disease conditions either one time or in an ongoing usage such as stethoscope, blood glucose level monitor, pulse oximeter, blood pressure monitor, electrocardiogram monitor, apnea monitor, weight scale, etc.
Feeding Equipment	Devices used for feeding, such as feeding tubes, enteral pump.
Voiding Equipment	Devices used for freeing urine or feces from the body, such as catheter, colostomy bags.
Infant Care	Machines used to monitor and treat infants, such as phototherapy, apnea monitor, bilirubin lights, etc.
Telehealth Equipment	Equipments used to transfer collected medical data at home environment to a remote monitoring professional, such as cameras, sensors, telephone, and internet connections.

2.1.2.1 Current examples of home use medical devices

Several examples of home care medical products that are available on today's market are presented below to have a better understanding of such devices which fall under some home use medical device categories that are previously introduced.

Medication administration equipment: Drug dispenser

Medication adherence is important particularly when users are required to take lots of drugs on a daily basis. Especially patients with physical and/or cognitive impairments, patients receiving multiple drugs with complex prescription -which are often prescribed by different doctors-, and elders who are living alone are more likely to have difficulties while managing their medication (Barat, Andreasen, & Damsgaard, 2001; Ownby, 2006). Non-adherence may result in worsening of elders' disease, may expend his/her healthcare cost and even death may be seen; technological medication helpers offer improvements in medication adherence behavior by precise medication tracking (Osterberg & Blaschke, 2005).

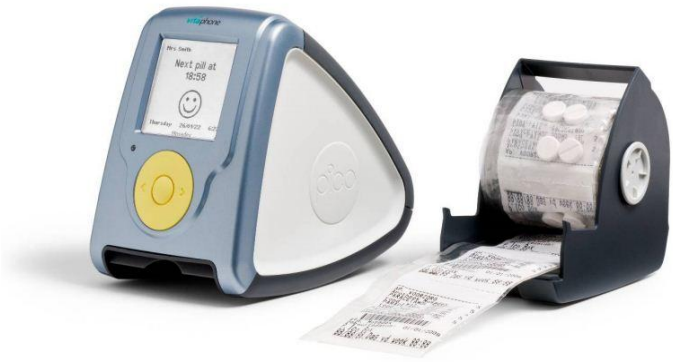

Figure 2.3 Pico Drug Dispenser by Vitaphone (retrieved and adapted on June 12, 2013, from: http://www.picocare.com/uploads/manuals/english/pico-information.pdf)

Pico Drug Dispenser (Figure 2.3) is a design-awarded telemedicine supported medication adherence system which uses prepackaged drugs in a roll that is placed in it with a cartridge. The device is an optical and audible warning device for medicine-taking times, detects forgotten medication and alarms both the patient and caregivers via GSM link to the telemedicine service provider. Medicine packages

can be taken single or multiple when going out, and SMS reminder service is also optional.

First aid equipment: Automated external defibrillator

Automated external defibrillator (AED) is a lightweight portable device designed for detecting irregular rhythm of heart and applying electroshock through chest to retrieve regular rhythm which is intended to be used by non-medical personnel and lay rescuers (American Health Association, 2012). The rescuer, who is preferred to be trained to use such devices, is helped by voice commands and graphic instructions. AEDs are recommended to be placed primarily in ambulances and public areas such as malls, airports, etc. On the other hand, %70-80 of cardiac arrest cases occur at home; even though it is not found effective to have an AED at home just in case, patients with high cardiac arrest risk who are not eligible for implantable devices or who are listed for heart transplant can benefit from such devices (Priori et al., 2004; Rho & Page, 2007)

Figure 2.4 Philips HeartStart Home AED (retrieved and adapted on June 12, 2013, from: http://www.healthcare.philips.com)

Philips HeartStart Home Defibrillator (Figure 2.4) is claimed to be the only AED available without a prescription which is "designed for the ordinary person in the extraordinary moment" (Philips Healthcare, 2013). Like most of the AEDs, it has a voice command, physical indicators and graphic instructions printed on its pads to guide the lay user through the defibrillation procedure.

Meters and monitors: Blood glucose meter

Blood glucose meter is a testing and monitoring device used for measuring the amount of glucose in user's blood. After pricking finger tip or side with a built-in or separate lancer, blood drop is placed on the disposable test strip which is inserted into the main device. The device calculates the glucose level by glucose-sensible chemicals on the strip or electricity emission or light reflectivity of the used strip (FDA, 2011a). Keeping track of blood glucose level is important for type 1 and type 2 diabetes patients or individuals who have diabetes risk. FDA (2011) explains the reasons of tracking glucose level in blood as: detecting possible danger of low or high levels of glucose, adjusting to treatment in daily basis and understanding how diet and exercise are affecting blood glucose level.

Figure 2.5 Accu-Chek Mobile Glucose Meter (retrieved and adapted on June 09, 2013, from: https://www.accu-chek.co.uk/)

Roche's Accu-Chek Mobile (Figure 2.5) is a design-award winning blood glucose meter which provides strip-free testing with a detachable finger pricker. It is loaded with a strip cassette with 50 continuous strip tapes and its finger pricker is loaded with 6 pricking needle to provide more hygienic, discreet and simple usage.

Respiratory equipment: Continuous positive airway pressure (CPAP) device

CPAP devices prevent the collapse of upper airway during sleep by applying continuous flow of mild air pressure through the upper respiratory tract and it is used by individuals who have breathing disorders. Breathing disorders, such as apnea, affect patients' life standards in various ways: their oxygen saturation falls notably during sleep which effects overall metabolism (Sahebjami, 1998), they wake up tired and feel daytime sleepiness, they experience work inefficiency due to reduced concentration, and even their driving experiences are affected (Engleman et al., 1996). All these problems significantly decline with the help of CPAP devices (Engleman et al., 1996; Sahebjami, 1998). In order to achieve improvements in sleep apnea patients' conditions, it is crucial to have a long-term (and sometimes life-long) adherence to CPAP usage.

Figure 2.6 ResMed S9 CPAP Device and its usage with an attached humidifier (retrieved and adapted on June 12, 2013, from: http://www.resmed.com/au/assets/documents/product/s9_escape/welcome_guide/368870_s9-escape_welcome-guide_apac_eng.pdf)

ResMed C9 CPAP is a design-awarded home use CPAP device (Figure 2.6). It is claimed that it has an intuitive design and technologic improvements by inviting controls with ease of use, reduced noise and titration, a new humidification system and data management options. The studies of Wimms, Richards, & Benjafield (2013) compare compliance of users between patients' already accustomed CPAP device and ResMed S9 CPAP. The results of this study propose that there is an improved user compliance which may be based on technology changes alone, such as improvements in humidification, improved comfort of breathing, and reduced noise.

2.1.2.2 Assistive devices and aging technologies

There are some devices that are particularly used by elders, generally to assist their life at home and these are often considered among home care too. In the related literature, these devices are categorized and named by their differentiated purposes as: homecare devices, aging technologies, preventive devices, assistive devices, adaptive devices, disease management devices, etc., and some of these devices may be categorized under two or more titles since their purposes may overlap or intersect. Whereas medical and/or assistive devices used at home develop and advance by time, the used terms are getting divided into branches more and more but they are mostly examined under the title of home care devices.

It appears to be useful to refer to assistive devices since they have a broader usage and they are often considered among home care medical devices. But it should be taken into consideration that, some of these devices are not always used for medical diagnosis or cure diseases/conditions but enable people with functioning problems to "maintain or enhance functioning and minimize disability" (Bougie, Heerkens, & De Kleijn-de Vrankrijker, 2010, p. 3). Assistive devices/products are defined by International Organization for Standardization (ISO), with the standard named ISO 9999 *Assistive products for persons with disability – Classification and terminology*, as:

> An assistive product is any product (including devices, equipment, instruments and software) especially produced or generally available, used by or for persons with disability
>
> - for participation;
>
> - to protect, support, train, measure or substitute for body functions/ structures and activities; or
>
> - to prevent impairments, activity limitations or participation restrictions. (as cited in Bougie et al., 2010, p. 6)

Also according to the medical device definition which is given by the GHTF (2012), "aids for persons with disabilities" are listed amongst the "products may be considered to be medical devices in some jurisdictions but not in others"(p. 6). This statement is given as an additional note to the medical device definition and the term *product* is used instead of *medical device*. ISO 9999 also uses the term *assistive products* instead of *assistive medical devices*. This overlapping choice of terms and definitions is mentioned by Bougie et al. (2010) also, and the reason is given as "many but not all of the assistive products are assistive medical devices" (p. 3).

The study of Alwan, Wiley, & Nobel (2007) scans state-of-the-art technology driven devices which affect the aging experience and refers to them as *aging services technologies*. Although these technologies can also be used by younger adults and children in case of need, authors specified the main audience as seniors, their care givers and healthcare providers. Their sorting (Table 2.2) can be useful to collect aging technologies used at home according to the "relationship these technologies address between the older adult and his or her environment (Safety), oneself (Health and Wellness), and others (Social Connectedness)" (Alwan et al., 2007, p. 8).

Table 2.2 Categorization of Aging Technologies (adapted from Alwan et al., 2007)

Safety technologies	**Health and wellness technologies**	**Social connectedness technologies**
• Fall detection and prevention technologies • Mobility aids • Stove use detectors • Smoke and temperature monitors • Door locks • Wander management systems	• Wellness monitoring technologies • Telemedicine and telehealth • Medication compliance technologies • Cognition	• Phones (specialized for senior usage) • Cell phones • Monitoring for social connectedness • Senior friendly e-mail and web portal systems • Video phones and two-way video conferencing

Safety Technologies

Fall detection and prevention technologies: Fall detection is used for detecting and alerting respective institutes (hospitals, community services) and/or people (caregivers, family) if the user falls. Mostly, an accelerometer and a tilt meter are used in these kinds of devices. Also, there may be a button to alert previously mentioned addresses, instead of carrying an extra device as a personal emergency alarm (Miskelly, 2001). Technologies such as hip protectors, weight detectors, and on-body emergency alarms can be given as examples for other preventive technologies (Alwan et al., 2007).

Mobility aids: Mobility aids, such as robotic prosthetic limbs, robotic walkers and wheelchairs help the user to stand, walk and/or climb stairs while keeping their body supported (Alwan et al., 2007).

Stove use detector: They are used for alerting if there is a possibility of a forgotten active stove top (Alwan et al., 2007).

Smoke and temperature monitors: These monitors are used for alerting by sound, bed shaking or flashing lights (Seiler, 2009), if there is a detection of fire aerosols or smoke or a sudden change in the temperature (Miskelly, 2001).

Door locks; Wander management systems: These devices are used for alarming caregivers to track elders if they are tend to wander at night, especially in cases of dementia such as Alzheimer's (Alwan et al., 2007; Miskelly, 2001). They may require wearing a on-body component such as a badge, a pendant or a wrist band (Alwan et al., 2007).

Health and Wellness Technologies

Wellness monitoring technologies: Wellness monitoring devices are being used for a wide range of purposes such as measuring and monitoring hearth rate, glucose level, respiration rate, body temperature, dehydration, cholesterol, etc. Some of them may collect and store data if needed. In addition to these general homeostatic measurements, special conditions can be monitored such as: electromyogram (skeletal muscles), galvanic skin response (emotion responses), bone density, and sleep patterns.

Telemedicine and telehealth: These systems are used for connecting professional health care providers with patients at home or on the go, to offer "specialist referrals, patient consultations, remote patient monitoring, medical education, and consumer medical and health information through networked programs" (Beard et al., 2011, p. 109).

Medication compliance technologies: These technologies help patients to manage their medication by reminding, dispensing and keeping history (Alwan et al., 2007).

Cognition Systems: These systems help individuals with cognitive decline, for instance, mental stimulation systems for example brain exercise software, reading

helpers and physical stimulation devices such as game consoles, speech synthesis and text production software (Alwan et al., 2007; Seiler, 2009).

Social Connectedness Technologies

Phones: Phones that are specially designed with bigger buttons, speed dials, amplified ringer and handset voice (Alwan et al., 2007; Seiler, 2009).

Cell phones: Cell phones that are specially designed for individuals with disabilities or dysfunctions such as vision impairments and learning disabilities. They consist of bigger screens and buttons with a simple interface. (Alwan et al., 2007; Pattison & Stedmon, 2006)

Monitoring for social connectedness: Devices that help individuals to socialize better, for instance Caller ID reminders can help elders with dementia (Alwan et al., 2007).

Senior friendly e-mail and web portal systems: E-mail or web portals specially designed for elders. For example, some hospitals encourage their patients to share their experiences, stay connected with other groups and receive support by an online blog (Beard et al., 2011).

Video phones and two-way video conferencing: Video call and video conference systems other than telehealth services (Alwan et al., 2007).

2.1.3 Shifting Care from Hospital to Home: Driving Factors

Health care industry is experiencing a grand transformation over the last decades. Advancement of several technologies (such as material science, computer-based developments and increasingly variable communication techniques, etc,) affects manufacturing developments. At the same time these advancements make possible to accomplish more successful medical procedures and deliver care after discharge from hospital which results in offering an improved quality of life and increasing life expectancy. At the same time socio-demographic changes affect the demands of

the society and governmental policies develop to adopt these processes to provide welfare-related economic and social administrations. This section will elaborate on the reasons behind the shift of care from hospital to home and therefore, why home use medical devices are becoming more important for today and future. A summary of the subsections are given in Table 2.3.

Table 2.3 Driving factors of the emergence of home use medical devices.

Demographic Changes	Life expectancy is increasing and fertility rate is noticeably decreasing. As a result, world population is getting older and this causes an increase in the number of people who need medical care. Also, dependency ratio is rising. That means increasing elderly population causes pressure on economic and social policies and home care is getting more important to relieve this stress on institutionalized care.
Epidemiologic Shifts	Non-communicable diseases are increased due to life style of the era, thus, these diseases have started to being handled at home instead of hospitals.
Changes in society & Healthcare mentality	Changes in family structures result in increasing shortage in caregiver pool. At the same time healthcare mentality is moving towards taking control of own diseases and staying involved with life at older ages. Therefore, Patient Empowerment and Successful Aging are becoming rising concerns of society.
Funding of healthcare	As healthcare spending is increasing due to changing demographics and epidemiologic, it becomes a burden on public funding of healthcare. As a result, governments are trying to reduce expenditure by promoting the distribution of healthcare between home care and hospital care.
Advancement of technology	Advancement of information and communication technologies enables the production and constant development of home use medical devices.

2.1.3.1 History of shift from hospital to home

World War II (1939-1945) played a phase-shifting role on health care technology and services. Before World War II, medical care was given at home by visiting doctors and nurses. Severely ill patients were primary targets for hospital care. After World War II, regarding the technological and medical developments of the era, hospital equipment improved towards being more complicated and successive; thus hospital-based care has become available for wider interventions (FDA, 2002; Randolph, 2001).

In the last decades of the 20th century, health care expenses started to become an expanding burden both in Europe and the United States (Collen, 2000; OECD, 2011d; Tarricone & Tsouros, 2008).

While in the United States "growing civil rights awareness, public support, and the support of hospitals and the insurance industry contributed to the achievement of the most significant health reform of the century, (...) health care costs had grown rapidly from 4 percent of the federal budget in 1965 to 11 percent by 1973, while millions of those under age 65 still had no health coverage" (Hoffman, 2009, p. 5). The rapid growth of health care costs have become more significant after the 1980s, due to "the increasing expectations and demands of patients for technology innovations that can extend life, and can support or replace worn-out organs, limbs, or joints" (Collen, 2000, p. 204).

The financial situation in Europe was similar to the United States. After 1960s, residential homes and home-based care were started to be promoted as a replacement for institutionalized care, to decrease long-stay bed occupancy rate (Tarricone & Tsouros, 2008). And the early 1980s was the time when European health system began to confront economic problems which is followed and enhanced by rapid development of medical technology in the early 1990s (OECD, 2011d).

Therefore, health care started to shift from hospital to home, predominantly due to financial and technological factors, but this time "as patients have been moved to the home and other non-medical facilities for their recuperation or long term care, the medical devices needed for their care (e.g., respiratory and intravenous therapy devices) have followed them" (FDA, 2002, p. 2).

Also it should be noted that there is a noticeable correlation between the recent history of care, and the regulations and the definitions addressing medical devices and home use medical devices. This relationship is illustrated in Figure 2.7.

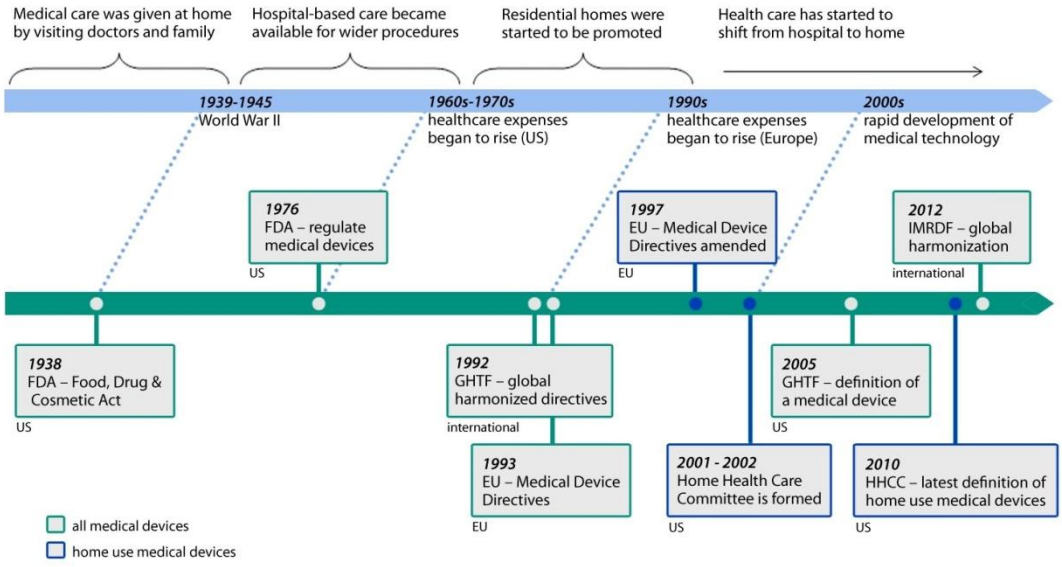

Figure 2.7 Timeline of recent history of hospital/home based care and timeline of regulations addressing medical devices.

2.1.3.2 Demographic changes

Changes in world population pose a great impact on the socio-economic needs of societies, such as health care systems (Lanzieri, 2011). Life expectancy and fertility rate are two factors that affect world population. And today's world is facing a population aging situation, due to the notable changes on these two factors (Lanzieri, 2011; Leonhardt, 2006; Maestas & Zissimopoulos, 2010; Smith, 2010). While world population is aging, socio-economic policies of countries are being challenged due to increasing dependency ratio (Lanzieri, 2011; Smith, 2010).

Life expectancy

Life expectancy has increased consistently over the last decades according to recent studies of World Health Organization (WHO) and The Organization for Economic Co-operation and Development (OECD). According to OECD (2011b), *life expectancy at birth* of OECD countries has increased on average by more than 11 years from 1960 to 2009. This notable rise is a result of "improvements in living conditions, public health interventions and progress in medical care" (OECD, 2013, p. 2). It is important to point out that especially in Turkey, life expectancy has gained a significant increase by more than 25 years between the same years (OECD, 2013) (see Appendix A). As another recent and primary source of global health, WHO Global Health Observatory Data Repository reveals that, life expectancy at birth for both sexes has risen from 64 to 70 since 1990 to 2011 on global scale (WHO, 2013a).

According to Leonhardt (2006), decline in mortally rate and infant mortality due to "improved health care, a continuous enhancement in hygiene, and access to a better diet" (p. 356) is one of the main reasons of this significant rise of life expectancy in addition to improved living standards, such as better living and working conditions. Also as stated by OECD (2011b), there are great improvements focusing on cardiovascular diseases because they are still the primary causes of death. The studies on narrowing down smoking behavior as a main risk factor and

advancements of medical treatments played great role on the decline in deaths from heart failures and other cardiovascular diseases (OECD, 2011c).

Fertility rate

While life expectancy is increasing drastically, fertility rate is noticeably decreasing. In 2009, fertility is generally declined across OECD countries below the replacement level with 1.74 child per woman (OECD, 2011b) and total fertility on global scale is declined from 4.95 to 2.52 between periods 1950-55 and 2005-10 according to UN Estimates (United Nations, 2011). Meantime, Turkey is among the few OECD countries that can replace population with fertility rate of 2.12 children per woman (OECD, 2011f).

According to Sleebos (2003), the reasons behind the decline in fertility rate are: woman participation in active work life outside the home, higher educational reflections on rational family decisions and the increased cost of raising children. At the same time, since 1960 the use of pregnancy control methods, such as contraceptives, played a sharing role (Leonhardt, 2006). There is a trend of postponing childbearing and there is a growing population of woman with single marital status that affect fertility rate as well, especially in countries with a mentality of society that have a strong link between marriage and childbearing (OECD, 2011e). Also, childlessness at the age of 30 rose all over the OECD countries in diverse age cohorts and it is believed that this is a reflection of educational attainment (OECD, 2012a).

Before the 1950s fertility rate declined first but then, in the post-World War II period it rose again and this situation affected 21st century's older population ratio. Nowadays this incident is referred to as *baby boom* as a demographic event (Eurostat, 2013b; Lanzieri, 2011) and the related generation is named *baby boomer*. Even though baby boom generation started to have babies after the mid 1970s and created an *echo baby boom* (Maestas & Zissimopoulos, 2010); recently baby boomer's large portion of women is getting close to the end of their reproductive

cycle in terms of participation in fertility rate (Sleebos, 2003) and according to Eurostat projections, even a *grandparent boom* may be approaching because there were three youngsters (0 to 14 years old) for every elder in 1960 (65 years and over), but it is expected to have two elders for every one youngster by 2060 (Lanzieri, 2011) which means families' expansion will be "more 'vertical' (more generations) than 'horizontal' (more siblings)" (p. 2). Even recent changes in the elder and youngster population are becoming obvious, which can be observed in Figure 2.8. Over the last decades, the effects of these demographic events on society are getting clearer, especially concerning dependency ratio.

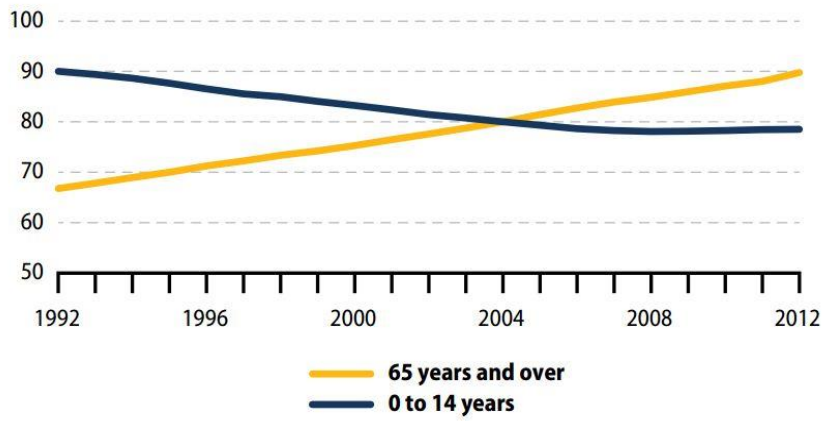

Figure 2.8 Population aged '0 to 14 years' and '65 years or over' in EU – millions/years (adapted from European Commission, 2013a)

Dependency ratio

Dependency ratio is the proportion of total population below the age of 15 and above the age of 64 in the working-age population between the ages of 15 and 64 (The World Bank, 2013). And *old-age dependency ratio* refers to the proportion of elders above the age of 64 in the overall working-age population (Eurostat, 2013a)

which helps to understand the pressure of -generally- inactive adults on the productive population. Increased life expectancy (increase in older population) and decreased fertility rate (decrease in population replacement level) have an important effect on old-age dependency ratio and thereby, on dependency ratio. On the other hand, compared to older cohorts, formal education takes more time and there is a rising trend of attending upper secondary level of education (OECD, 2012b). These changes in educational attainment also have effects on the dependency ratio in terms of labor force participation (Maestas & Zissimopoulos, 2010).

Eurostat projections show that, between the years of 2010 and 2060, old-age dependency ratio will increase from %26 to %52.5 and dependency ratio will increase from %49.3 to %77.9 on average across the EU (European Commission, 2011). According to OECD projections of year the 2050, Turkey has a younger population compared to other countries so it is expected to age more rapidly in the future, but still it will remain as one of the youngest populations with % 38 dependency ratio (as cited in Aegon Global Pensions, 2013). At the same time it should be considered that Turkey has nearly half of the other OECD countries' Gross Domestic Product (GDP) per capita (OECD, 2012e) which may mean rapidly aging population may cause a similar pressure on economic and social policies as much as other countries.

As dependency ratio increases, there will be some economic and social effects which can be summarized such as: (1) the growth of real GDP will be reduced (GDP is considered as a measure of life standards of a country), (2) income per capita will also be declined slightly, (3) considering working population is the contributor of health expenditures as tax-payers, governmental finances will be affected significantly (Sleebos, 2003). Specific effects of the growth in old-age dependency ratio are expected by OECD (2007) that: health, long term care and pension costs will receive a higher share from public spending.

On the other hand, technological changes affected the aging experience and quality and thus, today's elders are functionally younger and healthier than preceding

cohort so they can work productively for longer than before (Bloom, Canning, & Fink, 2010; Smith, 2010). Börsch-Supan (as cited in Smith, 2010) suggests that, new policies should be made regarding retirement age and quality of labor should be preserved by maintaining human capital and health of workers. Currently, average retirement age across OECD countries is 63.5 for men and 62.3 for women (OECD, 2011e) and it is expected that, "to keep pace with the projected increase in life expectancy until 2050, effective retirement ages would need to increase to around 66.5 for men and nearly 66 for women" (p.13). Therefore, trends such as successful aging and late retirement are becoming rising concerns of societies and governments with the aim of preserving productive capacity.

All of these mentioned demographic changes of life expectancy, fertility rate and dependency ratio are interrelated, and they constitute a common outcome together: people will live longer, society will get older and this situation seems to alarm governments in terms of social and economic consequences of these trends. On the other hand, there is a point where humankind may be proud that, the life span of human is appreciably increased mostly thanks to the development of medical technology. And again, the challenges that consequences of increased life span create can be overcome by medical technology, if medical device sector follows changing populations' needs. All of the mentioned changes in demographics and their economic and social outcomes are taken into consideration, there will be increasing need and demand for alternative solutions to substantial methods of care. At this point, according to Hurst, Huber, Izumi, & Hennessy (2003), home care provides a bridge between the distribution of health, social and employment policies. In the future, more people will need home care to decrease the burden on healthcare system, and medical device market will address not just hospital equipment buyers but also private customers: home use medical device users and their caregivers.

2.1.3.3 Epidemiologic shifts

Today's society is facing growing numbers of patients with non-communicable diseases such as diabetes, obesity, cancer, hypertension, cardiovascular diseases and chronic respiratory diseases. This situation can be related with the genetic factors, metabolism-changing nutrition and physically inactive lifestyle of the era, as well as tobacco consumption and excessive use of alcohol (Bloom, Boersch-supan, Mcgee, & Seike, 2011; OECD, 2011c).

OECD (2011b) states that "diabetes is increasing rapidly in every part of the world, to the extent that it has now assumed epidemic proportions" (p. 42) due to obesity, physical inactivity and family history with related diseases. According to International Diabetes Federation "around one-quarter of medical expenditure is spent on controlling elevated blood glucose, another quarter on treating long-term complication of diabetes, and the remainder on additional general medical care" (OECD, 2011b, p.42). Related with diabetes, obesity and overweight are other widely common health problems and as reported by latest surveys, half of the adult population is overweight or obese (OECD, 2011c). The main reasons behind the increase of obesity are reduced food prices and being physically more inactive (OECD, 2011c). Like diabetes, obesity causes many other chronic diseases by time and so, additional healthcare spending is also expected to rise by time.

In addition to diabetes and obesity, there are other chronic health problems that are investigated by OECD: Cardiovascular diseases are primary, and cancer is the secondary cause of mortality in nearly all OECD countries and respiratory diseases, such as asthma, are also among widely common diseases. Alcohol and tobacco consuming, obesity and being physically inactive are main common factors behind these health problems. Especially related with aging, dementia is another chronic condition which is expected to rise with the growing old cohort and included by many countries as a health policy priority (OECD, 2011c).

To conclude, because of their rising contribution on the increase in healthcare expenditure, non-communicable diseases have a strong impact on the need of home care. Diseases such as cancer, stroke, respiratory and cardiovascular diseases are moving to home care instead of hospitals, as well as Alzheimer's (the most common form of dementia) and other newly recognized manageable or treatable mental illnesses (Tarricone & Tsouros, 2008). Life-long monitoring and management procedures are required to prevent complications of diseases such as diabetes, hypertension, and asthma. Current health system is shifting towards self-management and self-monitoring thanks to the home use medical devices. Nowadays constitutionalized care is provided only when acute complications occur. Also, telehealth technologies are developing while targeting predominantly these chronic diseases.

2.1.3.4 Changes in society and health care mentality

Changes in family structures

As it is mentioned previously, before World War II medical care was mostly given at home by visiting doctors and nurses. After the initial professional intervention, patient care was a family affair and the caregivers were mostly women of the house where extended families are living under the same roof. This tradition still remains in rural areas across Europe, where consecutive generations live in the same household, but urban areas are experiencing fragmentation to smaller family units (Tarricone & Tsouros, 2008). Family members will remain as the primary caregivers across the world but there is a decline in caregiver pool due to "migration, changing rural and urban social environments, poverty, ageing, or health problems affecting family members themselves" (WHO, 2000, "Background", para. 3).

Arguably, following changes in the family structures may affect the available caregiver pool:

(1) Recently younger family members are leaving rural villages or moving away from parental homes due to better paying work conditions (Beard et al., 2011; Tarricone & Tsouros, 2008) and educational purposes. Even though advancing telecommunication technologies enable people to reach each other from long distances, developing countries may experience some challenges like economics or infrastructure (Beard et al., 2011).

(2) Living spaces are getting smaller; people started to prefer living in flats instead of detached or semi-detached houses (European Commission, 2013b) which may challenge hosting a senior.

(3) Living a solitary life is a rising trend of the era. For instance, single-person household is the most common household type (%34.4) in the EU (European Commission, 2013b). Although couple families (with or without children) are most common household type across OECD countries (OECD, 2012d), single-person households are expected to increase in all OECD countries in the future, which is much of a result of aging populations (OECD, 2011a).

Regarding Turkey, the results of the studies of Ediev, Yavuz, & Yüceşahin (2012) show that, Turkey's single-person household number will rise four or five times and the proportion of households with six or more people will be halved between 2000 and 2025. Even though six and more person household type was most frequent (%64) household type in 2000, it is expected to be least common type with a decrease of %35-45 by 2025 and these numbers are forecasted without including the population growth in the same years. Households headed by 40 years old and more will be doubled and, with a modernization approach, younger household heads will increase too. Also they assume that, with the increase of older population, large proportion of single-person households will belong to the elderly.

(4) There is a significant decline in marriage rates and at the same time, divorce rates are getting higher both in EU and OECD countries (Eurostat, 2012; OECD, 2012f). This may result in a rise in elders living in a single-person household but on

the contrary, the gender gap in life expectancy is narrowing down on global scale (WHO, 2013b), so this situation may enable elderly couples to support each other in the future (Shergold, Lyons, & Hubers, 2013).

(5) Predominantly, women are informal caregivers that are responsible for their family members who need care, and most of the formal caregivers are also women (WHO, 2000). But women are participating in work-life more than ever and this situation results in a shortage of available caregiver pool (OECD, 2011f; Tarricone & Tsouros, 2008). This increase in female employment is a result of increasing higher education attainment (OECD, 2011a), and rising encouragement and emphasis on career for women (Tarricone & Tsouros, 2008). In contrast to other OECD countries, in the last decade a large decline has occurred in female employment in Turkey (OECD, 2011a). In most of the countries, female employment rate lowers around childbearing years and as children are growing up, it rises again. But Turkish women have a tendency to leave their paid works permanently after having children (OECD, 2012c).

Table 2.4 Changes in family structures and their expected results.

Changes in family structures	**Results**
Young family members are moving away from their parental homes.	Aging parents are living alone without their children's support.
Living spaces are getting smaller.	Household sizes are becoming challenging to host a senior.
Single-households are increasing.	There will be more single living elders without the help of family members.
There is a decline in marriage rates and divorce rates are getting higher.	There will be more single living elders without the help of family members.
Female employment rate is increasing.	Housewife population, the primary source of caregiver pool, is decreasing.

All of the mentioned motives above (which are summarized in Table 2.4) point a need for alternative patient care which is less reliant on the family. If family care is not an option or not preferred, people with old age disability can choose to move from home to medical or residential institutions or choose to hire professional caregivers, but recently it is possible to continue to live at home and stay connected with others with the help of various technologies, such as home use medical devices, assistive technologies and telecare, as Beard et al. (2011) suggest.

Patient empowerment

The *patient empowerment approach* is introduced as an education and disease management for diabetes patients by the Education Committee of the University of Michigan Diabetes Research and Training Center (MDRTC) in 1991. It was offered with reason that, management of diabetes requires life changing choices, and patient empowerment approach aims to educate patients "to maximize the self-care knowledge, skills, self-awareness, and sense of personal autonomy of patients to enable them to take charge of their own diabetes care" (Anderson, Funnell, Barr, & Davis, 1991, p. 585). Starting with managing diabetes, this approach is adopted and implemented widely in other areas of healthcare (Walton, 2000) and now patient involvement in their own health care is seen as an important factor of successful disease management (Korhonen, Parkka, & Van Gils, 2003). Patients are likely to take more control of their situation and have the ability to implement required lifestyle changing disease management choices willingly when comprehensible information is given by medical professionals. Therefore, home use medical devices give patients desired involvement while dealing with their health conditions.

Successful aging

With the first impacts of baby boomer generation, accelerated rate of aging population was seen as a burden economically and socially because of the growing need for elder care and increasing gap between working and retired citizens. Therefore there appeared to be a need for a change in health care services, mentality

of society and lifestyle of older populations. *Successful aging* within the concept of *new gerontology* is firstly offered by Rowe & Kahn (1997) as "low probability of disease and disease-related disability, high cognitive and physical functional capacity and active engagement with life" (p. 433), and this notion resulted in research and practices targeting mental, physical and social well-being of elders since the first emergence of the concept. Nowadays, preserving physical health by managing and preventing diseases without being isolated and staying involved with life is getting easier, more affordable and available by rapidly advancing health care technology.

The studies of Barrett (2008) have explored how elders evaluate successful aging and what is their attitude towards home care technology. According to the findings of the study, most of the elders stated they would prefer to get care at home if they need any help. They are mostly aware of home care technologies. Physical safety, peace of mind, comfort and saving time are among the benefits associated with these devices, for both elders and caregivers. Their answers reveal their given level of importance to *successful aging values*, in respective order as:

> being in good health, having the ability to do things for myself, having friends and family there for me, feeling safe and secure, having the freedom to do what I want, being able to deal with whatever life brings, having enough money to meet my needs, staying involved with the world and people around me, being able to engage in physical exercise, continuing to learn new things. (Barrett, 2008, p. 10)

The demands and expectations of patients and elders are changing along with rapid advance of home care technology. It is reasonable to understand the desires of patients, who want to stay involved with life and stay less dependent on other individuals while dealing with diseases and disabilities.

2.1.3.5 Funding of health care

According to OECD's recent findings, health spending increased from %8.8 to %9.6 (2008-2009) in just one year and "health spending per capita since 2000 has increased more than two times faster than economic growth on average across OECD countries (4.0% versus 1.6%), resulting in an increasing share of the economy devoted to health in most countries" (OECD, 2011b, p. 150).

Access to health care is seen and praised as a citizen right and the expenses are supplied by public funds such as taxes and social health insurance system. Thus, national economy and the other public services funded by taxes are being affected. This situation is mostly being followed by regression of national economic growth and serious reductions in public health care expenses. Today, this can still be observed in some of European countries and in the United States. Different countries with different economic growth can be effected similarly as: (1) Countries which are in debt or have slow economic growth probably will experience difficulties in keeping the same level of health care services, (2) Developed countries which are funding all or most of their health care by national or regional governments may also experience difficulties in finding required funding to maintain same expected services, (3) Countries with high economic growth may want to keep same level of growth and international competitive exports and accordingly may experience some difficulties in raising the required funding for governmentally provided health care services and in brief, these possible problems may cause decline in citizens' trust in their governments' financial capacity to meet the needs of heath care services (OECD, 2011d).

As introduced in the Recent History section and explained briefly in the previous paragraphs, while equipment, tests and treatments are getting sophisticated in addition to increasing life expectancy and increasing elder population, governments started to embark on a quest to reduce health care expenditures. Medical staff is introduced with new enforcing constraints to eliminate unnecessary tests and

treatments which can lead to lawsuits against them if they are found not following the provided mandatory guidelines (Walton, 2000). Also according to Walton, *rationing* or as used by Honigsbaum et al. (as cited in Walton, 2000) *prioritization* is applied to healthcare, which means implicitly prioritizing services, expending waiting lists, providing fewer treatments and prescribing cheaper drugs, or explicitly rationing the available treatments for specific illnesses with the aim of reducing hospital's treatment expenses. Besides, governments do not want to reveal these rationing practices which may affect voting behavior of society (Walton, 2000). All of these enforcements may cause failures in diagnosis and treatment especially if doctors are afraid of possible lawsuits while dealing with blurred symptoms and complaints. Also procedures and prescriptions of patients who may need continuous monitoring or periodic testing may be avoided due to the same reasons.

The funding and provision of health care are being handled differently in different countries with the help of demographic assumptions and economic projections (European Commission, 2011). But the rising common idea is that there is a need for a change in the health care expense distribution between formal and informal care in addition to public and private financing, to reduce the stress on governmental social and health care systems (Milligan, 2006; Pickard et al., 2007; Price, Pollock, & Shaoul, 1999; Tarricone & Tsouros, 2008; Walton, 2000). At this point, change of mixed economy and approach of care "place an increasing emphasis on the home as the key site of care-giving with informal (or familial) carers forming the 'frontline' of primary care" (Milligan, 2006, p. 320). The reason and outcome of aforementioned situation is summarized by Story (2010) as:

> The formal health care system has become increasingly stressed, patients are being released from hospitals and other health care facilities still needing care. As a consequence, both laypeople and professional caregivers are making use of a wide variety of technologies, some of them quite complex,

> in non-institutional settings to manage their own health, assist others with health care, or receive assistance with health management. (p. 145)

To conclude, governments are trying to deal with the rising burden of health care by prioritizing services, procedures and prescriptions; to make sure of the stability of economic growth and to balance health care expenditures with other expenditures of public services. This situation may result in unfairness (Walton, 2000) and reduction of provided health care quality, since doctors are being forced to eliminate hospitals' expenditures as much as they can. Therefore, home use medical devices are seen as a relief on health care funding, in terms of easing the burden of escalating numbers of populations by carrying their care from hospitals to homes.

2.1.3.6 Advancement of technology

The convergence of sensor, microprocessor, and wireless communication technologies is playing a crucial part on today's design and application of products (Holtzman & WTP Advisors, 2012; Keckley & Underwood, 2008; Korhonen et al., 2003) and digital products are getting into the home continuously (Philipson & Roberts, 2007). As processing power increases continuously, electronic devices are getting obsolete faster but the cost of related technology decreases accordingly (Keckley & Underwood, 2008). Also, shrinking components, new material researches, developing manufacturing methods (autonomous manufacturing) and decreasing raw material costs enable to accomplish products that can be integrated in and engaged with our lifestyles more than ever. Medical device industry has also been affected by these technologies and progresses. Medical devices have started to become miniaturized, simplified and more affordable enough to find their way out of the hospital (Salditt & Bothell, 2004). Lately, emergences of low cost high resolution cameras, shrinking batteries with longer duration and miniature high-capacity data storage units, which are mostly developed for small digital products such as smart phones, give an extra boost on home use medical device development (Salditt & Bothell, 2004). Advancements of information and communication

systems and their usage in healthcare enable to track a patient's health at home and facilitate on-time interventions by the patient or the caregiver with the help of healthcare professionals guiding from the hospital (Reid, Compton, Grossman, & Fanjiang, 2005).

In the light of the explored subjects through Section 2.1.3, we can draw the following picture of where current world's converging trends are heading; people are living longer, world population is getting older, chronic diseases are increasing, technology is improving, healthcare expenditure is growing, health care mentality is changing towards self-care and it can be observed that all of these situations are associated with each other. At the intersection of these converging trends, there emerges a new trend: home care as a promising alternative for institutionalized care. Hereafter, the challenge is how medical device industry will respond to these needs and demands of changing society and changing health care delivery. Since medical devices will increasingly be used by patients and their caregivers instead of medical professionals, and also they will be used in diverse environments instead of institutionalized settings, these changing factors have to be considered when developing a home care medical device, to meet the new emerging needs of the current society and health care system.

2.2 Regulatory Complexity of Medical Device Industry

> The world of medical devices is a complex, fragmented and paradoxical one. Its boundaries and contours are difficult to delineate, its societal participants not always obvious or easy to discern, its rules of engagement variable and contested, information about it relatively difficult to obtain, its technologies multiple and interdependent, its technology classifications labyrinthine and bureaucratic. (Faulkner, 2009, p. 27)

As discussed in Section 2.1.3, the beginning of the 21st century is affected by two main factors: demographics and technology (Morgan, 2005; Philipson & Roberts, 2007). While world population is growing older, technology is improving rapidly.

At the intersection of these two factors, there is a growing desire to provide a more effective health care to the elder population with the help of improving technology; therefore medical devices have started to find their way out of the hospital into the home to meet with that desire. As a result, the medical device industry has to encounter already existing challenges of the health care system, in addition to the new ones which home care trend constitutes.

Health care is a complex field by its nature of having many elements, and therefore many challenges in the system. Carayon & Friesdorf (2006) explain this complexity as follows. The health care system consists of many people with different backgrounds and skill levels: there are doctors, technicians, nurses, providers, purchasers, patients and their families. Besides, the health care system confronts nearly 500.000 illnesses, each of which having various methods of diagnoses, treatments and managements. All these actions of dealing with illnesses take place in different settings, both geographically and socially; it can be a large hospital where interaction between people is affected, it can be a well-equipped or poorly equipped institution, and lastly it can be a home where the specifications and requirements are far different from hospitals. Between all of these combined diversities, there are medical hazards and uncertain or imperfect information that are caused and affected by aforementioned variables. Combined with all, this overall system is rapidly changing and advancing in terms of technology and knowledge which increase the overall stress as well, by its own volume and complexity.

Within this combined system, the industry which supplies this system is influenced by these elements too. Medical device industry is affected by the changing technology and knowledge and is concerned about how to make use of them effectively and safely. At the same time, a strong regulatory system exists to encounter the medical hazards that other diverse elements (the people that are involved in health care, diverse illnesses and treatments, the places where treatments and medical hazards are taking place) may cause. Therefore, regulatory

requirements have to cope with this complex and the technologically advancing system. Since home use medical devices are bringing new users and use environments into the existing scene, new concerns seem to be arising from the horizon in terms of medical device regularity system.

Design of medical and home use medical devices is strongly affected by medical device regulations and standards. Regulation of medical devices is a highly bureaucratic system that requires a lot of legal paperwork of technical documentation, several stakeholders to follow the regulatory processes, and expensive and time consuming clinical trials. In a safety crucial field, a strong regulation system is needed but, coping with the changing dynamics of the sector that the system controls is also needed.

To have an understanding on the subject of medical device industry's complex regulatory requirements, the current picture of today's medical device regulatory system is briefly portrayed in the following sections. In Section 2.2.1, regulation, classification and standards that apply to all medical devices will be explained, because home use medical devices do not have a specific regulating and standards system. Following that, in Section 2.2.2 home use medical devices classification and guidance documents related to them will be presented. Lastly, the current picture of the regulatory system in relation to the design of home use medical devices will be discussed.

2.2.1 Regulation of medical devices

Medical device regulations can help to ensure providing safe, effective and high quality devices and prevent usage of unsafe technologies, if they are applied properly (WHO, 2012). Medical device design is strongly affected by regulatory systems since they are prerequisite requirements for a device to be commercialized on the market. As mentioned in Section 2.1.1, medical devices are regulated differently in Europe and in the United States; other countries are generally adopting regulation systems among available ones. Home use medical devices are

considered among medical devices, for that reason medical device regulations are also binding for home use medical devices.

European regulation

Before European medical device directives, which are introduced in early 1990s, different regulatory systems were adopted by different countries and those systems were not consistent, not even between two countries; furthermore, there were countries without a regulation (Donawa, 2010). European medical device directives provided a technical harmonization between countries (Donawa, 2010).

Currently in Europe, medical devices are regulated by three main European Directives: (1) Council Directive 93/42/EEC concerning medical devices (MDD), (2) Council Directive 98/79/EC on in vitro diagnostic medical devices, (3) Council Directive 90/385/EEC on active implantable medical devices (European Commission, 2013a). Also a fourth directive exists, named Directive 2007/47/EC amending adjustments of directives 93/42/EEC and 90/385/EEC. This last amending directive is prepared to add usability requirements and help medical device manufacturers to reduce use errors by including risk analysis during device design (Donawa, 2011).

In order to have the right to be commercialized on the EU market, it is essential for a device to be labeled with the *CE Mark*. CE stands for -French of- European Conformity. To acquire CE Mark, *ANNEX I Essential Requirements* sections of the previously mentioned directives have to be fulfilled (Santos et al., 2012) and a *technical documentation*, which documents all related tests, manuals, design drawings, applied standards, etc., has to be prepared in order to inform notified body about the device's design, manufacture and performance (Orion Canada, 2010). Later a *Declaration of Conformity* has to be prepared in order to verify conformity of the device with the these requirements (Meijer, 2009; Orion Canada, 2010). As explained by Santos et al. (2012), the Essential Requirements section consists of two titles, one defining a set of general requirements for safety and

performance that is applied to all relevant devices; and the other, consisting of a set of specific and technical requirements on the design and manufacturing of devices, depending on their nature.

As stated by Alexander & Clarkson (2000), majority of the medical devices are subject of MDD in addition its essential requirements section is binding for every classification of medical devices and "although the directive does not address specific steps of design or validation, the general requirements [section] clearly outline the need to understand the user conditions, intended purpose, performance and risks of the de vice throughout its life cycle" (p. 7).

Recently, European Commission proposed a new regulation which will replace the existing ones, primarily due to "existing EU legislation, dating back to the 1990s, has not kept pace with the enormous technological and scientific progress in the past 20 years" (European Commission, 2012c, p. 2).

To provide a bridge between manufacturers and European legislations and to ensure medical devices are regulated according to medical device directives, there are *Competent Authorities* which are assigned by governments of each Member States of European Union ("MEDDEV 2.12/1," 2013). Also there are *Notified Bodies* that provide a bridge between manufacturers and Competent Authorities. A Notified Body is a public or private organization which is authorized and monitored by Competent Authority of the EU Member State with the aim of operating conformity with regulations assessment procedures; product certification, factory production control certification, and product type assessment are among the practices of notified bodies (European Commission, 2013d).

After partnership with Customs Union in 1995, Turkey - as an EU candidate state - took action to have the same rights and obligations with EU Member States aiming to remove trade barriers with the *Decision No. 2/97 of Turkey – EC Association Council of 4 June 1997* (Republic of Turkey Ministry of Economy, 2012). After that, Turkey has started to transfer several EU acts. In 2004, Republic of Turkey

Ministry of Economy declared that 23 EU directives are adopted and will be implemented after the date given ("The CE Marking in Turkey," 2012). Competent Authority of Turkey is General Directorate of Pharmacy and Pharmaceuticals Biomedical Engineering Department which is established under Ministry of Health of Turkish Republic (European Commission, n.d.). Currently there are 19 Notified Bodies in Turkey and 6 of them, including Turkish Standards Institution, have authorization of medical device directives (Republic of Turkey Ministry of Economy, 2012).

United States regulation

In 1976, FDA is given the authority by Medical Device Amendments (MDA), to regulate medical devices by FD&C Act (Santos et al., 2012). The objective of the amendment is stated in *Medical Device Amendments of 1976* as: "to provide for the safety and the effectiveness of medical devices intended for human use and for other purposes" (para. 1). Manufacturers have to acquire an approval from FDA before a device is commercialized, and Center for Devices and Radiological Health (CDRH, which is formed within FDA) is responsible for the review of medical devices (Johnson, 2012). There are two paths for manufacturers to get an approval according to devices' risk level: Premarket Approval (PMA) or Premarket Notification (510[k] Review) (Johnson, 2012).

For moderate and high risk medical devices, PMA is essential to get an FDA approval. PMA requires scientific review by conducting clinical studies and proving the device is safe and effective to obtain a permission named *FDA approved* (Johnson, 2012). FDA reviews the documents and decides if the device is applicable in 180 days, however the total process may last varying from 6 months to 2 years due to clinical studies and documentations (Santos et al., 2012).

510(k) Review, which is named after the related section of FD&C Act, can be chosen for low-risk devices. To achieve a 510(k) Review, the manufacturer has to demonstrate the medical device is *substantially equivalent* -by means of intended

use and technological properties- of another device (referred as *predicate device*) that was approved by FDA before (Johnson, 2012). This path does not require clinical studies and requires a 90 day review (Santos et al., 2012). It is more cost and time effective, thus, it enables improvements of previous devices and increases market competitiveness (Zuckerman, Brown, & Nissen, 2011). If a medical device acquires a 510(k), it attains *FDA clearance*, instead of *FDA approved* (Johnson, 2012).

2.2.1.1 Medical device classifications

In Europe, devices that are a subject of MDD have to identify themselves under one of the device classifications and these classifications are defined with 18 rules in the Annex IX section of MDD. There are four classes which are decided by "potential hazards and possible failure, duration of contact with the body, degree of invasiveness, and local versus systemic effects" (Santos et al., 2012, p. 8). The classes of medical devices defined by MDD are:

Class I - Low risk medical devices,

Class IIa - Medium risk medical devices,

Class IIb - High risk medical devices, and

Class III - Highest risk medical devices.

According to Annex IV section of MDD (1993), all non-invasive devices are classified as Class I, Class IIa or Class IIb, according to their amount of channeling or storing body fluids and amount of contact with injured skin. Similarly, invasive devices can belong to one of the four classes according to their risk possibility, invasiveness level and contact duration. In general, Class III devices are invasive devices which are in direct contact with heart, central circulatory system and central nervous system or which may dissolve inside body (pp. 36-40). Only some Class I devices, which do not feature sterilization or measuring, can be investigated by its

own manufacturer with a self-declaration of meeting general requirements to be affixed without a notified body investigation, rest of the devices need to be investigated by notified bodies (Meijer, 2009; Orion Canada, 2010). Also Class III devices have to prepare a more detailed technical documentation which is named Design Dossier (Orion Canada, 2010).

Regarding the United States, FDA categorizes medical devices under three classes, according to the possible risk that the device involves (Johnson, 2012) and required FDA approval process to commercialize the device (Santos et al., 2012). These classifications are presented as:

Class I - low risk medical devices,

Class II - moderate risk medical devices, and

Class III - high risk medical devices.

Class I requires *General Controls* - prerequisite requirements that all medical devices should comply with; Class II requires General Controls, 510(k) or *Special Controls* - requirements that may be needed to reduce possible risks that are not controlled with general controls; Class III requires 510(k) or PMA in addition to General Controls (Johnson, 2012; Santos et al., 2012).

2.2.1.2 Medical device standards

Harmonized European Standards provide assistance to fulfill Essential Requirements which are defined by European directives and although compliance with these standards is not obligatory, it helps to demonstrate compliance with Essential Requirements (Donawa, 2011). Harmonized Standards mean European Standards (EN - *European Norm*) that are supporting EU Directives and Regulations (CEN, 2013). European Commission requested from European Standardisation Organisations to develop Harmonized Standards aiming “to meet

the essential requirements or other provisions of relevant European Union harmonisation legislation" (European Commission, 2013d, para. 1).

Three standards are listed by Alexander & Clarkson (2000) as quality systems for medical devices: (1) *ISO 9001 Quality Management System* may provide a compliance with general requirements of Essential Requirements, (2) *EN 46001 Quality System - Medical devices* (of 1997) may enable to fulfill specific requirements for medical devices since EN4006 is a document provided for applying requirements of ISO 9001 to medical devices, and (3) *EN 724* (of 1994) which was providing a guidance on the application of aforementioned standards for non-active medical devices (Alexander & Clarkson, 2000a).

EN 46001 is replaced by *ISO 13485 Medical devices - Quality Management System* that is published in 2003 and became a harmonized quality standard for medical devices directives in 2004 (Orion Canada, 2010). Its aim is stated as "to facilitate harmonized medical device regulatory requirements for quality management systems" (ISO 13485:2003) so some unrelated ISO 9001 requirements have been excluded while some needed medical device requirements have been added. GHTF recognizes and recommends ISO 13485 and states that it is efficient enough to be required alone without ISO 9001 (Miura, 2004). Also FDA supports ISO 13485 but does not accept it as a consensus standard (Orion Canada, 2010).

There are various other harmonized standards that provide guidance for different devices, technologies and procedures such as: dentistry equipment, prosthetics, sterilization of medical devices, clinical practice, and so on. Also, several usability-related standards exist and *EN 62366 Medical Devices – Application of Usability Engineering to Medical Devices* is the primary standard for improving usability and this standard is applicable for all medical devices. It defines the process of analyzing, verifying and validating design and usability with the help of reducing design and use errors (Donawa, 2011).

On the subject of applicability and effectiveness of European Standards, Alexander & Clarkson (2000) state that, “few [of standards] offer practical guidance on good design practice to enable the integration of design and validation” (p. 7), and “they [standards] outline what must be done, but they do not provide guidance on how it should be done” (p. 8). Also on the same subject, Kossack et al. (2007) stated that “[such standards and guidelines] provide only general, high-level guidance” (p. 493); therefore, inexperienced designers and human factors professionals may implement them as strict rules while experienced ones may challenge their implementation by interpreting them as recommendations.

In the US, Quality System Regulation (QSR) is developed to provide “the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device” (FDA, 2011b, "Flexibility," para. 1). QSR is also known as Good Manufacturing Practices (GMP) and it is aimed to be harmonized with international medical device quality standards: ISO 9001 and ISO 13485. QSR is authorized by FD&C Act and it is in Part 820 of Code of Federal Regulations’ Title 21 (FDA, 2011c). Due to QSR being required for all medical device classes, it is flexible in terms of being reliable to the manufacturer; QSR defines essential elements of quality plan but how to comply with them is the manufacturer’s responsibility (Alexander & Clarkson, 2000a; FDA, 2011c). Also, complying with procedures of QSR alone may not allow a product to be commercialized. Only some devices which are considered low risk and exempt from premarket evaluation, can be commercialized with only complying with QSR (Maisel, 2004). Others will have to comply with the previously mentioned relevant US approval paths.

QSR has various sections such as definitions, quality system requirements, design controls, labeling and packaging control and so on. As stated by Alexander & Clarkson (2000), the design control section provides definitions for validation and verification routes and this section concerns with good design practice.

2.2.1.3 Verification and validation practices

Verification and validation practices are applied to the design process with the aim of meeting user needs and intended usage (Figure 2.9). These two processes are required to comply with both ISO 13485 and QSR. The results of verification, validation and design review have to be presented with a design history file (the US), and technical documentation or design dossier (EU).

These two terms generally overlap and their relationship may be confusing (FDA, 1997; Wiklund, Kendler, & Strochlic, 2011). On this subject, Alexander & Clarkson (2000b) state that, the reason behind this confusion is unclear official definitions of verification and validation. According to Alexander & Clarkson verification seeks answer to the question "are we building the right thing?" and validation addresses the question "`have we built the right thing?" (p. 53).

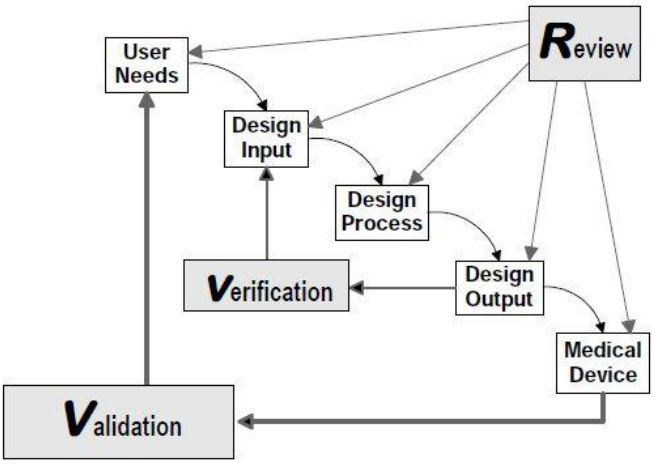

Figure 2.9 Application of Design Controls to Waterfall Design Process showing the Verification and Validation tasks (adopted from FDA, 1997)

Design review (shown as ‘review’ in Figure 2.9) is used for ensuring whether “design input requirements are adequate before they are converted into the design specification” and whether the overall design is sufficient enough before the final prototype is manufactured (FDA, 1997). User needs are interpreted as design input, which is then defined as design requirements. These requirements are translated into design specifications, these specifications are turned into design output through the device design process. And when a design output verifies that higher design specifications are meeting design input requirements, then again this design output constitutes a design input for the following level. This cycle of design review is repeated within the design process when taking important decisions (FDA, 1997).

Verification is performed to confirm that each requirement specified for the design input is fulfilled by the design output (Alexander & Clarkson, 2000b; Wiklund et al., 2011) According to FDA, verification process is among the studies of human factors (FDA, 2011b). V*alidation* is an evaluation performed to make sure if the medical device meets its intended user needs by confirming whether the designed device is fit for its purpose, and is consistent and complete in terms of what was initially determined as its function within a context (Alexander & Clarkson, 2000b).

2.2.1.4 Guidance documents for medical devices

To provide more practical help to medical device manufacturers, organizations publish guidance documents. As shown illustrated in Figure 2.10, even though implementing the requirements of these documents is not obligatory, they provide specific and more comprehensible information to comply with regulations and standards (Alexander & Clarkson, 2000a).

On the subject of European Regulations, there are three types of guidance documents:

(1) EU Commission Guidance documents, published by European Commission with the intention to provide additional information about directives;

(2) Guidance MEDDEVs, published by Working Groups (representatives of related medical device sector organizations) with the aim of providing a common understanding between manufactures, competent authorities, and notified bodies, to ensure a harmonized application of directives;

(3) Notified Body Guidance Documents, published by Notified Bodies themselves or Notified Bodies Operations Group in order to provide a uniformity among notified bodies and competent authorities these documents can later gain a MEDDEV status with the consent of Medical Devices Experts Group ("The Role of Guidance," 2007).

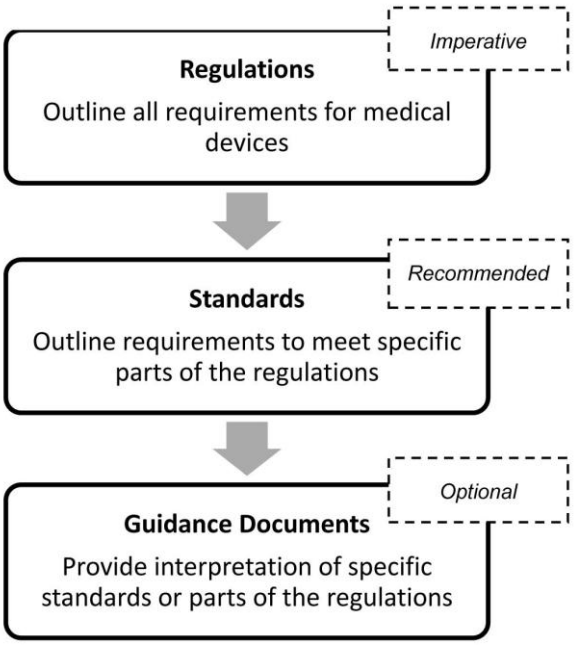

Figure 2.10 Relationship between regulations, standards and guidance documents (reproduced from Alexander & Clarkson, 2000)

It can be observed that, these guidance documents mostly focus on directives and the communication of stakeholders which take part in the process of complying with them. Europe falls behind the USA on the subject of providing a more practical guidance on the development of medical devices and practical guidance on human factors studies; since medical device directives of Europe mention them "in only the most indirect terms" (Ward & Clarkson, 2004, p. 10), so there is a need for more well established guidance documents.

In relation to United States Regulations, FDA publishes guidance documents. Especially, *Design Control Guidance for Medical Device Manufacturers* (FDA, 1997) is the most comprehensive and practical one among them (Alexander & Clarkson, 2000a). This guidance is prepared to offer further explanation to the previously mentioned QSR of the FDA and by this guidance, verification and validation process of design and manufacturing of medical devices is explained in detail. Also there are three human factors related documents which are published by FDA: (1) *Do it by design: An introduction to human factors in medical devices* (Sawyer & CDRH Work Group, 1997), (2) *Medical device use-safety: Incorporating human factors engineering into risk management* (Kaye & Crowley, 2000),and (3) *Applying Human Factors and Usability Engineering to Optimize Medical Device Design* (FDA, 2011b). These guidance documents provide an introduction to human factors engineering practice and risk management by emphasizing the importance of usability studies and presenting information of some device evaluation methods with several examples.

In addition to European and United States' organizations, GHTF published guidance documents with the aim of providing globally harmonized guidance. These documents provide knowledge on the following main subjects related with medical devices: pre-market evaluation, post-market surveillance, quality systems, auditing, and clinical safety/performance (IMDRF, n.d.).

According to interviews conducted by Shefelbine (as cited in Ward, Shefelbine, & Clarkson, 2003), although there are several guidance documents , it is observed that

designers are almost afraid of regulatory requirements and critically have little knowledge of device regulations. Alexander & Clarkson (2000a) studied several guidance documents which are published by different sources, and they state that guidance documents are "more useful than the regulations and standards, but they tended to be very specific" (p. 12) and concluded that the revised documents did not cover the integration of validation the design, planning and production of devices.

2.2.2 Regulation of home use medical devices

Home use medical devices are not regulated by a separate system. They are subject of the medical device directives in Europe, and subject of the FD&C Act in the United States. Also there is a lack of a standard system specifically prepared for home use medical devices.

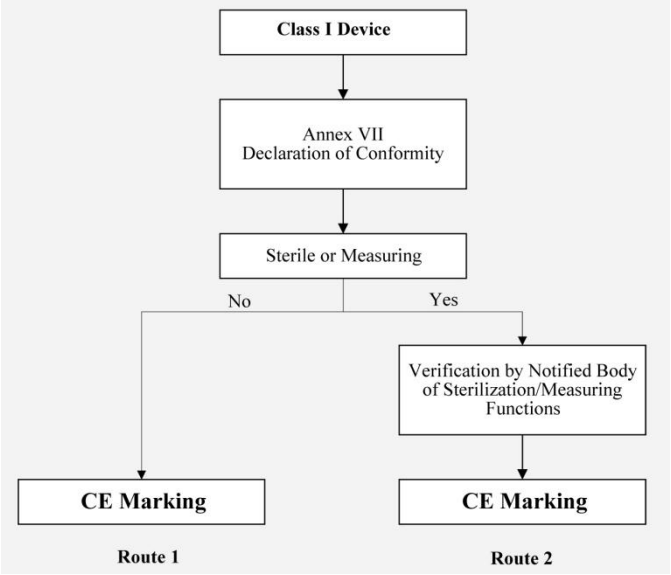

Figure 2.11 Class I devices, CE Mark process (adapted from Orion Canada, 2010)

Home use medical devices are generally considered among Class I devices according to the European regulatory system (Meijer, 2009). As it is mentioned

before, Class I devices are low risk devices which can acquire CE Mark by fulfilling General Requirements section of medical device directives. Only some of the Class I devices may obtain CE Mark without a notified body approval. As shown in Figure 2.11, Route 1 is applicable for devices which do not feature sterilizing or measuring. According to Annex VII of MDD, the manufacturer prepares a technical file and a written Declaration of Conformity for further investigations of competent authorities and then labels its device with the CE mark. Route 2 is applicable for rest of the Class I devices. Along with the previously mentioned process, a notified body approves whether the device is applicable for the CE mark (Orion Canada, 2010).

Home use medical devices are also subject of previously mentioned standards. Standards are needed especially in the progress of developing home use medical devices concerning their diverse user groups, and guidance documents are helpful in the progress of complying with standards. As stated by Story (2010) "Standards are helpful, but you still have to know what you are doing with them" (p. 36). Therefore, these documents guide manufacturers through the process of compliance. Lately, particularly with a focus on human factors studies, two documents are published by FDA, which are addressing home use medical devices:

Design considerations for devices intended for home use - Draft guidance (FDA, 2012): This guidance aims at providing guidance for manufacturers to "comply with applicable standards of safety and effectiveness and other regulatory requirements" (p. 4) in the process of developing a home use medical device. It consists of introduction to device environments and device users, a brief background about human factors studies with an emphasis on usability studies, and lastly brief information on post market considerations.

Medical device home use initiative (FDA, 2010): This document provides an introduction to home use medical devices with their benefits and challenges, and lists several device-related problem cases. Lastly, in the document, it is stated that "FDA has not articulated a clear regulatory pathway for devices intended for home

use" (p. 7) and it is pointed out that FDA is planning on providing a more detailed guidance on recommend actions to comply with FDA *approval* or FDA *clearance,* with a focus on home use medical devices.

It can be observed that European auditing authorities lag behind the auditing authorities of the USA on the subject of addressing home use medical devices in particular. It is notable that, in 2001 Home Health Care Committee (HHCC) was formed within FDA with a purpose of understanding and studying the usage of medical devices in the home environment by patients and lay caregivers and to make these devices more safe and effective. Also, most concentrated guidance documents available on home use medical devices are published by FDA. Even though auditing authorities have started to pay increased attention on home care field, there is still few guidance provided addressing particularly home use medical devices. Converged with the already existing challenges of the regulatory system, home use medical devices seek a more focused attention about how to regulate and guide the related field.

Current situation

Because of the effort of meeting high safety requirements, the development of medical devices is a process that is different from other consumer electronics. Medical device industry is similar to aviation and nuclear industry in terms of complexity of binding regulations and standards (Santos et al., 2012; Walsh & Beatty, 2002). Medical device design requirements may have high costs and high levels of complexity due to being more dependent on new technology, remaining incomplete and resulting from "ambiguous situations" (Santos et al., 2012, p.17).

Arguably, in relation to the presented regulatory system, current medical device industry may be experiencing the following challenges;

(1) Medical device regulations are prepared way before the last decade's sociodemographic changes and technological developments; they date back to the

1990s. Especially concerning the emerging field of home care, solely complying with these regulations may not be adequate enough to meet with the requirements of home use medical devices. In addition, even though European Directives are announced to be replaced by a new one in the near future, there are concerns that the new directive will be too restrictive and therefore it will undermine home use medical device development (Brophy, 2013).

(2) Regulation and standards system requires a process which is highly bureaucratic, restrictive and technical. That situation results in a time and cost consuming design and conformity verification process, as well as being complicated to follow up. Therefore, performance of the industry is affected by a strict regulation process in a way that, innovations and researches -which are lately focused on home care- may be slowed down by it. For instance, compared to the FDA's regulations, European directives have a relatively easier way to confirm compliance so, innovative products can find its way on the market faster by taking the European path (Santos et al., 2012). For that reason, some of the American manufacturers may choose the European approval process which later on, acquired approval mostly results in approval in the USA as well (Brophy, 2013; Connolly, 2013). Even this situation is a strong example of how bureaucracy of regulatory system is effective on manufacturers and innovative product development.

Also, as pointed out by Santos et al. (2012), new technologies are usually studied on by small and medium sized companies which are mostly established as a sequel of a particular university-studied technology; on the other hand, big companies are usually focused on advancing existing technologies. As a result, these small and medium sized companies may not survive this highly bureaucratic, technical, time and cost consuming process, considering their limited sources (Santos et al., 2012). In addition, aforementioned plan of the new European directives is being speculated to be overly cost, time and source consuming for small companies which prefer less-demanding the European regulatory path (Brophy, 2013; Connolly, 2013).

Lastly, as stated previously, medical device standards are dating back way before latest technological and scientific advancements. In general, standards tend to be conservative and they rarely represent recent user experiences, but on the contrary there is a need for a well-established, up-to-date system (Hale et al., 2007). Conservative and bureaucratic system itself is a challenge for confronting the need for an up-to-date one because "[timely update of design standards] is not feasible for industry standards that undergo extensive and bureaucratic revision processes" (Hale et al., 2007, p. 321). To overcome this challenge, Hale et al. (2007) suggest that, in addition to complying with existing standards, designers have to develop their own *internal design standards* with the help of gathering most recent user experiences (p. 321).

(3) Only complying with the current system's requirements may not be adequate to provide safe and effective medical devices. There may be a misunderstanding that, solely complying with standards and regulations will result in efficient devices. Designers may think that, further product development studies and tests are not needed (Fadier & De la Garza, 2006; Hale et al., 2007). Furthermore, regulatory system is risk management oriented (Martin et al., 2008), therefore other aspects may be missed, such as; whether the device keeps up with activities of daily life, whether the device is found aesthetically pleasing, whether users are customizing the devices on their own terms, etc.

On this subject, Kossack et al. (2007) state that, medical device industry is historically focused on providing safety by eliminating predictable misuse and use errors but a little attention is given on the other aspects. For instance, the industry has a conservative design approach with a tendency of maintaining a conservative medical appearance (Kossack et al., 2007). But on the other hand medical devices are changing hands and environment; the user group is expanding by including patients themselves and home is becoming a new medical device setting. Therefore, manufacturers should check whether the device meets its users' requirements by usability studies, instead of solely designing with the help of standards and guides.

(4) An overall international harmonization of the systems is not achieved yet. There are various country-specific regulations and standards, Europe chooses a separate path, the USA has its own system, and in the midst of this vast range of different paths, GHTF publishes their own medical device requirements with the intention of providing a harmonized system.

On the other hand, patients are getting more mobile noticeably, and their medical devices are travelling with them. Furthermore, especially small digital devices are being sold on the international market increasingly. Since a home use medical device specific regulation and standard system does not exist, this situation may pose a threat if devices are being manufactured based on different standards. On this subject, Meijer (2009) states that, an *international* standard system has to be developed in order to adjust with today's international market and mobile patients, thereby this harmonized system might enable a collaboration of data among countries.

(5) The tests and evaluations, which are prerequisite to have a regulatory authorities' approval, do not always take place in the exact use environment of the medical device (Farberow et al., 2008; Matern & Büchel, 2011; Wiklund & Wilcox, 2005). For instance, some manufacturers may test the device in an office or laboratory environment with some potential users; and even though this approach could provide useful knowledge, it may also distort the results in that isolated environment (Matern & Büchel, 2011; Wiklund & Wilcox, 2005); thus those results are not completely transferrable to the actual context of use (Matern & Büchel, 2011). Especially on the subject of home use medical devices, this situation becomes crucial considering that, the ambiguities of the physical environment and social environment of the home are much more unpredictable than a controlled hospital environment.

(6) There is a lack of practical guidance and explanations about how to apply regulatory requirements (Alexander & Clarkson, 2000a; Ward & Clarkson, 2004;

Ward et al., 2003). Mostly regulations and guidelines provide general principles of safe design, instead of providing comprehensive and detailed information on where the device will be used, who will use the device, etc (Ward & Clarkson, 2004). For instance, the following example is given by Ward & Clarkson (2004) as;

> HE48 section 15.5.1.4 [of ANSI/AAMI HE48-1993 Human factors engineering guidelines] quotes: 'Controls should be compatible with the lowest anticipated skill level of users'. But what exactly is this level? (p. 11)

Complexity of regulatory system and absence of practical guidance cause designers to know little about how to apply regulatory requirements on devices. As stated before, although there are several guidance documents, designers are almost afraid of regulatory requirements and critically have little knowledge of device regulations (Ward et al., 2003).

To sum up, the medical device regulation system does not provide up-to-date and practical guidance for manufacturers and designers. Also, relying solely on regulatory requirements may deceive the manufacturer and designer as the device being safe and efficient enough. On the other hand, medical devices are increasingly being used by patients and their caregivers instead of medical professionals, and also they are being used in diverse environments instead of well-equipped institutionalized settings. Since regulatory systems are aiming for device safety, in addition to existing risk management oriented requirements, these changing contextual factors have to be considered as device requirements, as well. The next section will elaborate on these contextual factors and relevant notions.

2.3 Usability and Home Use Medical Devices

Currently, auditing authorities and studies on the related field have an increasing attention on human factors studies. As it is mentioned previously, guidance documents which are addressing home use medical devices emphasize the need for human factors studies with the intention to "decrease the occurrence of adverse

events by minimizing the risks to patient and user safety" (FDA, 2012, p.6). Manufacturers have to perform risk analysis studies as a part of design controls requirements. But, human factors studies are required to be performed if risk analysis reveals a risk of use error or if a device on the market is being modified because of use related problems (FDA, 2011b). Therefore, these studies are integrated to the medical device manufacturing with a risk management concern. In addition, generally human factors related studies are conducted after a product is finalized and end-user involvement does not take place during device development phases (Czaja & Nair, 2006; Fairbanks, Caplan, Bishop, Marks, & Shah, 2007; Martin et al., 2008). Also, manufacturers are distributing their devices through suppliers and distributors, and this situation causes a gap between manufacturers and end-users (Taft, 2007). According to Martin et al. (2008), regulatory requirements create constraints to study on human factors and to include end-users; because, medical devices have to meet particular requirements of regulatory systems before being tested by end-users. After studying with users, product developers do not want to make changes in order to not to resubmit their devices for assessment procedures of regulations (Martin et al., 2008). As stated before, only consulting to and complying with human factors related standards and guidance may be inadequate (Ward & Clarkson, 2004); hence, designers have to gather their own latest user experiences as internal standards (Hale et al., 2007), and human factors studies have to be implemented to all phases of device development, from early concept generation to production (Wilson, 2005). Through this section, human factors studies and context of use within usability activities will be explored initially, and since home use medical devices are generally used in home environment by a diverse group of lay users, related contextual factors will be explored afterwards.

2.3.1 Human Factors Studies and Usability

Human factors field studies human beings and their interaction with products. The International Ergonomics Society defines human factors as; "the scientific

discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance" (IEA, 2013). Czaja & Nair (2006) refines the focus of human factors as "the application of knowledge about human capabilities, limitations, and other characteristics to the design of human–machine systems." (p. 32). Main aims of human factors studies are enhancing human performance and reducing use errors by designing products according to user needs; therefore users will be enabled to perform efficient, effective and safe product usage (Drake, 2002; Ward & Clarkson, 2004). The system or product that human beings, i.e. users, interact with, may be both a simple tool and a complex system such as a factory production system (Czaja & Nair, 2006). Human factors may also be referred to as ergonomics, usability, user centered design and human engineering; all of these terms are repeatedly being used interchangeably to an extent that, they are used as synonyms in the literature (Drake, 2002; Wilson, 2005).

Applying human factors studies on product development is started to being recognized by manufacturers with a concern of having advantage over their market competitors (Jordan, 1998). End-users may not know much about usability but they understand when a product works, at the same time manufacturers may not know much about usability studies but they know when they have a product success and how their profit reduces if users have recourse to their customer services a lot (Drake, 2002). Users do not willingly accept products with difficult use, and consequently they abandon manufacturers which produce these products (Jordan, 2005). On the other hand, this concern has become a trend such that, manufacturers claim their products as being "user friendly" with commercial purposes; but not all the products are user-friendly, especially when there is not any involvement of human factors (Wilson, 2005).

2.3.1.1 Usability

Human factors field usually applies “fitting the product to the person” with the focus on usability and this is commonly referred to as “ensuring that the product is easy to use” (Jordan, 2005, p. 10). Usability may be confused with utility; utility is about “what the product can do” but usability is a dynamic aspect with the consideration of “how well people are able to use that functionality” (Wilson, 2005, p. 27). According to Bligård (2007), the most recognized definition of usability is provided by ISO as; “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" (ISO 9241-11:1998).

The goals of usability are explained as following:

- *Effectiveness:* The accuracy and completeness with which specified users can achieve specified goals in particular environments.

- *Efficiency:* The resources expended in relation to the accuracy and completeness of goals achieved.

- *Satisfaction:* The comfort and the acceptability of the work system to its users and other people affected by its use. (ISO 9241-11:1998 as cited in Bligård, 2007)

Satisfaction aspect is usually considered as a measure of perceived effectiveness and efficiency because it is assumed that if users carry our task efficiently and effectively, they become satisfied; but according to Green & Jordan (2004), satisfaction is the only dimension which addresses feelings, opinions and attitudes of users instead of being only a measure for other aspects of usability. On the other hand, Nielsen (2010) proposes that usability has more dimensions than that and he presents five attributes:

- Learnability: The system should be easy to learn so that the user can rapidly start getting some work done with the system.
- Efficiency: The system should be efficient to use so that once the user has learned the system, a high level of productivity is possible.
- Memorability: The system should be easy to remember so that the casual user is able to return to the system after some period of not having used it without having to learn everything all over again.
- Errors: The system should have a low error rate so that users make few errors during the use of the system, and so that if they do make errors they can easily recover from them. Further, catastrophic errors must not occur.
- Satisfaction: The system should be pleasant to use so that users are subjectively satisfied when using it; they like it. (Nielsen, 2010, p. 6)

On the contrary of the multi-dimensional characteristic of usability, usability-based studies usually have a focus on making users complete required tasks with a view of products merely as tools (Jordan, 2005). Human factors field have a concentration on solely usability issues in general, and in the process it is expected that determining users' needs will be achieved somehow as well; but this is not a way to understand all of the user needs, some factors (e.g. aesthetics, pleasure, experience) go beyond usability (Jordan, 1998).

2.3.1.2 User centered design

Main starting point of usability is "understanding user variance and designing for it" (Wilson, 2005, p.28) and User Centered Design (UCD) puts the user in the center of the each phase of the product design process, as the name suggests. In order to represent the users with needs and demands, UCD provides a wider perspective which considers product use with their users and their experiences in a more holistic way (Jordan, 2005).

UCD is recognized as a process for product design (Wilson, 2005). There are four UCD activities in the process of product development which are defined by ISO 13407. The relationship between UCD activities is illustrated in Figure 2.12.These activities are:

(1) understand and specify the context of use;

(2) specify the user and organizational requirements;

(3) produce design solutions;

(4) evaluate designs against requirements. (ISO 13407)

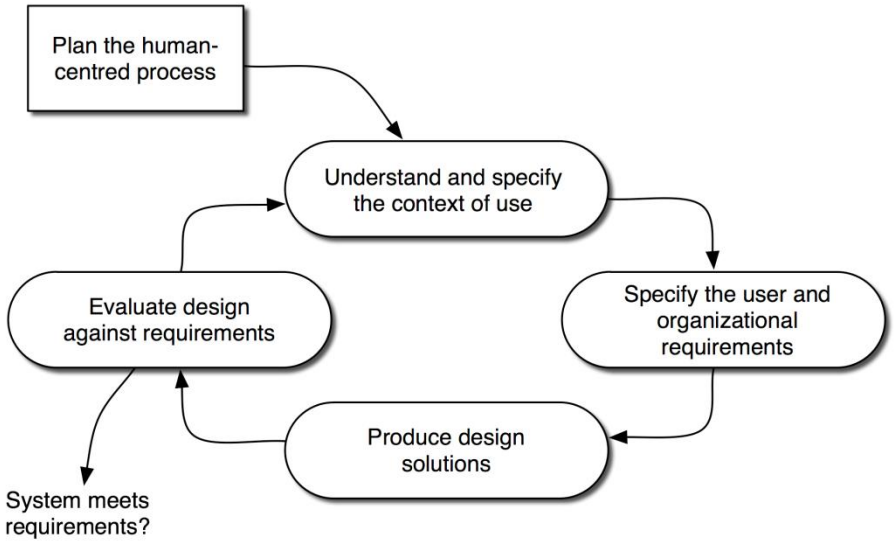

Figure 2.12 User Centered Design activities (adopted from ISO 13407; as cited in http://journal.code4lib.org/articles/561)

Planning phase is required in order to make an assessment on which particular actions should be taken to achieve a successful project. Understanding the context of use provides basis input for requirements; specifying users and requirements are

needed to achieve user performance and satisfaction; producing design solutions is needed to be done based on previously specified users and requirements. Testing design solutions with mock-ups in early phases and evaluating them with computer simulations in latest phases provides feedback about whether the system meets specified requirements (Bevan, 2009). Also, meeting the requirements is achieved by acquiring design feedback through evaluations from a user perspective, which can be obtained by expert evaluation and user-based methods (Bevan, 2009).

There are barriers to employ UCD in product development process and this situation results in failure to acquire user feedback and user needs. These barriers are stated by Bevan (1999) as:

(1) *Methodological barriers* are finding appropriate methods, techniques and tools in order to apply UCD in the product development (Bevan, 1999);

(2) *Commercial barriers* are widespread resistance against making investment in UCD activities due to manufacturers' perception of UCD activities as an additional cost (Bevan, 1999). Also, "companies and organizations have traditionally had little indication of how usable a product would be, how productive its users will be, or how much training and support its users would need" (p. 26) and benefits of improved usability are not well-known; therefore, comparing products, planning for support and assessing total cost is found challenging (Bevan, 1999).

(3) *Incomplete requirements* pose a barrier because there are traditional approaches which are focused on functional requirements and which underestimate non-functional requirements; on the other hand, from the perspective of users, quality in use is as important as functional requirements (Bevan, 1999). (Quality of use is used synonymously with usability in the ISO 9241-11 definition of usability [Bevan, 1999]). "Contextual requirements associated with scenarios of use, and high level quality in use goals (also called usability goals)" (p. 25) are among other requirements which are proposed by Maguire (1998; as cited in Bevan, 1999).

(4) *Practical barriers* are posed by unidentified characteristics of context of use in which the product will be used (Bevan, 1999). In conventional product development, considering contextual factors are neglected but acquiring characteristics of users, tasks, and environment of products is essential "in order to guide early design decisions, and to provide a basis for evaluation" (Bevan, 1999, p. 25).

2.3.2 Context of use and usability

All needs and demands of users may not be gathered by simply asking them directly what they need; possible user problems and overall user product interaction experience can be understood in their context of use to make sure to include them as design considerations (Wilson, 2005). Since usability of a product is assessed in "specified context of use" and the activity of "understand and specify the context of use" is identified among the main activities of UCD (ISO, 1999), considering that context of use is an essential component of product development.

The benefits of considering context of use in the product development phases are given by Maguire (2001) as;

- providing an understanding of the circumstances in which a product will be used;
- helping to identify user requirements for a product;
- helping to address issues associated with product usability;
- providing contextual validity of evaluation findings. (Maguire, 2001, p. 6)

User, task, and environment are characteristics of the context and they are as important as the characteristics of the device itself; usability of a product may change in accordance to any change that is made in any aspect of the context of use (Bevan, Kirakowski, & Maissel, 1991; Bevan & Macleod, 1994), therefore as stated by Bevan et al. (1991), "a product is not itself usable or unusable, but has attributes

which will determine the usability for a particular user, task and environment". The aspects of product and the aspects of context of use, mutually, have an influence on users' experiences of product use (Arhippainen & Tähti, 2003).

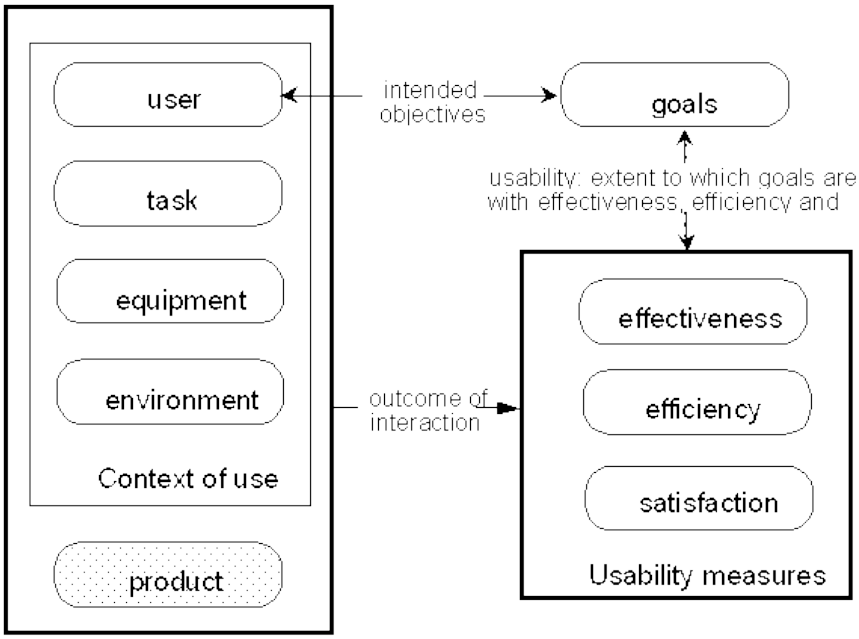

Figure 2.13 Context of use within usability framework (adapted from Bevan, 1994; as cited in www.usability.ru/sources/iso9241-11.htm)

2.3.2.1 Users and tasks

User characteristics such as age, gender, training, knowledge, skill, experience, education, physical attributes, motor and sensory capabilities, language and attitudes provides basis for design decisions (Maguire, 2001).

Development of technology and autonomous production has enabled manufacturers to achieve more complex systems (e.g. products) and this situation affected the design activities as well. Design is already a complex activity due to being the result

of a long period of study in ambiguous conditions, involving many people having different professions and varied knowledge levels, and being effected by several factors such as economic, technical, organizational, etc.; but actually, amidst these influential factors involved in the design activity, user is the main interest for whom the system is designed for (Czaja & Nair, 2006).

According to Norman (1990) designers have become experts of the product they work on to a proficient degree such that, they have started to have troubles to notice which aspects are causing difficulties for users. On the other hand, they tend to consider themselves as a typical user. While encountering a product, a typical user has to rely on knowledge in the world; but a designer relies on the knowledge in the head as a result of their training (Margolin, 1997; Norman, 1990). Therefore, it is difficult for a designer to envision all possible problems that the user will encounter.

Tasks are defined by Maguire (2001) as "the activities undertaken to achieve a goal" (p. 7). Each task to operate a product has to be studied in order to provide efficient, effective and satisfactory product use. Tasks are not only related with product functions or features; specified activities and steps should be considered to reach the associated goals (Maguire, 2001). Evaluating usability and specifying user requirements can be achieved by selecting representative subsets of contextual tasks among entire set of tasks (Maguire, 2001).

2.3.2.2 Environments

Environmental characteristics of products can be investigated under the three types of environments (Maguire, 2001):

Technical Environment consists of hardware and software features of products, and these technical characteristics influence usability (Maguire, 2001). For instance, Maguire (2001) gives the example of the processor power. To extend this example, it can be said that, the processor power of a computer affects efficiency because it affects the required time to complete tasks. Also, some tasks may not be achievable

due to low processor power therefore effectiveness may be affected, because the success of the task to reach a goal is obstructed by processor power. Because of the processor power, user may experience a pleasant and comfortable usage or the reverse; therefore satisfaction may be effected.

Physical Environment influences usability. For instance, lighting conditions may obstruct reading a digital user interface; a hot kitchen may affect the experience of using a powerful oven; a background noise, such as TV noise, may prevent hearing a low auditory signal of a baby monitor.

Social or Organizational Environment have an effect on usability as well, for instance, interruptions caused by the way of working of colleagues or suddenly visiting relatives may have an influence on the success of a task and the time to complete a task.

The roles of designers and design researchers are mutually interdependent to an extent that the boundaries are becoming blurred; designers should observe experiences and expressions of users and they should use this information as a source for their designs; in other words, even though users are not a part of the design team, their voice should be heard in the team through design research (Elizabeth & Sanders, 2005).

Hale et al. (2007) draw attention to several attitudes of designers which may result in poor usability and which may be related to not considering context of use as well. They explain that designers are more focused on "how the design should be used" than "how it might be used" (Hale et al., 2007, p.314) in order to relieve their workload. On the other hand, not considering real usage scenarios may result in misuse; because in reality, a product may be used in and out of designers' predicted safe limits. As stated by Hassenzahl (2003), "there is no guarantee that users will actually perceive and appreciate the product the way designers wanted it to be perceived and appreciated" (p. 33). Designers may not even visit and observe actual conditions of where the product will be used and who the product will be used by

(Hale et al., 2007). The study of van Duijne et al. (2005; as cited in Hale et al., 2007) revealed that some designers underestimate the significance of use trials because they think that these kind of studies do not always show unexpected behaviors, and they are hard to complete and very unreliable. Therefore designers think that studies with users are "unrewarding" (Bishop, 2000; as cited in Ward et al., 2003).

As another issue, Hale et al. (2007) explain that designers may fall short in terms of predicting and including use environment factors, which results in considerable problems which could be eliminated by design if use environment factors were considered. Designers define the limits of product usage and use environment too excessively, but in reality products end up in far different conditions than designers have envisioned (Fadier & De la Garza, 2006; Hale et al., 2007), and when the problems occur, users are charged with the responsibility of using the product outside the specified limits (Hale et al., 2007). Actually, it is also seen that users may really take responsibility; in a study reported by Tsao & Chan (2011), losing control of the product and inappropriate operation cause users to blame themselves and in return they feel embarrassed . Even though losing control of the product most of the time is a result of products' failure, they think that other users do not confront the same issues. Most of the time inappropriate operation is a result of misunderstanding the operation and function of the product, but users believe that this is caused by their own *carelessness* and *absentmindedness* (Tsao & Chan, 2011).

Moreover, Hale et al. (2007) explain that designers mostly undervalue the maintenance tasks of the products which results in risky and inefficient maintenance work for who is responsible for such acts. Also, designers have a tendency to restrain uses which may cause misuse and risks; on the contrary, users think that designed restrains are limiting and annoying to an extent that they find a way to remove or dodge around them; therefore instead of only providing restrains for such

incorrect uses, guiding and supporting correct use may help to overcome such acts of users (Hale et al., 2007).

As a result of the given attitudes towards studies with users in products' environment, misuse and use errors may occur because predictions of usage scenarios may not match with reality.

2.3.3 Contextual Factors of Home Use Medical Devices

Health care is a serious issue, and the devices used for delivering health care are equally important as procedures provided by health care professionals. Medical device field is a safety crucial area and eliminating risks and hazards is essential. Risks and hazards may be device related and use related and there is a difference between device related hazards and use related hazards. As stated by Kaye & Crowley (2000), device related hazards occur when the device or its components fail which are free from users' way of interaction with the device; on the other hand, use related hazards may be caused by the following reasons:

- Devices are used in ways that were not anticipated.
- Devices are used in ways that were anticipated, but inadequately controlled for.
- Device use requires physical, perceptual, or cognitive abilities that exceed those of the user.
- Device use is inconsistent with user's expectations or intuition about device operation.
- The use environment (...) affects device operation and this effect is not understood by the user.
- The user's physical, perceptual, or cognitive capacities are exceeded when using the device in a particular environment. (Kaye & Crowley, 2000, p. 7)

Therefore, use related hazards occur in relation to the users' characteristics, use environment and to applying adequate procedures to perform the required tasks. As stated by Story (2010) "some medical devices may not be safe for all users or use environments, but medical device manufacturers have a responsibility to recognize and mitigate hazards to the greatest extent possible" (p. 155) to provide safe and effective device use; since it is found out that, frequency of use related hazards is greatly more than device related hazards (Kaye & Crowley, 2000; Ward & Clarkson, 2004).

In addition to the challenge of mitigating hazards, home use medical devices have the following unique challenges which are stated in the guidance document *Medical device home use initiative* (FDA, 2010);

(1) *Caregiver knowledge* is important because some devices may be too complex for lay users. Also, there are many cases reporting that lay users may use a device which is designed for professional users and institutionalized settings. Lastly, lay users may not know how to respond if there is a device failure or malfunction.

(2) *Device usability* is essential especially in several cases. First of all, an old device without proper labeling and operation manual may find its way in the hand of lay users. Also, labeling of the device may be too complex and may confuse lay users, or the device manual may be hard to understand considering the fact that most of the time manuals are not written for lay users.

At the same time, from where the device is acquired may be another concern which puts device usability on doubt, even if the device has labeling and manual. Generally home use medical devices are prescribed by doctors who may not know or consider users' capabilities, lifestyle, home environment, etc. If the device is purchased from a distributor or a supplier, a particular model or brand may be presented as an only option without considering users and their environments requirements. Also, the internet is offering home use medical devices without demanding a prescription and without an interaction with the users. As a

consequence, without considering varying factors of users and their environment, the purchased device may not fulfill users' needs.

(3) *Environmental unpredictability* of home use medical devices' use environment is the latest challenge presented by FDA. If there is an unexpected event, home may not have hospitals' handling conditions (e.g. electricity shortage, acute complications). Also, there are many variables which may affect device performance (e.g. presence of children or pets, hygiene issues).

It can be observed that, most of the challenges and hazards of home use medical devices are influenced by contextual factors. Main contextual factors of home use medical devices are; the medical technology/device itself, user characteristic of patients as primary users, the physical and social environment of home, and in which ways the tasks, required for operating the device, are executed. These distinguishing factors require a special attention in terms of home use medical device usability. Since medical devices are developed with the concern of complying with regulations and standards, and since these regulatory systems are aiming at device safety, these factors are gaining more importance considering factors such as users' capabilities and disabilities, lack of medical intervention if there is an emergency case, uncontrolled and ambiguous physical and social environment of home.

In Figure 2.14, the relationship between the components of care at home is given in relation to the contextual factors surrounding users' capabilities and demands. Each component and their interaction between them affect efficiency, effectiveness and safety of the overall system (National Research Council, 2011). These components will be examined in further sections.

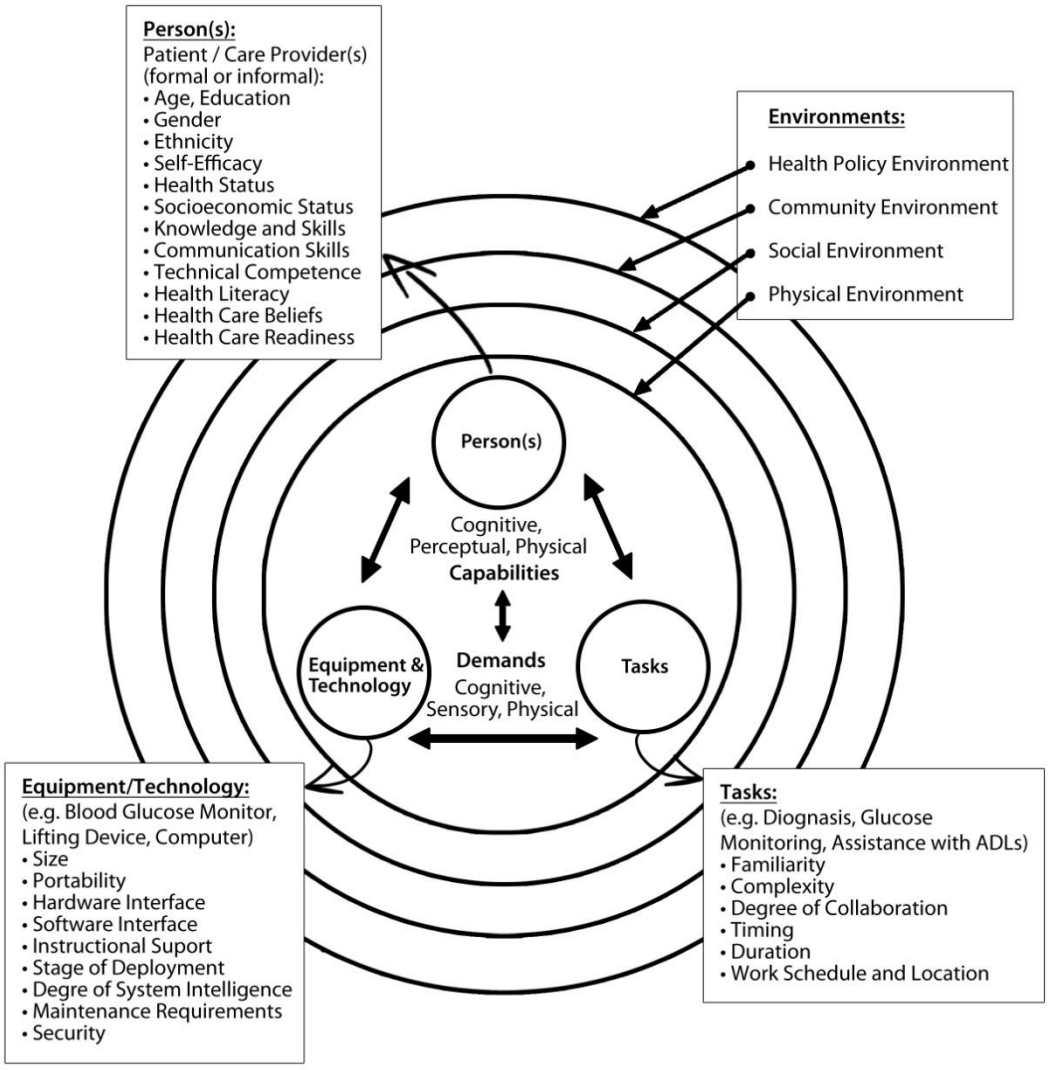

Figure 2.14 Components of home health care (reproduced from National Research Council, 2011, p. 62)

2.3.3.1 User Characteristics

Shah & Robinson (2008) defines a medical device user as "'a person who uses a medical device for the treatment and/or care of him- /her-self or someone else" (p. 6), and defines an end-user as "a person who is the ultimate beneficiary of the usage

of a medical device and who can also be the user of medical device if using the medical device for him- /her-self" (p. 6).

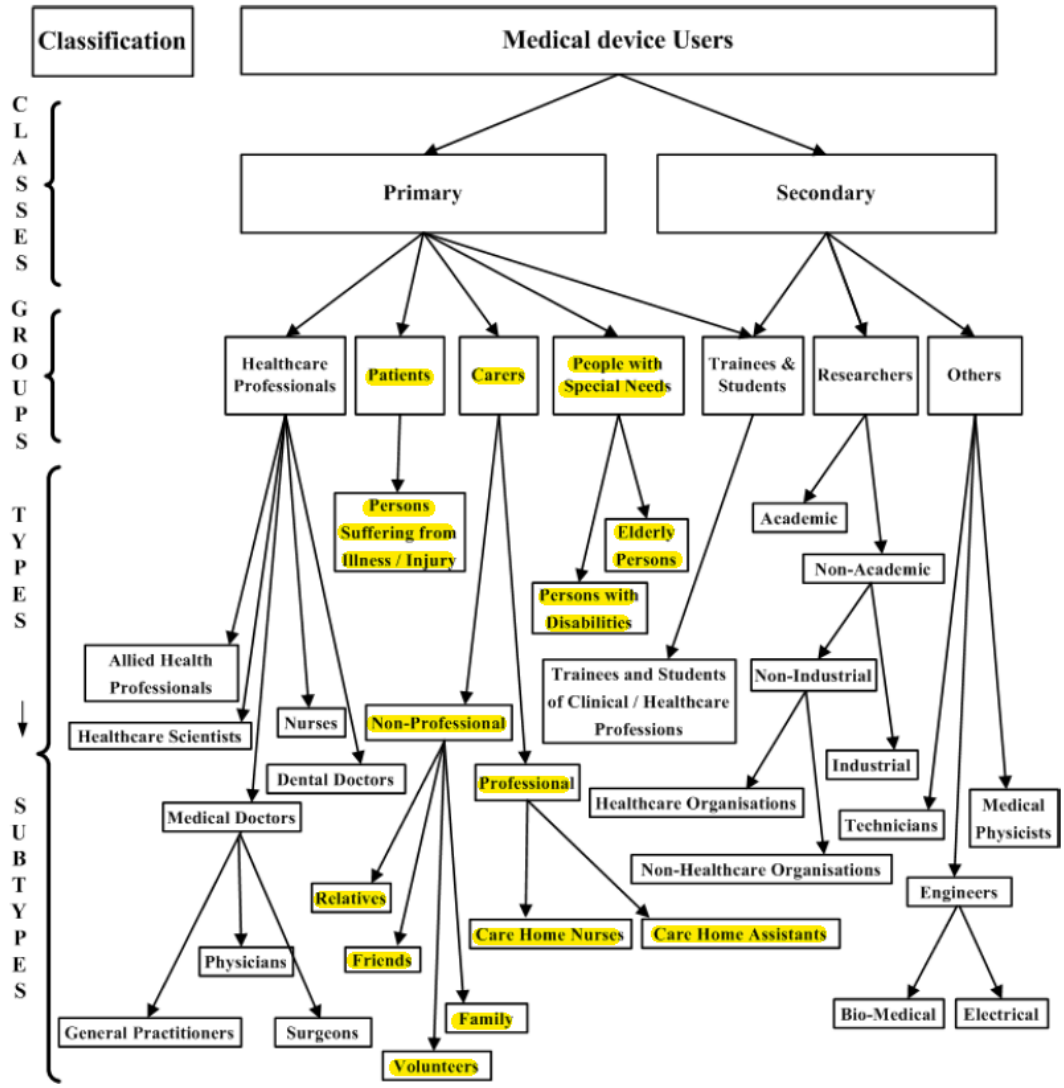

Figure 2.15 Users of medical devices (adapted from Shah & Robinson, 2008, p. 7)

In a hospital environment, if a doctor uses a product on a patient, the doctor becomes a user, and the patient becomes the end-user. But in the home care field,

patients are often both users and end-users. Medical device users were traditionally *ill-defined* as just clinicians and patients; but considering that medical devices are becoming widely used at home, this categorization has to be reconsidered in relation to where the medical device is being used and what type of medical device it is (Shah & Robinson, 2008). If this diversity is recognized at first and user is defined as human factors significance, meeting their needs and requirements will be easier due to knowing who these medical devices are designed for (Hignett as cited in Carayon & Friesdorf, 2006; National Research Council, 2011; Shah & Robinson, 2008).

Figure 2.15 illustrates the diversity of users of medical devices. Possible users of home use medical devices are highlighted. It can be observed that, users of home use medical devices fall under the primary user category, which includes health care professionals, patients and people with special needs themselves, and their professional or non-professional carers. Also family members of the patients are among the heterogeneous group of home use medical device users (Bitterman, 2008), since they may use the device to provide informal care for patient or they may experience device related issues while patient is using the device.

Home use medical device users may have diverse capabilities and disabilities. This diversity of user characteristics has a direct influence on safe and effective device usage. These characteristics, which should be taken into consideration while designing home use medical devices, are given by Story (2010) as:

- physical size, strength, and stamina;
- physical dexterity, flexibility, and coordination;
- sensory capabilities (i.e., vision, hearing, tactile sensitivity);
- cognitive abilities, including memory;
- comorbidities (i.e., multiple conditions or diseases);
- literacy and language skills;

- general health;
- mental and emotional state;
- level of education and training relative to the medical condition involved;
- general knowledge of similar types of devices;
- knowledge of and experience with the particular device;
- ability to learn and adapt to a new device; and
- willingness and motivation to use a new device. (p. 153)

For instance, according to FDA (2012), the interface of the device has to be visible in different lighting conditions for users with different visual capabilities. In order to match with different hearing abilities, audible signals have to be distinguishable from other noises, and handling the device has to be carefully taken into account considering the users with tactile impairments. Operating the device should not be overwhelming and should not cause anxiety considering patients' and caregivers' emotional sensibility; also, learnability and adaptability of the device operation is important because literacy levels and processing information time may vary for users with cognitive disabilities (FDA, 2012).

As discussed before, medical devices are getting more complex, with the application of advancements of the related technologies and due to the features they are required to have. According to Kossack et al. (2007), the challenge is to reduce the perceived complexity by designing for all user populations, whether it is the nursing workforce in a hospital setting, the elderly homecare patient, or globally divergent users located around the world. Especially given the nature of home use medical devices, small product size is a desired feature in order to travel with the device when it is needed. But as a result, all features embedded in a small body and interface may cause use problems. For instance a small display may be unsuitable for visually impaired patients (Charness, 2010) and a complex layout of an interface with several features may be unsuitable for computer illiterate users. Therefore,

perceived complexity and anthropometric suitability of these devices should be considered in relation to diverse user characteristics (Kossack et al., 2007).

As mentioned earlier in Section 2.1.3, elder population and chronic diseases are increasing; therefore most of the users are and will be elder users and users with disabilities that have special needs. Especially the decline in physical, visual, auditory and cognitive abilities of elders should be taken into consideration in order to match with their special needs (Bevan, Petrie, & Claridge, 2007). Also elders are not only patients; they may also be the ones who provide care. For instance, a caregiver with auditory impairment may not realize an indication of acute intervention if there is not a strong audible or visual signal.

Moreover, elders spend time in home more than other age groups (Cummins, Curtis, Diez-Roux, & Macintyre, 2007; Oswald & Wahl, 2005); and as a result, "the home acquires new meaning in old age because it serves to compensate for the reduced functional capacity of the aging individual, especially in very old age"(Oswald & Wahl, 2005, p. 25). Also users may not want to be seen as needy and incapable; for instance, "people want to believe they are competent and capable and they are happy to ignore the safety risks associated with not using assistive technology, for the sake of appearing competent" (Caust & Davis, 2006; as cited in Field & Jette, 2007, p. 211). Therefore, avoiding *the image of sickness or disability* is important in order to maintain the meaning of home for elders and to improve willingness and motivation as an added dimension to the usability of the device (Bitterman, 2008; Hirsch et al., 2000). Lastly, elders are not familiar with technology as much as other age groups and people with disabilities experience difficulties because of poor usability of technological devices; thus, accessibility and usability require additional consideration while designing devices for these user groups (Bevan et al., 2007).

Training the user is another issue considering that some home use medical devices require training of users and their caregivers. Users of home use medical devices

usually are not trained to maintain their devices and they may be unaware where to obtain needed supplies; thus this situation may result in serious problems (Story, 2010). Training (and sometimes re-training) the user is time and cost consuming and it is usually done by nurses or other health care professionals, which is seen as another burden on health care. On the other hand, well designed devices do not require much training and they encourage the user to use it, relieving the strain on the user, on the health care staff, and if taken as a whole, on the health care system (Story, 2010).

It is recommended that *Universal Design* principles should be employed in the design process to achieve safe and effective use of home use medical devices for all aforementioned users with diverse characteristics (Field & Jette, 2007; Hersh, 2010; Kossack et al., 2007; Pattison & Stedmon, 2006; Story, 2010). UCD provides framework to achieve Universal Design, which is a notion that focuses on the process of designing products and systems, usable to an extent that "widest possible range of users, particularly young and older people, and those with physical, sensory and cognitive limitations"(Bevan, Petrie, & Claridge, 2007, p. 2) can use the product or system without the need for special adaptation or specialized design (Bevan et al., 2007; Field & Jette, 2007). Universal design, Design for All and Inclusive Design are common terms which are used synonymously (Field & Jette, 2007). There are seven Universal Design principles which are offered by Centre for Universal Design, these principles are (Story, 2011);

- *Equitable use:* The design is useful and marketable to people with diverse abilities.
- *Flexibility in use:* The design accommodates a wide range of individual preferences and abilities.
- *Simple and intuitive:* Use of the design is easy to understand, regardless of the user's experience, knowledge, language skills, or current concentration level.

- *Perceptible information:* The design communicates necessary information effectively to the user, regardless of ambient conditions or the user's sensory abilities.
- *Tolerance for error:* The design minimizes hazards and the adverse consequences of accidental or unintended actions.
- *Low physical effort:* The design can be used efficiently and comfortably and with a minimum of fatigue.
- *Size and space for approach and use:* Appropriate size and space are provided for approach, each, manipulation, and use, regardless of the user's body size, posture, or mobility. (Chapter 4.3)

"On the demand side, consumers are generally unaware of universal design and of many potential interventions. Modifications can look industrial and institutional rather than residential. Consumers see devices and technologies in homes and react negatively to them" (Sanford, 2010, p. 50). Therefore, implementing universal design with a concern of enhancing users' attitudes and fitting in home environment is crucial as well as providing safe and effective product use. Universal design can be achieved by analyzing and evaluating user needs and especially for older users' specific requirements can be addressed by adopting universal design principles in the overall stages of product development. Universal Design is equally relevant for other consumer products as well as home use medical devices (Hersh, 2010). Home use medical devices differ from other products in terms of being safety crucial and being used by the widest possible range of users including elders and people with disabilities; thus, it is getting more important to adopt Universal Design principles.

2.3.3.2 Tasks and use errors

The primary task of a medical device user is caring for the patient by delivering high quality of care, and the secondary task of the user is operating the device by interacting with it (Kossack et al., 2007); therefore the design of medical devices should match with this goal of users.

Users who do not have experience with medical device operating or do not have medical training may experience errors more frequently; while performing a task, untrained users are prone to skip a step or to repeat a step they already carried out (National Research Council, 2011). Also, it is more likely that untrained users misinterpret visual and audible information and signals; consequently they are prone to making false judgments and taking false actions depending on misunderstood information; and even if they interpret the received information correctly, they may not comprehend implications of that information (Senders, 1994; as cited in National Research Council, 2011). Especially if the device has complex features, proper labeling becomes crucial; clear narrative instructions and step-by-step explaining figures are needed. It should be clearly understandable which buttons to press at what moment, to provide intuitive use (Lathan, Bogner, Hamilton, & Blanarovich, 1999). Also, undo or reset buttons would be helpful in order to allow the users to step back, therefore confusion and errors can be preventable and users may feel freedom and control over the device (Lathan et al., 1999).

As stated by Norman (1990), designers have a tendency to consider themselves as typical users, but in reality they are experts of the device they design. At the same time designers do not approach a product like a lay user may approach because of the nature of designers' close relationship with products (Margolin, 1997; Norman, 1990). This situation changes when it comes to medical devices. This time designers are neither an end-user nor an expert of the product because, they are "simply unfamiliar with the complicated tasks" that the technology helps to enable health care professionals (Lehoux, 2004). In addition to this, when these devices move into the homes, the tasks are not only unfamiliar to designers, but they are unfamiliar to the end-users of the device as well. Therefore, the importance of the effort that designers should put in becomes more apparent.

Problems with medical device use usually reveal themselves through use error and there are several ways to prevent use errors and their consequences; (1) good design

and choosing right device, (2) procedural and administrative problem solving, (3) user education and training (National Research Council, 2011). The best solution of preventing use error is through design because, procedural and administrative solutions do not exist in the homes, and user education and training have a tendency to fail or gradually vanish due to irregularly changing cognitive abilities (as a result of disease progression, pain drugs, etc) of patients (National Research Council, 2011).

Maintenance tasks of the home use medical devices are often performed by users. In order to provide safe and reliable operation by proper maintenance of the device, the following features should be considered: Adequate labeling and coding; easily reachable and controllable screws and components; designing components and choosing materials for easy cleaning; parts that are easily locatable visually and by touch; providing self-diagnostic feature; easily understandable component arrangements; choosing durable materials which does not degrade user interface; providing ease of maintenance with easy-to-find tools (Sawyer & CDRH Work Group, 1997).

2.3.3.3 Environmental characteristics

It may be assumed that, problems of home use medical devices may be similar to the problems of devices that are used in institutions, but home is more unpredictable and hard to intervene in case of a problem. Some medical devices may be hard to use even for doctors and nurses in hospital conditions and in home environment, these conditions may become more difficult due to conditions like design of the house and its decoration elements, electrical instability, climate, absence of medical assistance, contaminants, children, pets, and so on. The home environment has a wide range of such kind of variables, and most of the time the activities in the home are led by these ambiguous physical and social factors.

FDA (2012) outlines environmental conditions that should be taken into account while designing a home use medical device, which are listed as; location, physical

location, contaminants, water supply, fluid exposure, temperature, dampness and humidity, atmospheric pressure changes, air flow, childproofing, tampering, travel and international use. First of all, intended use *location* of the home use device and effects of these places on the users and devices have to be considered. Electromagnetic interference possibility should be eliminated. The *physical location* of the home use medical device should allow portability inside, in and out of the environment. Crowded environments may pose threats of bumping the device around, entangling with other objects and obstructing device usage and movement. There are *contaminants* in all environments; as very environment is not sterile the device should be designed in order to not being effected by fluids and air particles. The *water supply* that provides water for cleaning and operating the home use medical device should be specified. *Fluid exposure* is another concern, and the devices should be resistant to fluid spills. The home use medical device should be resistant to the variable factors of *temperature, dampness and humidity, atmospheric pressure changes* and *air flow* in order to operate effectively. *Childproofing* is also a concern for the design of these devices. The devices should be designed with the consideration that children may remove or swallow small components, therefore detachable parts and such, should be kept to a minimum, or other precautions should be taken to avoid children interfering with the operation. Home use devices should be resistant to *tampering*, including intentional or non-intentional misuse. In some cases, users may have to carry their portable devices while *travelling*, and this may include *international use* as well; therefore, adequate labeling about the required voltage rate should be applied. Also, it should be noted that users' on-body devices may be exposed to x-ray because of security screening, so the device should not be interfered by screening systems.

According to the device type, some arrangements might be required to be made in the home. According to the design of the home, stairs, flooring, carpets and door dimensions may make it hard to move the devices. In case of elders extra grips and handrails might be helpful; especially when they are walking with their device

attached to them. Electrical outlets, heating system and lighting conditions should be reconsidered according to the device type.

Aesthetical concerns of fitting in the style of the home decoration and users that are being affected by fashion and design trends are among the challenges that the home constitutes (Bitterman, 2008). Even though medical devices may be seen as one of the most distant product groups to fashion and decoration, these devices may be approached just like any other consumer products in the home. Also, aesthetics adds a positive dimension to the usability, which motivates users and promotes device usage (Forlizzi, Hirsch, Hyder, & Goetz, 2001; Hirsch et al., 2000; Norman, 2004). When it comes to home use medical devices, this motivation may have a great impact since, as Forlizzi et al. (2001) explain, the user's self-esteem and emotional outlook may be affected when medical devices used at home look as if they are meant to be used in a hospital. Therefore, fitting into the home environment and being aesthetically pleasing should also be considered.

In the case of travelling, the home use medical device use is not limited to the home, users may take their devices to their workplace, or use while travelling. In that situation, ambiguity of the environment increases drastically. Therefore, especially devices which are used on-body or which need to be used outside the home should be more durable in case of fall, bumping and fluid exposure. Also portability, therefore weight and size, matter much more. Lastly, users may want to use their devices in discreet or without feeling odd, for that reason the device appearance, casing and size should be paid extra attention to.

Social environment is another factor variable that has to be considered when it comes to home use medical devices. Social environment is referred to the social circle of the user that the home use medical device is used among, which may consist of family members, guests, neighbors, formal/informal caregivers, colleagues, classmates, and so on.

The social environment might take part in the usage of home use medical device actively, as a caregiver. As stated before, family members, especially women of families are still primary source of care. Therefore, sometimes the social environment of a device user might be a user of the device too. At this point every factor might be effective on the social environment as well.

To point out possible hazards, the following factors are listed by FDA (2011b) which are related to social environment;

> • Unauthorized users, such as children, might be present and could hurt themselves (e.g., playing with a syringe), damage the device (e.g., chewing on or misconnecting the tubing), or change device settings (which might not be noticed by the operator before using the device the next time).
>
> • Other individuals and activities in the vicinity may cause distractions. (p. 13)

In addition to hazardous factors, cultural beliefs, values and attitudes of surrounding society might have effect on home use medical device usage. Especially in the case of *familism*, "the subordination of individual interests to family concerns" (p. 55), altogether decisions may be made regarding adopting or refusing a device usage (National Research Council, 2010). Also, family members may have an attitude towards having a medical device in their home, due to their unwillingness to turn their home into a hospital according to their perceptions (National Research Council, 2011). The social circle of the home use medical device user may not want to change their life style (changing meal and sleep times, not having guests, obligation of rearrangements in the decoration of the home, not leaving home in particular hours, etc.) if the device requires a change. These situations may affect the medical device user negatively, to the extent of abandoning device usage.

Compared to home environment, hospital environment may pose some problems for patients as well, especially for elders. Some difficulties are stated by Rabkin (1989) as;

(1) Hospital beds are at different height than patients own beds and floors are slippery due to being hygienic; therefore patients with visual impairments may experience injuries due to falls;

(2) Due to unfamiliarity of hospital environment converging with new medications and different diet, patients may experience confusion. Also, unfamiliar meal schedules and salt restricted unfamiliar meals may result in anorexia;

(3) Sleep cycle and bowel patterns may be disturbed, and loosing track of day and night cycle may occur;

(4) Roommates and their visiting relatives may be disturbing;

(5) Immobile hospital beds may pose a threat on blood circle and the mat may cause bed sores;

(6) Patients, especially elders may experience "damaged sense of their own identity, ability, and self-esteem" which may lead to depression due to being in "a passive and regressed role" and being among young and fast health care team (p. 83);

(7) Patients' opinions and concerns are often ignored and considered unreasonable in order to keep "the pace of life in hospital" (p. 83).

Therefore, considering the difficulties of the hospital environment, the home environment offers patients to manage and to prevent their illnesses and disabilities in a less time consuming, and less stressful way within the comfort and familiarity of their homes. But the crucial point is that, the devices that are used in home environment should be designed with the consideration of challenges that the home environment causes.

According to Buurman (1997), “usually with consumer products there are neither clearly specified users, goals, nor contexts of use.” (p. 1161). Since home use medical devices have started to being seen as a consumer product by time, it should be recognized that there are sector specific challenges while adopting consumer product trends in the design of medical devices (Kossack et al., 2007). In addition to the sector specific challenges (which have been initially investigated in section 2.2), the importance of contextual factors becomes more apparent when designing home use medical devices; therefore these devices should not be considered as simple consumer products because the safety risks will remain as long as they are ‘medical’ devices.

Not considering contextual factors in the design of home use medical devices may have serious consequences. It is reported that, 19.000 adverse events related with medical devices took place in the home environment between the period of 1997 and 2009 (FDA, 2010). Some examples of these events, which are provided by FDA (2010), are listed below to have a better understanding on the significance of the subject;

Inadequate Information or Training for Users:

- According to a report, a user bought a new infusion pump which has a different delivery of medication than his previous device. The patient programmed the pump as he used to do before, thinking that it looks similar with his previous device and consequently he overdosed himself.
- A cardiac monitor patient was getting instructions on the phone because she received her device by mail. When she applied the electrodes on her chest she felt a sensation of skin burn. She was directed by the instructor to use other electrodes in the box and after several tries, she lost some skin by pulling electrodes from her body in the last attempt.

Absence or Failure of Safety Features:

- An infant that was tied to a ventilator is reported dead because the ventilator's alarm did not ring when the device stopped cycling on its own.

Lack of Consideration of Users' Physical Capabilities:

- A home dialysis patient was lost caused by loss of blood, because she was unable to clamp her catheter by herself after disconnecting from the device.

Environmental Hazards:

- A father with an implantable defibrillator was playing with her son, and whenever the son drove his remote-controlled car over his chest, the device beeped.
- A mother lost her child because she did not hear her child's ventilator's disconnecting alarm because of ambient noises (e.g. television) in the home.
- A home dialysis patient moved her cat's box into her bedroom. Even though she did not let her cat near when she was on dialysis, cat fur got into the tubing and caused abdominal infection.

Throughout Section 2.3 usability and context of use related concerns of home use medical devices are investigated. Human factors studies and usability concerns are explored initially. It is found evident that, context of use has strong influence on usability and usability can be enhanced by adopting UCD in the process of product development which considers product use with users and their experiences. Also, understanding and identifying context of use is a key activity of user centered design which provides data for design decisions.

According to Norman (1999) UCD is " a process of product development that starts with user's needs rather than with technology" (p.186) but on the other hand "medical devices are frequently technology driven rather than resulting from an identified un-met need" (Martin et al., 2008, p 275). Technological developments have strong effect on the medical device development and "extensive use of technology puts large demands on the operators' capabilities to handle the

equipment in a proper way" (Osvalder & Bligård, 2007, p. 3). The results of this situation may create serious problems for patients; for that reason designing medical devices with high usability is essential, and this can be achieved by UCD. Also, adopting universal design principles in product development may provide safe and effective product use for the diverse user group of medical devices. However, medical device manufacturers have difficulties of implementing UCD and human factors studies in medical device development processes, and some of the manufacturers do not find any benefits of implementing them (Money et al., 2011; Vincent & Blandford, 2011).

When medical devices migrate from the hands of professionals to the hands of lay users with diverse characteristics, adopting UCD and Universal Design principles becomes more important since nearly every context of use aspects changes and as stated before, any change that is done in the contextual factors affects device usability. Home use medical devices with poor usability may result in use errors and these errors may have serious consequences. Also, designers' attitudes towards studies with users in products' environment may cause misuse and use errors, since predictions of usage scenarios may not match with reality.

Human factors field concentrates on interaction between people and products, and a successful interaction can be achieved by matching users with the related demands of the elements of the overall system; if the demands of the system exceeds user's capabilities, it is not possible to perform tasks (National Research Council, 2011). To prevent this situation, analysis of users, tasks, technologies, and environmental context is the most appropriate solution.

CHAPTER 3

FIELD STUDY

This chapter presents the conducted field study in order to explore the main concern of this thesis, which is, exploring the contextual factors that have effects on the use of home use medical devices and on the users. In-depth interviews have been conducted with a selection of users in order to acquire their experiences and opinions on the medical device use at home and the contextual factors that play a role.

3.1 Introduction to Field Study

3.1.1 Research Questions

To have an understanding on the subject, a field study is conducted in order to gather information on the following main research question:

- What are the contextual factors that have an effect on the use of home use CPAP devices?

In relation to this question, the following sub-questions are explored:

- In what ways are users affected by these contextual factors?
- Which factors play a positive role on the use of home use CPAP devices?
- Which problems do users encounter while using a home use CPAP device?
- How do users handle problems regarding use error and maintenance?
- How do users choose their home use medical devices?

3.1.2 Selection of the Medical Device for the Study

Continuous Positive Airway Pressure (CPAP) devices, previously introduced in Section 1.2, are used by individuals who have breathing disorders. In order to achieve improvements in conditions of patients with breathing disorders, it is crucial to have a long-term (and sometimes life-long) adherence to CPAP usage.

CPAP devices differ from other commonly used, over the counter home use medical devices due to absolute necessity of device adherence. Also CPAP devices are *home use* medical devices (with the exception of usage during travelling), since they are required to be used in the bedrooms of the users.

Medical device developers and designers have a limited access to the end-users and context of use (Martin et al., 2008). Given the nature of the usage environment of CPAP devices, i.e. users' bedrooms, it is already challenging to have an access to the context of use with the aim of gathering on-site information. Due to the mentioned challenges of vital need for an absolute commitment to CPAP usage and specific difficulty to reach CPAP devices' context of use, this field study is carried out with users of CPAP devices in their usage environment.

3.1.3 Selection of the Methodology for the Study

The field study was structured in order to obtain qualitative in-depth information and it was conducted face-to face by the author, in the form of in-depth interviews. In-depth interview method is chosen because it enables and encourages participants to talk about their personal experiences and opinions when they are considered as expert, and the interviewer approaches the interviewee with the motivation of the desire to learn everything that s/he expresses on the research subject (Milena, Dainora, & Alin, 2008). Therefore, in order to gather detailed and deeper understanding on the subject, in-depth interview method was chosen.

3.1.4 The Interview Questions

The questions of the semi-structured interviews were formed with the aim of gathering significant aspects of CPAP device usage of participants in relation to their different home surroundings. The context analysis guide, which was prepared by Thomas & Bevan (1996), is considered while developing the interview questions, in order to acquire information within the frame of context of use factors.

Structured context analysis of Thomas and Bevan (1996) initially identifies the description and specification of the target product. After that, it is recommended to investigate the product in terms of the following titles: Users, Tasks, Organizational Environment, Physical Environment and Technical Environment (Appendix B). Users are identified in terms of types (primary and secondary) and their characteristics. Tasks are identified to list what kinds of tasks are carried out to evaluate during the analysis. Organizational Environment consists of organizational and social circle conditions that the users are affected. Technical Environment identifies hardware, software and network conditions of the analysis. Lastly, Physical Environment consists of the physical location and characteristics of the surroundings of the product. It should be noted that, Thomas and Bevan suggest their proposed context analysis to be done in *context meetings* which are recommended to be carried out with different stakeholders that take part in a product's development and use, such as project managers, designers, user representatives, auditing authorities and other potentially related groups. A study carried out by Karapars (2004) for her master's thesis investigates the contextual factors using the same structure that Thomas and Bevan offers. She investigates the contextual factors of washing machines in terms of usability, and compares two different socio-economic groups while doing so, which results in finding relationships between socio economic factors and usability problems in relation to use context.

In this thesis, Thomas and Bevan's context analysis guide constitutes a framework for the study questions; on the other hand, the analysis of the study was carried out as a separate thematic analysis. The reason behind this decision was that, the context analysis of Thomas and Bevan is proposed for the monitoring of the context of use factors of a product. On the other hand, this study aims at gathering information on the context of use factors affecting usability, according to the users' statements. Therefore, although the interview questions are prepared using the themes that Thomas and Bevan offers as a result of his context analyses as a guideline, the interview is not structured as a report of contextual factors. These factors are questioned by semi-structured interviews in order to derive the contextual factors from the users with their own statements. The findings of the study are a thematic analysis of the gathered statements of the participants.

3.1.5 Forming the Sample Group

This study is performed within the restriction of finding participants who would allow the interviewer in their private use environment (i.e. bedroom), in addition to being conducted independent from institutions or funding. CPAP device is not a commonly used home use medical device and its usage environment requires users' hardly acquired permission to conduct the study in their private area of their homes. The author tried to reach users through her own personal contacts, who were CPAP device manufacturers and medical device distributors. The two main CPAP manufacturers in Ankara, Turkey, reported that they are not in touch with their customers because they put their devices on market through different distributors. Also their technical service departments were not keeping record of their customers' contact information. This situation may be an indication of how much device manufacturers are disconnected from their end-users. At the same time, strict patient information privacy policies of hospitals were among restrictions for reaching users through doctors and institutions. Finally, a device distributor agreed to share a list of customer information but only five of the contacted users (four male -one of which was omitted, and one female) agreed to participate in the study,

mostly because nearly all of the contacted users were male, and males were not available during the daytime. The rest of the participants were reached through the author's personal contacts.

The other limitation of the study is gender imbalance of the sample size. Males have higher risk of having sleep apnea than females; therefore most of the CPAP users are male in general. This situation had a reflection on the sample group.

3.2 Interviews: Conducting the Field Study

3.2.1 Sample Group

The interviews were conducted with ten participants. Eight interviews were used for the study, after omitting two interviews. The reasons for omitting two of the interviews were that the one participant was a CPAP manufacturer employee and he approached the interview in a product presentation manner which was heavily biased; the other participant met with the interviewer in his work environment, even though he said the address was of his home.

The sample group was chosen among the users of a prescribed CPAP device. Chosen participants were users of a CPAP device for at least 1 month and at most 10 years. Sleep apnea is the main reason of using a CPAP device and males have higher risk of having sleep apnea than females (Kapsimalis & Kryger, 2002; Walker, Durazo-Arvizu, Wachter, & Gopalsami, 2001); consequently, the number of male participants were more than female participants in this study. Six participants were male and two were female. Also, even though all age groups may be in need of a CPAP device, most common reason of CPAP usage is decrease in muscle tone of upper airway after middle age; therefore the age range of the sample group is between 45 and 67. All of the participants were married. Age, gender, occupation, self reported computer knowledge level, and CPAP use duration of the participants are presented in Table 3.1. Lastly, the study was conducted with the participants' own devices.

Table 3.1: Sample Group

Participant Number	Age	Gender	Occupation	Computer knowledge	CPAP user for
P1	45	Male	Hospital Personnel	Moderate	1 month actively (on and off for 1 year)
P2	57	Male	Retired Manufacturer	High	10 years
P3	55	Female	Housewife	Low	2 months
P4	48	Male	Self-employed	Moderate	3 months
P5	57	Female	Retired Worker	Low	1 month
P6	67	Male	Retired Banker	Moderate	10 months
P7	62	Male	Self-employed	High	1 year and 6 months
P8	56	Male	Retired Worker	Moderate	7 months

3.2.2 Conducting the Interviews

Interviews took place in the homes of the participants and in front of their CPAP device. Each interview was initiated with a small talk about the participant's sleep disorder history, and is followed by informing the participants about the aim of the research with the help of a consent form which consists of introduction to the study, consent request and interview questions (Appendix C). After signed by participant, one copy of the consent form was given to the participant with the contact information of the interviewer. The interview's question order and follow-up questions varied to meet the participants' understanding and answers, but the

interviewer followed a semi-structured guide in general with the help of a sheet that is prepared for reminding the topics of grouped questions (Appendix D). So, all of the interviews were not in an exact form and questions were not asked in the same order, but interviewer checked out the answered question topics while the interviews were being carried out. As a result, interviews were conducted in an informal conversation manner, which were led by the participants, under the guidance of the interviewer. Also, participants were requested to demonstrate how they use their CPAP device before going to sleep as a part of the interview.

'User types' are the various users who are involved in the usage of a product; consist of primary users and indirect users (secondary users). The primary user is defined as the one who uses the device, and the indirect users involve the individuals in the primary user's social environment who affect and who are affected by device usage.

In this study, the primary users were the participants themselves. Indirect users were stated by participants as; spouses (all participants), children (P1, P4, P7, P8), grandchildren (P3, P5), and houseguests (P3, P4, P7). In general, the main idea was that, spouses are indirect users in the first place because they are considered as being affected by users' device usage. These are explained in further sections.

Lastly, the spouses of all of the six male participants were interviewed as well, after (P2, P4, P7, P8) or during (P1, P6) the interviews with the CPAP users themselves. Wives of P1 and P6 attended the last minutes of the interviews while they were offering tea as an act of traditional Turkish hospitality, and wives of other participants are interviewed during the tea-talks in the living rooms. Spouses were mostly asked about their thoughts about CPAP devices in general, if they are affected by them, and what have changed after their arrival in their house. Husbands of two female participants were absent at the time of interviews due to their working hours.

3.2.3 Data Collection Method and Tools

The interviews have lasted approximately an hour or a little shorter. During interviews, collection of the data was carried out by tape recording the sessions. Also, the interviewer took notes of any observational remarks which could not be documented by voice recording. All of the participants were informed about voice recording and their consent was obtained. Also, the environment where CPAP device stands was photographed by a digital camera with participants' permission. Seven out of eight participants gave permission to photograph only the place where the device stands, without the whole scene of their bedrooms, while one participant did not give permission to take a photograph.

3.2.4 Data Analysis

Thematic analysis is used for identifying, organizing, analyzing, and later on describing and reporting patterns and themes which are sought for and found in a rich set of data, which helps to interpret different aspects of a research topic (Braun & Clarke, 2006). It is indicated that thematic analysis requires the researcher's effort in the identification of the patterns and themes that reveal from the data. Since this study consists of in-depth interviews with eight participants, which provides a vast amount of information gathered from a small sample group, the qualitative form of thematic analysis is chosen for analyzing the gathered data, with the help of the systematic approach of Braun and Clarke (2006).

After each interview, the collected verbal data recorded during sessions were transcribed word by word initially. The transcribed data were prepared as separate excel sheets per participant, under the interview topics and questions, with the intention of preparing *data items*. Later on, each participant's answers were segmented according to statements as *data extracts*, without losing the track of the subject they are talking about. After more familiarizing with the data extracts by thorough understanding, they were assessed in order to identify recurring and differentiating statements (potential patterns) with the specific questions in mind

about the subject of context of use. Each potential pattern was separated from the other by color coded highlighting the data extracts; through the entire excel sheets, which later on provided a basis for *codes*. After going through each participant's sheet with the same method, these coded data per participants were collated together under the separate code sheets (each code was collated separately by gathering each participant's data extracts under the same code). After reorganizing and regrouping related codes together in a meaningful way, these codes were sorted by their relations and relevancy. Lastly, these sorted codes were combined under *themes* and sometimes *sub-themes* "to capture the contours of coded data" (Braun & Clarke, 2006, p. 91). After some refinements, thematic maps were prepared in digital tables in a meaningful way, in order to present findings of the conducted study (Appendix E). Also, some strong explanatory expressions of participants were kept and presented in the findings as verbatim in order to provide direct examples from the interviews.

3.3 Findings of the Field Study

As a result of the analysis, it was seen that participants mentioned various factors related to the usage of their CPAP home medical device that could be grouped under eight main themes. The themes are formed according to participants' own reporting and expressions. These are: Factors Related to User Characteristics, Problems, Motivating Factors, Tasks, Storage & Environment, Assistance, Factors Affecting Purchase Decisions, and Preferences for a new CPAP device. Appendix F presents the themes and subthemes obtained as a result of this analysis. In the following sections, results of the analysis of the study are presented.

3.3.1 Factors Related to User Characteristics

Information related with the user characteristics such as age and gender, training, skills, limitations were gathered with the aim of identifying whether they are related with the CPAP device usage as a significant factor. At the same time, feelings and thoughts in the adaptation phase and attitudes towards the CPAP devices were

found related with the user characteristics (Figure 3.1). In this section these factors are presented.

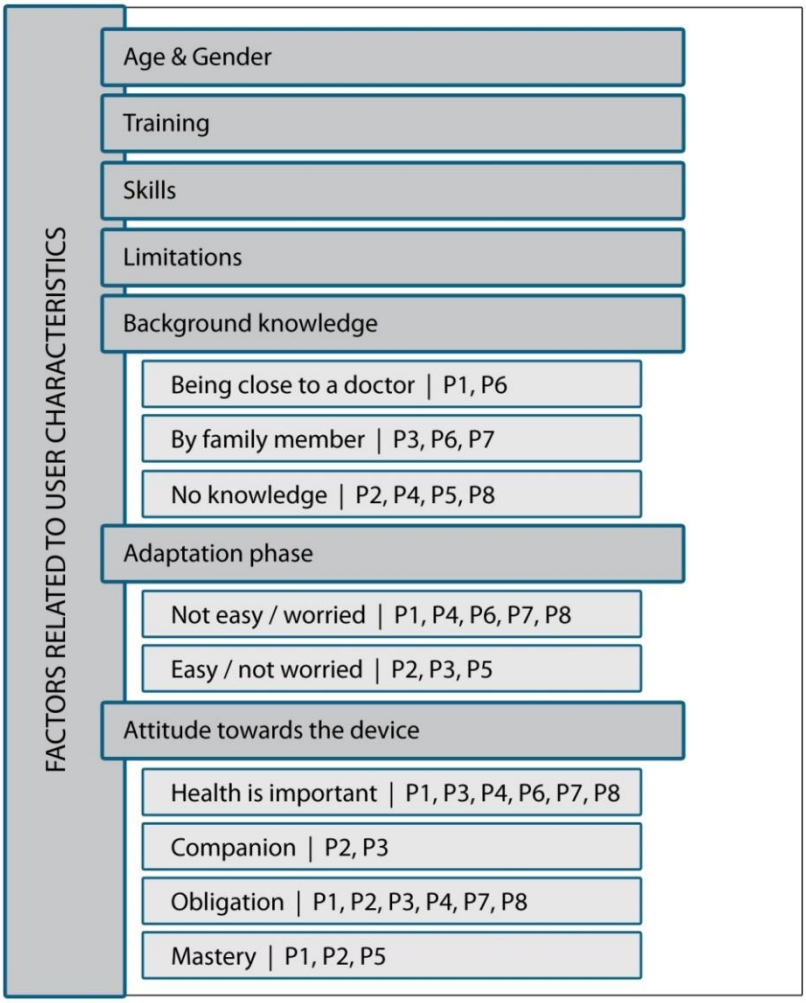

Figure 3.1 Factors Related to User Characteristics

3.3.1.1 Age and gender

As it can be seen in Table 3.1, the age range of the participants was between 45 and 67. At the same time, there were six male and two female participants. No age or gender related issues are mentioned by participants.

To point out gender related differences among the data, females were very relieved that they are not snoring anymore; therefore they were much more positive about their device usage. On the other hand, males were much more concerned with the possibility of disturbing their wives due to their device usage. Also, even though there were male participants who have grandchildren as well, only female participants stated their concerns about their grandchildren in relation to their CPAP device usage (these concerns are explained in Section 3.3.2.4).

3.3.1.2 Training

All of the participants stated that they are learned to use the device by their distributors. Also, three of them (P5, P6, P8) are trained in the sleep laboratory by the hospital personnel as well.

Seven of the participants (except P5) stated that, the distributor adjusted their device and showed only how to turn on and turn off it by its power button. They said that the distributor did not teach what other buttons do and what information the display shows. Also, P1, P3 and P8 were really afraid of touching other buttons to not to change its settings.

Only three of the participants (P1, P5, and P7) have read the user manual and only P5 stated that she read the manual carefully. Maybe that is why only P5 was confident when pressing device buttons, without the fear of changing its adjusted settings. Also, P6 stated that he did not read the user manual, because there was no need after he was trained.

According to P5, the user manual ‘book’, which has vast amount of languages, is more complicated and hard to understand. But the only-Turkish user manual ‘booklet’ is more understandable because it is simpler (actually the printed information was same, but there were many languages). Also P5 was keeping user manual near the device because if she forgets something, she looks at it again.

3.3.1.3 Skills

All of the participants stated that, they never used such kind of medical device before their CPAP devices. Six participants reported that they are in good terms with computers and such technologies (Table 3.1). On the other hand, none of them knew their devices’ features and what does the display shows, except the power button. Both of the two females stated that they have any knowledge about such kind of technologies, but P5 was the only participant who stated to know every device features and display information correctly, because she said that she had read user manual very carefully.

All of the participants were Turkish-speaking. All of the CPAP devices’ display information was in English; however the user manuals were in Turkish. That may be among the reasons why seven of the participants (except P5) do not care to look on display.

3.3.1.4 Limitations

Two of the participants (P1 and P7) stated that they are prone to have lung diseases because P1 had pneumonia before, and P7 has chronic bronchitis. For that reason these two participants were worried that the cold air that has been blown to their lungs by the device may cause their lungs to catch cold. Also, both of them stated that, the temperature of the bedroom affects how much they are disturbed with the coldness of the air pressure that the device produces. P1 stated that their bedroom does not have heating because only their living room has stove; that is why he is more pleased with Auto-CPAP, which does not give high pressure every time. P7

stated that, he keeps his bedroom more heated because of the same reason; he does not want to feel colder in addition to device's cold air pressure.

Three of the participants (P5, P6, and P7) were using eye glasses because of near sight impairment. Except P5, none of the participants were checking display of the device, so they did not experience any effect of their eye impairment. But P5 stated that, she keeps her glasses near her bed now, because she cannot see display of the device (in addition she keeps a little torch near, to see the display).

One participant (P5) stated that she has diabetes and therefore she wakes up frequently and drinks water. As a result, her husband gets disturbed by the sudden noise of the air pressure when she takes of the mask, so he has been sleeping in another room since the device arrived at their home.

P3 stated that she is a very 'hygienic person', so she never leaves her device outside its bag to keep it hygienic, when it is not used. Also, the possibility of her grandchildren playing with the device was among the reasons of keeping the device hidden in its bag.

None of the participants had any other physical or mental limitations which may affect the CPAP device usage.

3.3.1.5 Background knowledge

Table 3.2: Background knowledge

No knowledge	P2, P4, P5, P8
Being close to a doctor	P1, P6
By family member	P3, P6, P7

Four of the participants (P2, P4, P5, and P8) had no knowledge of CPAP devices before they were prescribed for CPAP therapy. P2 stated that, he was among the first users of a CPAP device, such that, he had hard times in airports, explaining the device to the security staff. The other three participants were introduced to their devices by their doctors.

Four of the participants stated that they have heard of CPAP device before they used it. It is found out that, being close to a doctor and family members who are using a CPAP device provides background information about CPAP therapy. One of the participants stated that (P7), he had seen a relative's device before and that relative has told that CPAP devices are hard to use; therefore, he had a prejudice that it will be hard to use his device too. He also stated that after using the device, it was not that scary and weird as much as he imagined. The others users stated that, that background knowledge helped them to spot their own need for such kind of device.

3.3.1.6 Adaptation phase

Five of the participants (P1, P4, P6, P7, and P8) have experienced difficulties during the first nights of their device usage. The main concerns were feeling uncomfortable because of the mask, being worried and demoralized about getting used to the full-night adherence. All of these participants stated that they got used to their devices because they feel the difference in their quality of sleep and health.

Table 3.3: Adaptation phase

Not easy/worried	P1, P4, P6, P7, P8
Easy/not worried	P2, P3, P5

3.3.1.7 Attitude towards the device

All of the participants had a positive attitude towards their device. All of them stated that, after using it regularly, they recognized the improvements in their health and in their sleep quality; therefore all of them were favoring their devices.

Table 3.4: Attitude towards the Device

Health is important	P1, P3, P4, P6, P7, P8
Companion	P2, P3
Obligation	P1, P2, P3, P4, P7, P8
Mastery	P1, P2, P5

There were four main attitudes towards the CPAP usage;

Health is important: All of the participants stated that health is important more than anything, therefore they got used to their devices. *"What is more important than health?"* was the common expression among the participants.

Companion: P2 and P3 had a *buddy* attitude towards their devices. P2 referred to the device as his friend, and P3 referred to the device as her baby.

> *"(...) I say that this device is my friend; this is my motto (...)"* **(P2)**
>
> *"(...) I call this [device] my little baby, I bundle this up thinking like that."* **(P3)**.

Obligation: Six of the participants expressed that they feel obliged to use their devices, but they were also positive in terms of their improving health.

"(...) Even if I give you money for putting this on, I know that you won't do it. Only someone who is lacking would use this." **(P1)**

"(...) You can't say I couldn't use it and gave up. You are going to choose using it or dying" **(P2)**.

Mastery: Three of the participants (P1, P2, and P5) stated that they became experts of their device by time. P2 was using a CPAP device for 10 years and he stated that he is among the first users of a CPAP device. P5 was using it for one month but she was self-confident that she mastered the device by reading its user manual carefully. Also P1 stated that he knew CPAP devices since 2007, so he considered himself as an expert too.

"(...) I do not feel the need to see my doctor; I just call my distributor if necessary... 10 years, I became master of this device, master (...)" **(P2)**

3.3.2 Problems

The brands of the CPAP devices of the participants are presented in Table 3.5. It should be noted that, even if there are same brands of devices, models of the same brands are varied. Three of the participants were using CPAP devices (P2, P7, P8), and the rest of them were using automated CPAP devices. All of the participants were thinking that automated CPAP devices are better than CPAP devices. The participants using CPAP devices that are not automated, stated that they would like to buy an automated one, but it is too late now, because they are too expensive and their health insurance provided them these non-automated ones.

Only two participants (P2, P5) were using a heated humidifier, which they bought themselves. The rest of the participants mentioned that they would like to have a humidifier to heat the cold air pressure and to not have a dry mouth and throat. But since National Health Insurance does not cover humidifiers, they hesitate to buy one.

Table 3.5: The Brands of the CPAP Devices

P No	**Brand of Device** (with differing models)	**Brand of Mask** (with differing models)	Device Type	Humidifer
P1	Weinmann	Weinmann	Auto-CPAP	None
P2	DeVilbiss and Weinmann	Weinmann	CPAP	Heated Humidifier
P3	BMC Medical	Weinmann	Auto-CPAP	None
P4	Weinmann	Weinmann	Auto-CPAP	None
P5	Weinmann	Weinmann	Auto-CPAP	Heated Humidifier
P6	Philips	Philips	Auto-CPAP	None
P7	Philips	Philips	CPAP	None
P8	Weinmann	Weinmann	CPAP	None

None of the displays of devices had a backlight, and none of the displays were viewable despite looking from the top, 90 degrees directly. The device of P7 did not have a display.

None of the devices have an audible signal, according to users. Also, all of the devices had same labeled icons for power, ramp, humidification level, up/down and information buttons, even though there were different models and brands of devices.

According to the participants, they experience some problems related with their CPAP usage. These problems are clustered significantly under the following sub-themes: Problems related with the device, Problems related with the mask, Problems related with the social environment, Problems related with the physical environment, Appearance of the device and its mask, Problems related to health, Problems related to lack of knowledge and training, and Problems related to maintenance.

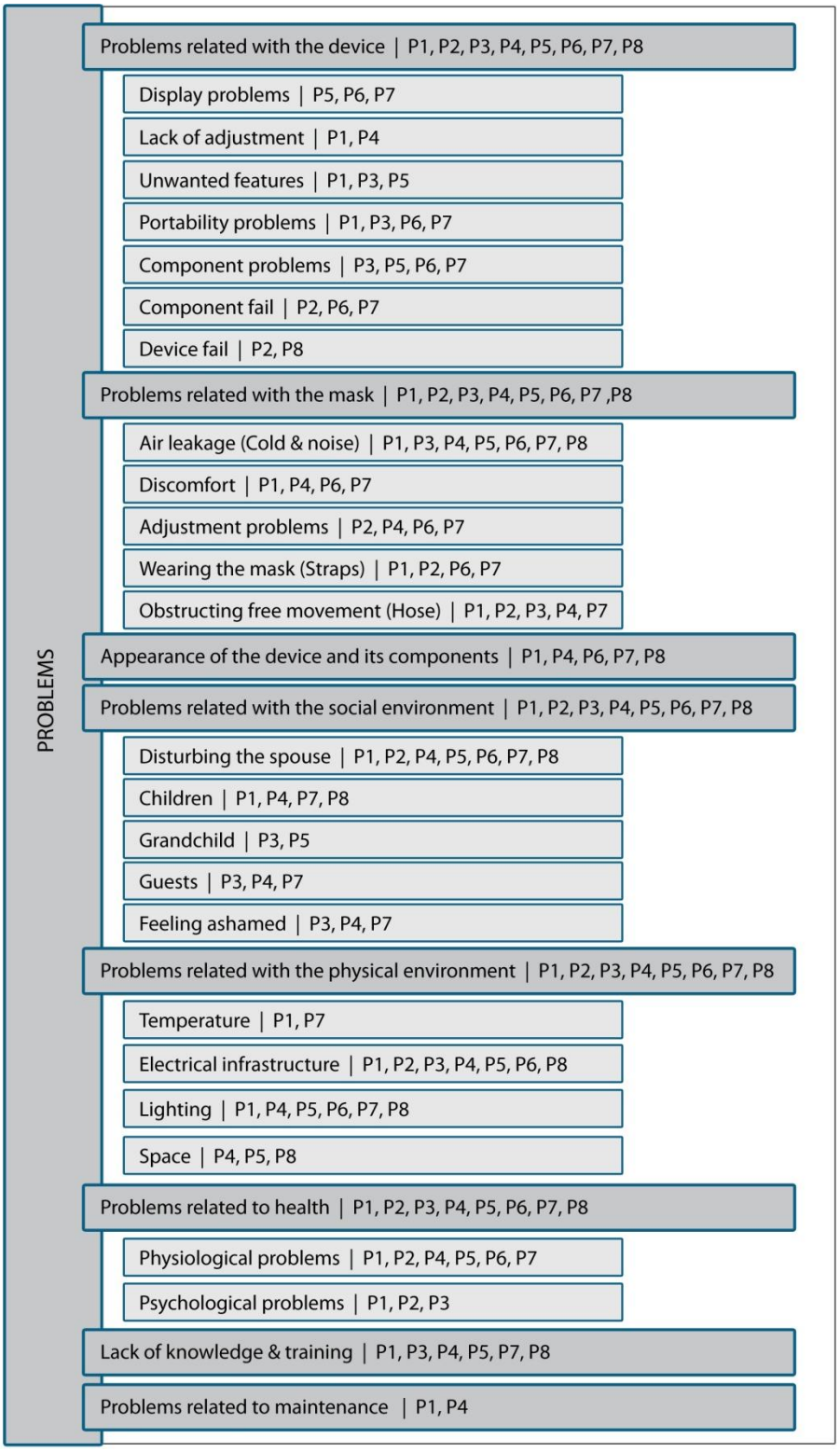

Figure 3.2 Problems

3.3.2.1 Problems related with the device

Most common device problems were portability of the device and problems related with components.

Table 3.6: Problems related with the Device

Display problems	P5, P6, P7
Lack of adjustment	P1, P4
Unwanted features	P1, P3, P5
Portability problems	P1, P3, P6, P7
Component problems	P3, P5, P6, P7
Component fail	P2, P6, P7
Device fail	P2, P8

Display problems are stated as being too small to read and showing unknown or unnecessary information. None of the displays of devices had a backlight. And, even though it was not stated as a problem by the participant himself, it should be noted that only the device of P7 was not featuring a display. Also, he was not aware of his device's ramp feature until the interview, therefore not seeing actual pressure level on a display might be the reason behind this situation.

Lack of adjustment caused two participants to abandon their device until they were adjusted properly. The outcome of lack of adjustment was feeling like being choked due to high levels of air pressure.

The common ***unwanted feature*** was not having a switch button and therefore having to unplug the device every time. Other unwanted features were vibration and noise of the device itself, and not featuring a self-lighting which shows the buttons in the middle of the night.

Portability problems were the main reasons behind not carrying the device for short trips. Portability problems were stated as being too big and hard to wrap up.

> *"(...) I would have taken this with me [for short trips] if it was smaller. I am carrying this like a school bag."* **(P6)**

Component problems were about detachable parts and component placement. Female participants have experienced difficulties during the interview while attaching/detaching filter cover (P3) and humidifier's water tank (P5).

Figure 3.3 Tinfoil covered hose - P2

P2 covered the hose between the CPAP device and its humidifier with tinfoil because it was leaking air. He stated that, he never searched for another solution; he just managed it like that (Figure 3.3).

Two of the participants' CPAP devices (P6, P7) were different models of the same brand and they were positioned backwards, because their hose socket were at the top of the device. When the device is placed in order to keep the hose towards user, the icons of the buttons were facing the other side towards the wall (Figure 3.4). For instance, while talking about air pressure value, P6 thought that the display shows the number of 9, but it was showing 6.

Figure 3.4 Position of P7's CPAP device

Component fail was experienced by three participants. P2 had problems with the hose-plug frequently, which was being changed by the service repeatedly. Two of the participants' masks (P6, P7) were same model of the same brand. And both of the participants stated that the forehead pillow of the mask came off. P6 bought a

new one and placed it in its place by himself, and P7 did nothing about it. P7 thought that he had to buy a new mask; he did not know that there are replacement parts which are provided by the service.

Device fail was experienced by two participants and they had to send their devices to repair services for a change of electronic card.

3.3.2.2 Problems related with the mask

All of the participants stated that they are having problems with their devices' mask and its components, which were mostly related with poor ergonomics.

Table 3.7: Problems related with the Mask

Air leakage (Cold and noise)	P1, P3, P4, P5, P6, P7, P8
Discomfort	P1, P4, P6, P7
Adjustment problems	P2, P4, P6, P7
Wearing the mask (Straps)	P1, P2, P6, P7
Obstructing free movement (Hose)	P1, P2, P3, P4, P7

Air leakage from the mask was the most common problem, which disturbs both the participants and their spouses. The most common outcomes of air leakage of the mask were the cold air flow towards participants and towards their spouses. Also, the loud noise of the leaked air wakes up and disturbs both the participants, and their spouses.

Air leakage occurs when the participant turns on his/her side, when the straps are not adjusted firmly or when the mask is taken off without turning off the device. Adjusting the straps firmly causes skin discomfort; consequently air leakage was the most repeated, and therefore, the most significant problem among participants.

Discomfort of the mask was among the serious issues. Hard plastic materials, too tight straps, and the pressure that the straps apply were expressed as discomfort by the participants. The outcomes other that feeling of discomfort were headaches and skin irritations.

Adjustment problems were stated by the participants and also observed by the interviewer. Especially the masks were not fit for most of the participants' foreheads. As a result, forehead pillows were too loose, and straps were too tight for the nose and cheeks.

Wearing the mask (Straps) was another problem related to mask usage. Four participants stated that they have problems with putting on and taking off the mask because of hard-to-adjust hook and loop fasteners (Velcro strips) as straps. All of the four participants stated that they put on and take off their masks without detaching the hook and loop fasteners to avoid adjusting them every time they wear it. Therefore, it was stated and also observed that they struggle for a while to put the mask on properly. It should be noted that P1 changed his mask with an easy-to-remove mask, which features clips instead of hook and loop fasteners. Also, as stated before, two of the participants' masks (P6, P7) were same model of the same brand and they both had the same problem of worn-out straps. The other participants who did not complain about wearing the mask had mask models which feature clips to detach the cotton straps.

Obstructing free movement (Hose) was stated among mask related problems by five participants. The problems are expressed as: entangling with the hose, fixed hose plug which does not rotate with the user, being unable to sleep in prone position (on stomach), being unable to turn and sleep on sides, disturbing the spouse

by the contact of the hose, and waking up in the middle of the night and feeling something pulling the head back. Participants who like to sleep on stomach and who turn frequently while sleeping were obstructed by the hose's hard material and fixed hose plug, which does not rotate freely.

3.3.2.3 Appearance of the device and its components

Five participants (P1, P4, P6, P7, and P8) expressed their concerns about the appearance of their CPAP device and its components. Two of the participants stated that the *main box* of the device is too *rough.* Roughness was associated with being huge and rectangular. Also the color of the device was among the stated appearance related problems, black/dark colored devices were not appreciated as much as white/light colored ones. Also, P7 and wife of P4 pointed out that the hose of the device looks exactly like an outlet pipe of a washing machine or a hose of a vacuum cleaner, which was considered far from pleasing.

It should be noted that, all of the wives of these five participants stated their displeasure about the appearance of the devices. Wives of P1 and P6 stated that the black straps of the mask make their husbands' faces *scary* and *unfamiliar* in the dark.

Also wives of P4, P7 and P8 said that, the appearance of the CPAP device with its cables, hose and mask, transforms their bedroom to a hospital room They stated that they hide the device while it is not in use because it does not fit their bedroom's decoration, due to its dark color, hospital-like appearance, and featuring too many cables.

3.3.2.4 Problems related with the social environment

The most common problem related with the social environment was stated by participants as disturbing their spouses. Also, the participants stated as a problem

that, the participants' social circle, which included their children, grandchildren and guests, affected the device usage and were, affected by the device usage.

Table 3.8: Problems related with the Social Environment

Disturbing the spouse	P1, P2, P4, P5, P6, P7, P8
Children	P1, P4, P7, P8
Grandchild	P3, P5
Guests	P3, P4, P7
Feeling ashamed	P3, P4, P7

Disturbing the spouse

Seven out of eight participants stated that, their spouses are getting disturbed by their device usage due to device's own noise in addition to the air leakage noise and cold air flow. In addition, when the mask is removed, air flow noise level increases suddenly in the middle of the night and wakes their spouses; therefore all participants stated that they are doing their best to prevent that. Also, four of the participants (P1, P2, P4, and P5) stated that, when they wake up in the middle of the night (e.g. going to WC, drinking water, etc.) they have to turn the lights on to put the mask on, and they wake their partner up by doing so. It should be noted that, this problem about disturbing the spouse was the most significant problem which was referred to repeatedly.

Spouses of Participants: As it was mentioned before, spouses of six participants participated to the interviews partially, and also the other two participants were

asked about their spouses' ideas or acts related to their device usage. Problems of the spouses of the participants are collected as follows.

P1's wife stated that, they considered separating their beds at first, because of the noise of the device and the cold air flow. Also she was not pleased because of the hanging hose on the wall (Figure 3.11) which spoils the decoration of their bedroom.

P2'wife stated that she is disturbed because her husband is too addictive to his device; even when the electricity goes off in the middle of the night, they go to their husband's office to sleep on sofas there. Also she claimed that, P2 feels an anxiety of being left without his device, which is why she thinks that he has two separate devices even though these devices are very expensive; as a result, she found this situation worrisome. Lastly, she mentioned that the cold air pressure that is leaking from the mask still makes her feel cold, however she got used to its noise by time.

> *"(...) Can you believe that we have to get up in the middle of the night, change clothes and leave our home when electricity goes off? Yes we do, we sleep in the office, on the sofas separately, just because he cannot do without his device now. He takes me with him too! He became addicted or something, I don't know (...)"* **(Wife of P2)**

P3 stated that her husband feels very relieved because she does not snore anymore. She said that her device is silent when her mask is on, and she turns off the device before taking her mask off; that is why the device does not release the sound of blowing air.

P4's wife stated that she does not want to see the device in their bedroom, so she puts a cloth on the device. She said that, she covers it both for protecting from dust and hiding it from her sight. Also, she stated that she is disturbed by the noise and cold of the leaking air from the mask.

"(...) I don't want to see it; human beings want to be healthy. Also I care about appearance, for instance I hate cables. It has cables, hoses, it does not look good ... I care for the decoration, design of my bedroom. Doesn't it look like a hospital room?" **(Wife of P4)**

P5's husband started to sleep in another room since the device arrived in their home, because P5 was waking up in the middle of the night frequently and making noise, due to feeling the need of taking off the mask to breathe by mouth (CPAP users cannot breathe from their mouth while using the device because the device is already flowing air through their noses). P5 was feeling like being suffocated sometimes, that's why she wakes up in the middle of the night and takes off her mask. She is also a diabetes patient; therefore she wakes up frequently to drink water.

"(...) When I take off the mask, the blowing air makes a noise suddenly. My husband, he even left and went to the other room, he sleeps there since then. This device separated us, I say. We will get used to it by time, he does also have apnea problem, he snores but he does not go to the doctor (...) but of course he is helpful, he wants me to recover." **(P5)**

P6's wife stated that they cannot sleep face to face; they are trying to stay back to back because the cold air makes her feel chilly. P6 himself said that he is trying to sleep on his back, but he cannot control himself while sleeping. Also his wife said that when it is a summer month, she is more disturbed because they use a light blanket; but if it is a winter night, she puts the blanket between them to prevent the air to flow towards her side. At the same time, she stated that she can even be disturbed by the ticking of a watch, so she was leaving the bed due to the noise of the air pressure. But she said that she got used to it, and now she leaves when only she can't sleep. Lastly, she stated that in the first weeks she found P6's appearance weird and scary while he was sleeping; the black straps of the mask made him look like a stranger with thick eyebrows and a black moustache.

"(...) When I hear an air leakage noise, I nudge him a little so he relocates his mask. But at first I slept in the other room for a while; even the tick of a sound annoys me, therefore whenever I heard a noise, I took my pillow and left. Because when my sleep is interrupted, I cannot sleep anymore that night." **(Wife of P6)**

P7's wife stated that she does not want to see the hose and the mask of the device and she hides them under the blanket; because she thinks that they turn their bedroom to a hospital. However, she said that she does not find the *box* of the device disturbing. Also she was very concerned about the hose of the device because she was worrying about whether the hose would entangle around the neck of her husband. In addition, she stated that she is feeling very cold, and she thinks that the bedroom becomes windy because of the cold air pressure of the device; she feels the need to cover herself much more than before. Lastly, she said that the noise of the leaking air pressure wakes her up frequently, but she got used to it by time.

"(...) I hide the hose and the mask between his pillow and the blanket, I don't know, I don't want to turn the bedroom into a hospital room; except for the hose and the mask, I am not disturbed by the box of the device... I am the one who hides the cables behind the furniture; I am the one who hides the mask under the blanket. Sometimes he leaves them outside, and then I immediately put them inside the bed (...)" **(Wife of P7)**

"(...) I was afraid that, me and my wife will not be able to sleep in the same bed at first; I thought she would not be able to sleep because of the noise of the air pressure, also my hose was going to her side. Now we got used to it by time ... when she wakes up because of noise or cold air, she warns me and I turn to the other side or adjust my mask (...)" **(P7)**

P8's wife said that the noise of the device itself and the noise of the air leakage are getting disturbing by time. Also she stated that, while she is cleaning the bedroom

and tidying up the bed, she is disturbed by the roughness of the device; therefore she said that most of the time she puts the device in its own bag in daily basis. Roughness is referred to due to the big size of the device. She said that if the device was smaller, she would not think like that. Lastly, she stated that she cannot get close to her husband due to the high noise of the device; she avoids looking at him and turning to his side while they are sleeping.

Children

Four participants stated that their children see them while using the device which was weird for children at first, but later on they got used to it (P1, P4, P7, and P8). P1 said that his children were observing him while he was sleeping out of curiosity in the first weeks of his device usage; he stated that he feels like *a robot*, like *an alien* when he wears his mask on. P7 stated that he is not taking off the mask while going to WC or kitchen in the middle of the night due to his mask's hard-to-adjust straps; therefore he said that his son was mocking him while he was wandering around, by likening him to *a pilot* and *a bionic man*. But according to P7, if he wears two masks now, no one will notice because everyone in the home got used to it.

Grandchildren

Both of the female participants (P3, P5) stated that, they avoid being seen by their grandchildren because they may be afraid of the appearance of their grandmother while her mask is on.

> *"(...) I asked my grandson to sleep together as we always do, but he did not want to. His grandfather warned him about the noise before. I also do not want to scare him, what if he wakes up at midnight and sees and hears that? My other grandchild did not see it yet, but I would not want to scare them."* **(P5)**

Also, P3 stated that she never keeps the device outside its bag and only takes it out before sleeping, because she lives in the same apartment with her two married sons and they visit her house nearly every day and she babysits her grandchildren; as a result, she thinks that her grandchildren may play with the device.

Guests

Three participants (P3, P4, and P7) said that they frequently have houseguests and they do not want the device to be seen by them because guests may ask too many questions because of curiosity which requires too much explaining.

P7 stated that at first their guests were cynical and they found the device strange but their negative approach has changed towards positive because he told them the positive change in his health, but he said that he still does not want to explain it every time.

P3 stated that people may make fun of her if she is seen with her mask. Also all of the three participants had the concern of taking their devices with them while visiting some relatives; they said that they would take their device for nightlong visits but they would not want to be seen while using it.

> *"(...) Do you know how much people are cynical now, and they do not see themselves? Even my mother said that I look like a turkey with my mask and its hanging hose. She snores as well but does not use this, she deserves it..."* **(P3)**

Feeling ashamed

Three of the participants (P3, P4 and P7) stated that they feel ashamed for some reason, because of the situation of using a CPAP device. Especially P4 stated that his spouse feels ashamed of him somehow, but her spouse corrected him that, she does not feel ashamed but she finds that using such kind of a device does not suit her husband.

"(...) It is not like feeling ashamed of you [to P4]; it is more like... finding that it does not suit you. No woman would think of her husband like that, in need of a device." ***(Wife of P4)***

3.3.2.5 Problems related with the physical environment

The most significant problems related with the physical environment of the CPAP devices were problems with electricity and lighting of the bedroom. Temperature of the bedroom and the space that the CPAP device was placed were the other factors affecting the usage negatively.

Table 3.9: Problems related with the Physical Environment

Temperature problems	P1, P7
Electrical infrastructure problems	P1, P2, P3, P4, P5, P6, P8
Lighting problems	P1, P4, P5, P6, P7, P8
Space problems	P4, P5, P8

Temperature problems

Even though the temperature of the bedroom is mentioned by all participants, there were two participants who pointed out direct problems related with the physical environment. P1 complained that, their home is heated by a heating stove and his bedroom does not have a heating; therefore he and his wife are feeling much colder because of the leakage of cold air pressure that the device produces. Also he stated that, he feels he is filled with air in the stomach, which may be related with the device or the temperature of the winter. P7 stated that because of his chronic

bronchitis, he feels like he is in a windy environment while using the device due to cold air leakage from the mask. Also in winter, if the room is not well-heated, the effects of the device's cold air pressure get more recognizable in a cold room.

Electrical infrastructure problems

Seven participants stated problems related with the instable voltage of their neighborhood, they were afraid of burning the circuits of their devices. Besides, two participants (P1 and P2) complained about the disturbance they feel when the electricity goes off such as waking up suddenly and the feeling of being left breathless. As another concern, P6 said that he was worried about whether his device will be provided with suitable voltage on a cruise trip. Also, it was observed that, P1, P4, P5, and P8 was using an extension cord.

Lighting problems

It was observed that, the bedrooms of P5, P6, and P8 were dark due to dim lighting choices. Also, P1, P4 and P7 stated that, they feel the need of a lamp when they are putting on their mask and turning on their device at midnight. In addition, P5 was keeping a small torch in her drawer in order to read the display.

Space problems

Problems related to the space of the device were experienced by three participants. P4 complained that he cannot place his cell phone on his drawer like he did before, because there was no room left for it after the arrival of his CPAP device. P5 had a plug near his husband's side of the bed, and also she was unplugging the device every morning, therefore she has to turn around the bed every time to plug and unplug the device. The extension cord for the device of P8 was hanging between the bed and the wall due to being too short, which may pull somebody's leg.

3.3.2.6 Problems related to health

Seven out of eight participants complained about problems related to their health which were affected by the CPAP device.

Table 3.10: Problems related to health

Physiological problems	P1, P2, P4, P5, P6, P7
Psychological problems	P1, P2, P3

Physiological

Four of the participants (P1, P4, P6 and P7) complained about the sores and marks on their cheeks and nose that the straps cause, and two participants (P1, P4) complained about the headaches which were caused by the same reason. Two participants (P5, P7) were coughing in the mornings and feeling like they are being choked because their throats were tired. As stated before in Section 3.3.1.4, two participants (P1, P7) were prone to getting lung diseases due to their patient histories, therefore their lungs were sensitive to the cold air pressure. Also, one participant (P1) stated that he feels pressure on his diaphragm when he eats too much at dinner, and CPAP usage increases that feeling since the device applies pressure through his airway.

Psychological

Two participants stated that, somehow they felt a *psychological* disturbance after device usage such as suffocation and oppression. P1 stated that, at first he got disturbed by the thought of wearing something suffocating, which later on affected him psychologically. P3 stated that, she was very relaxed and on good terms with

her CPAP device, but later she felt that some *evil eye* affected her and she felt suffocated for a couple of days. Later on, she decided not to speak about her good relationship with the device. The wife of P2 complained that her husband got too obsessed with and addicted to his CPAP device to an extent that, he cannot close his eyes for a second without it.

3.3.2.7 Lack of knowledge and training

Six out of eight participants (P1, P3, P4, P5, P7, P8) expressed their lack of knowledge and training about their CPAP device such as: being unable to understand display information, confusing the button functions, not knowing how to clean the filters of the device, not knowing when to renew the mask, not knowing about the features of the devices, and mistaking the adapter of the device for a rechargeable battery.

3.3.2.8 Problems related to maintenance

Two participants (P1 and P4) stated their problems about maintenance. P1 stated that, the silicone of the mask and the plastic of the hose smell bad and the blue straps of the mask go dark by time. P4 said that, the filter of the device gets dirty too fast because of the lack of a plastic cover on the white filter. Also the wife of P4 complained about how to clean the device among all those cables and components.

3.3.3 Motivating Factors

According to the participants, there were some motivating factors (Figure 3.5) which help them to keep on using their CPAP devices. All of the participants appreciated the improvement in their health and also, all of them used some positive statements according to their devices' different properties.

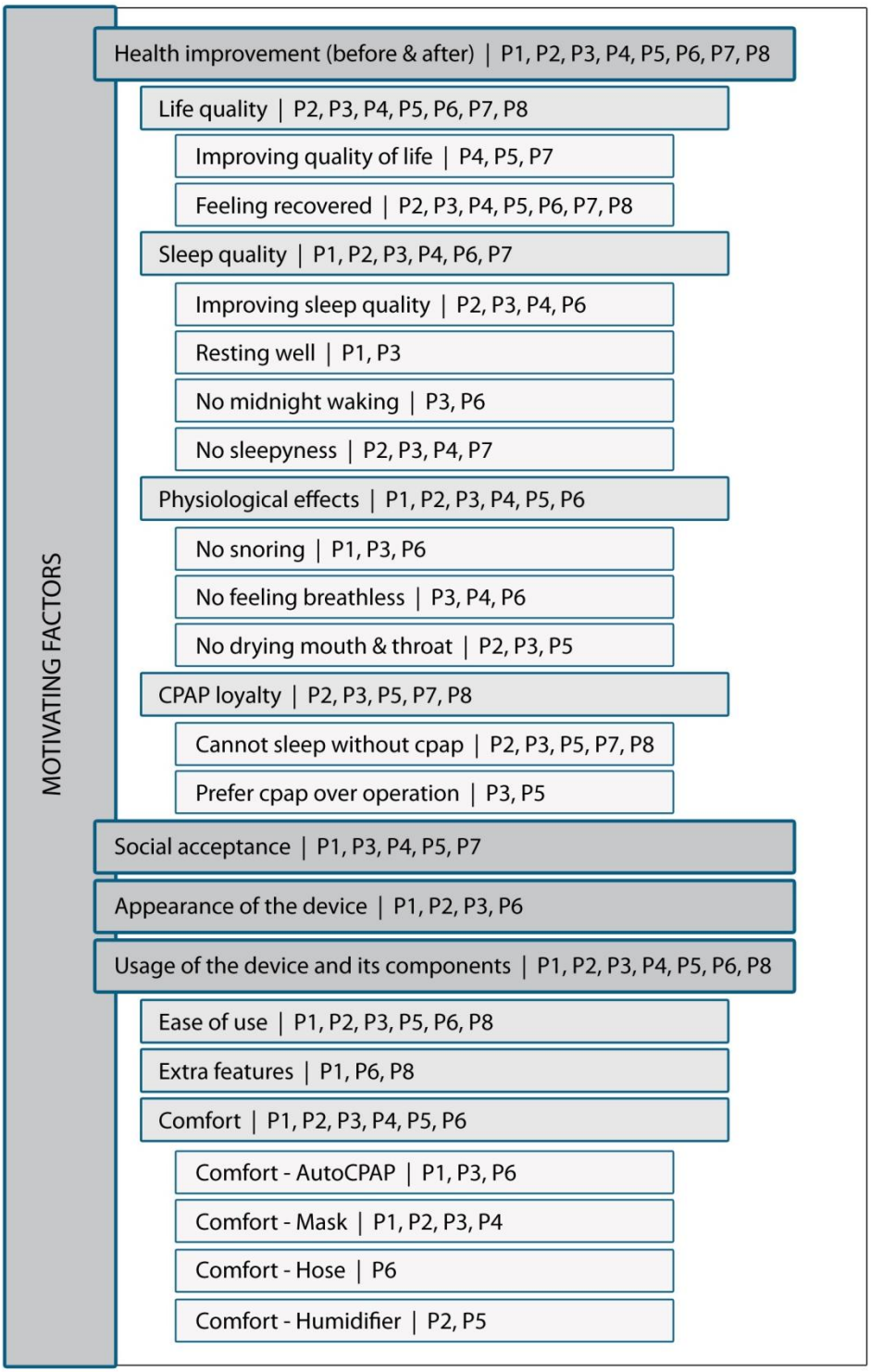

Figure 3.5 Motivating Factors

3.3.3.1 Health improvement (before and after)

All of the participants pointed out how their health is improved after CPAP device usage. Mentioned before & after effects can be seen in Table 3.11.

Table 3.11: Health Improvement as a Motivating Factor

Life quality	P2, P3, P4, P5, P6, P7, P8
Sleep quality	P1, P2, P3, P4, P6, P7
Physiological effects	P1, P2, P3, P4, P5, P6
CPAP loyalty	P2, P3, P5, P7, P8

Life quality

Seven participants (P2, P3, P4, P5, P6, P7, and P8) believed that they have an improved life quality because their sleep apnea and related illnesses are cured after their CPAP therapy. Also, three participants (P4, P5, and P7) mentioned improved quality of life in terms of extending life span and making life easier.

> *"(...) I feel like I sleep better even if I don't use my CPAP device. But my doctor said that, using a CPAP device is similar as using glasses. Your apnea doesn't get better, but with the help of the device you don't feel the effects of it. Therefore, according to that, it shouldn't be cured. But if you ask my opinion, I feel like my apnea is cured (...)"* **(P4)**

Sleep quality

Six participants stated that they are sleeping better than before. P1 and P3 said that they are sleeping and waking up on time, P3 and P6 mentioned that they are not waking up in the middle of the night any more. P2, P3, P4, and P7 stated that they are not feeling sleepy while driving, having breakfast or watching TV.

> *"(...) This device makes me feel rested. If I sleep seven hours a day, it is enough. Before that, I was sleeping till 10 o'clock, now I wake up at 5 or 6 o'clock."* **(P1)**

> *"(...) Now I learned that having a bad sleep was a habit for me, I had no idea how other people were sleeping that restful..."* **(P4)**

> *"(...) He was always falling asleep on the coach before, but now he doesn't do that anymore..."* **(Wife of P7)**

Physiological effects

Six participants stated specific improvements in their health which helps them to have a better sleep and a better life. P1, P3, and P6 were not snoring anymore; P3, P4, and P6 mentioned they are not feeling breathless while sleeping anymore; P2, P3, and P5 said that they are not having a dry mouth or dry throat anymore.

> *"(...) Before the device, my tongue and my throat were drying because I was sleeping with an open mouth. I was waking up frequently to drink water. I was restless. I was waking up my family. Now I sleep soundly with a closed mouth. Even my tongue got smaller (...)"* **(P3)**

CPAP loyalty

Five of the participants stated that they cannot sleep without their CPAP devices after they recognize the improvements in their health. Also, P3 and P5 stated that

they would prefer using a CPAP device instead of having a surgery, even if it is possible (Some patients may be suitable for a surgery for obstructive sleep apnea).

> *"(...) I feel uncomfortable without my device. I was so uncomfortable before using it, therefore now I know how relaxing it is. I cannot sleep without it anymore."* **(P2)**

3.3.3.2 Social acceptance

Five of the participants (P1, P3, P4, P5, and P7) mentioned that they are feeling better after their social circle accepted their CPAP device and appreciated its positive effects on their life.

> *"(...) I was ashamed of sleeping among other people. I was ashamed of sleeping on the bus, I was ashamed of visiting relatives, and I hated snoring while I was having guests overnight in my house. Now, my children who are living downstairs say that I sleep silently, I don't disturb them anymore."* **(P3)**

P1, P3, P4, and P5 mentioned that their improvement of health and snoring is appreciated by their spouses. P1 was pleased that he is not snoring anymore, therefore their neighbors and guests are not disturbed. P3 stated that she is not waking up frequently in the middle of the night and disturbing their children's family, who are living at the adjacent flat. P4 stated that by using a CPAP device, he has accepted that he is snoring and proved his wife is right, which makes his wife happy. Also wife of P4 stated that she feels relieved because she does not have to check P4's breathing anxiously like before since he will not pass out while sleeping. P7 mentioned that their guests were so curious and cynical about his CPAP device at first, but now they are positive because most of them learned about such kind of a device and their sleep apnea problem thanks to him.

3.3.3.3 Appearance of the device

Four participants (P1, P2, P3, and P6) mentioned that, they appreciate some of the appearance features of their devices. P1 said that the white color of his current device seems better than his previous black device. At the same time, P6 said that the dark navy color of his device is pleasing and fitting for his bedroom. P3 appreciated that her device is not too rectangular like his relative's device and P2 said that his device is invisible in terms of its small size and being suitable for their bedroom.

> *"(...) This one was more pleasing among other options of device models, it is more aesthetically pleasing; its material, its dark navy color, it matches with the environment (...)"* (**P6)**

3.3.3.4 Usage of device and its components

There were several motivating factors related to the usage of the device and its components which are collated under the titles of ease of use, extra features and comfort. These are presented in Table 3.12.

Table 3.12: Usage of device and its components

Ease of use	P1, P2, P3, P5, P6, P8		
Extra features	P1, P6, P8		
Comfort	P1, P2, P3, P4, P5, P6	Comfort - Auto-CPAP	P1, P3, P6
		Comfort - Mask	P1, P2, P3, P4
		Comfort - Hose	P6
		Comfort - Humidifier	P2, P5

Ease of use is mentioned by P1, P2, P3, P5, P6, and P8. P1 appreciated the clips of the mask which makes it easy to put on. It should be mentioned that P1 had a previous mask which does not have clips therefore which was hard to put on. P2 and P6 stated that they can use the device with a press of a single button. Even though P3 and P8 stated that they did not see other models and types of devices, they stated that their device is easier to use than others. Lastly, P5 mentioned her device's user manual is easy to understand and therefore it makes the device easy to use.

Extra features of devices such as having a sleep-recording data card (P1), featuring an adapter which prevents high voltages (P1), being silent thanks to being an automated CPAP (P1, P6) and being safe in terms of not being prone to trip over (P8), are appreciated.

Comfort is mentioned by six participants. P1, P3 and P6 stated that it is comfortable to have an automated CPAP device because an automated device adapts itself to their breathing and it does not suffocate them because it applies less air through their airway at the beginning of their sleep.

P1, P2, P3, and P4 stated that their masks are comfortable because of the following reasons. P1 said that his mask's clips make it easier to remove the mask while he is going to the WC in the middle of the night. P2 stated that his previous mask was too loud and was leaking cold air compared to his current one, because it was more unfitting to his face and there were big gaps leaking air. P3 stated that her mask releases the air mildly due to its well-arranged air-releasing vents. P4 said that his current mask is better than his previous one due its rotatable hose plug which lets the hose move freely without entangling with his neck.

P6 stated that the hose of his device is made from a soft plastic; therefore it is comfortable in terms of being able to move freely.

The only participants (P2, P5) who had a humidifier stated that, having a humidifier is comfortable in terms of relaxing them by preventing exhausting and drying of their throat.

3.3.4 Tasks

There are some statements of participants that are related with device usage which are gathered while they were demonstrating how they are putting on their masks and how they are using their devices. In this section these statements are presented (Figure 3.6).

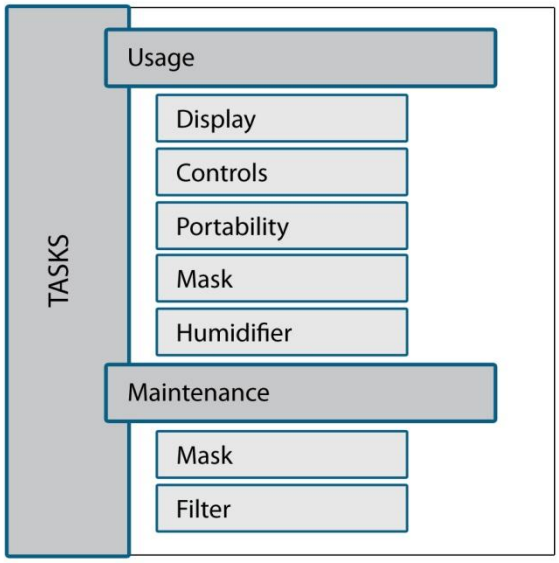

Figure 3.6 Tasks

3.3.4.1 Usage

P1, P2, P3, P5, P6 and P8 stated that they use their devices' ramp feature before sleeping, but it should be noted that they were not activating the ramp feature by

themselves with help of the ramp button; the ramp features were automatically adjusted by their distributors.

Ramp feature increases the air pressure of the device gradually for a previously adjusted period of time, until it reaches the prescribed pressure. Ramp feature should not be confused with auto-CPAP; auto-CPAPs adjust the air pressure according to the breathing of the user during different phases of sleep, all through the night. Even though P2 and P8 did not have an auto-CPAP, they were using the previously adjusted ramp feature of their devices to relieve the feeling of pressure while falling asleep. It should be noted that, even though the non-automated CPAP device of P7 had a ramp feature, he did not know this, and he discovered the feature during the interview. Before that, he was complaining that he cannot pass to sleep because of the choking feeling of high air pressure.

Display

P1, P2, P3, P4, P6 and P8 stated that they do not look at the displays of their devices. The device of P7 did not have a display.

P6 stated that, he already feels how much pressure the device applies therefore he does not feel the need to look at the display. Also he mentioned that the display shows nothing concerning him, and even though the information is given for his own good, he does not understand any of the four icons. He stated that the display shows information which may be useful only for the service staff; therefore he questioned the purpose of the display for the user. Also he added that, it would be better to have a button for him which turns the display to a clock, instead of the information which he does not understand.

Even though P1 did not look at the display before, he tried to guess what it shows during the interview. Due to the English units for hours (h) and minutes (m), he confused the total usage time of the device with the pressure that it applies. At the same time, while the wife of P1 was suggesting looking at the user manual, he

feared that he changed the settings of his device by pressing the ramp button because of the changing numbers on the display.

Also, except P5, all of the users said that the display is for maintenance of the service and adjustments of the distributor. P5 was the only user who knows all of the display information correctly, because she said that she had read user manual very carefully. She demonstrated every device button and all the information that the display shows respectively.

Controls

Except P5, participants only have knowledge about the power button. None of the participants have knowledge of what the other buttons do and what information the display shows. They were too concerned with not to change the adjustments of devices; all of them said that distributor adjusted it and it is better to not to touch them.

P3 stated that she visited her distributor's office just to ask what happens if she touches the other buttons of the device by mistake.

> *"(...) I would not want to cause trouble for him [distributor] and for me by changing the settings by mistake (...)"* **(P2)**

> *"(...) P1: There are other buttons here but I do not meddle with them, the distributor adjusted the device. I tried the other buttons, they do nothing, I have no idea about what they are used for. This button does nothing [ramp feature]; it just shows the applied pressure value (...) this button [humidifier steam feature] shows the seconds, this button [information] changed the pressure... I don't understand this...*
>
> *Wife: There is a user manual, isn't it in Turkish?*

P1: Sometimes we push the wrong buttons. See, it shows the number of 3, what is this? And what does this button do, there is a sign on it...

Wife: Maybe the user manual explains it... Do not break down something...

P1: [presses power button] See, the device is good now (...)" **(P1 and his wife)**

Portability

All of the participants said that they would and will take the device with them when they are travelling. All of them stated that health is more important than having to carry the device bag.

P1, P2, and P5 stated that it is easy to tidy up the device because of its own bag which is divided according to the component sizes. P2 stated that he would take the device with him no matter what. Also he said that, just for that reason he has two devices; one for travelling, and one for keeping at home. P3 said she will take the device wherever she goes in order to not to snore, but she does not want to be seen with it. Also she stated that she would like to have a smaller device in order to carry with ease. P6 and P7 stated that they would not take the device if they are going somewhere just for one night. But for longer trips, they would take it with them.

Mask

Except for P7, all of the participants removed their masks totally, if they woke up in the middle of the night. P7 stated that he goes to the kitchen or WC with his mask on his face, which he detaches himself from the device by the hose plug, because he finds it too troublesome to deal with the hook and loop fasteners in the dark with a sleepy head. P6 and P4 stated that, it would be nice to remember to detach themselves by the hose plug, but they remove their mask completely; which makes it hard to put on and adjust its straps. P1 and P3 stated that they are removing their mask's straps easily with the help of their clips. Lastly, P5 stated that she removes

her mask in the middle of the night with the help of a little torch that she keeps in her drawer.

Humidifier

Two of the participants (P2, and P5) had a humidifier attached to their devices. Both of them had to place their devices beneath their bed level in order to return drops of steam back into the humidifier tank with the help of gravity. P2 stated that he does not use his humidifier during summers despite the fact that, in the summer the air gets drier. Also P2 did not know how to adjust the humidifier level; he said that he only knows how to press its power button.

3.3.4.2 Maintenance

Every participant stated that they learned the maintenance of the device from their distributors. However, all of them have different habits in order to maintain their devices.

Filter and Mask

Every participant stated that they learned the maintenance of the device from their distributors. However, all of them have different habits in order to maintain their devices;

P1 stated that he washes his mask and its straps with water, detergent, and a little amount of bleaching liquid, because he sometimes smells a plastic odor. He appreciated the detachable cotton straps of the mask, which can be easily washed. Also P1 did not know how to clean the filter and when to change the mask. He stated that he discovered by himself that his device has a filter.

P2 was washing his filter with water and soap once a month, but he never washed his mask in the past two years of its usage time. At the same time, it was observed that his mask's silicone components have turned yellow and got harder by time.

P3 stated that she washes the filter and the mask once in 20 days with water and soap.

P4 washes the filter once in a week. P4 stated that no one mentioned the filter; he discovered it by himself and felt the need to wash it. Also, even though the distributor mentioned the mask and its straps are washable, he did not tell him how to do that. Therefore, he did not apply any maintenance to his mask yet.

P5 said that she washes the mask and its straps with soap once in three days; but she stated that, she forgot about the filter's maintenance terms. Also she stated that she only uses boiled water for her humidifier.

P6 stated that he washes his mask and filter once in a week without a detergent. He also added that if he catches flu, he washes them every night with soap to keep himself from bacteria that he left in the previous night.

P7 stated that he washes his filter once in three days in summers, and once in a month in winters because they open the windows in summer and more dust gathers in the filter of the device. Also P7 stated that his wife washes his mask once every 15 days. At the same time, it was observed that his mask's silicone components have turned yellow and got harder by time.

P8 washes the filter and the mask once in three days. Also P8 mentioned the HEPA filter inside the device, but he said that he does not know when to change it.

3.3.5 Storage and Environment

Participants were asked about the physical environment and storing conditions of their CPAP devices. Space and surroundings, temperature, lighting and electrical infrastructure were the significant factors that are related with the CPAP device usage.

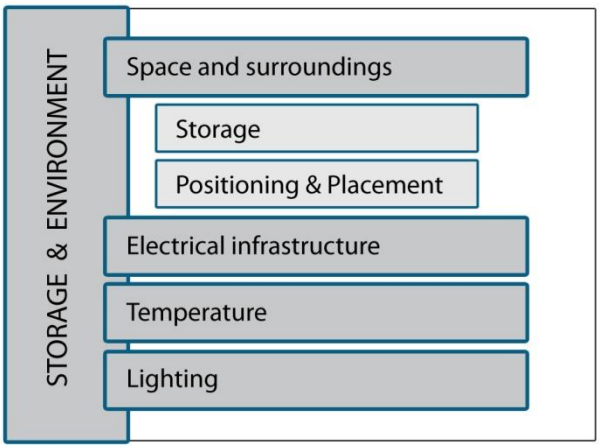

Figure 3.7 Storage & Environment

3.3.5.1 Space and surroundings

Storage

Six of the participants cover their device with a cloth while they are not in use (P1, P2, P4, P5, P6, and P8). P1, P2, P5 and P6 put a cloth on the device to protect it from dust (Figure 3.8 and Figure 3.9). The wife of P4 puts a cloth on the device to not to see its cables, hose and mask which make the room like a hospital room. P6 stated that with a cloth cover, it is not aesthetically pleasing therefore he suggested a box designed for the device also he was keeping his mask inside its PET package.

P7 keeps his device uncovered, but hides its hose and mask inside the bed because the wife of P7 does not want to turn their bedroom into a hospital room.

P3 keeps her device in its bag and inside the wardrobe because she wants to keep it ‘hygienic’ and she does not want her grandchildren to play with it. Also the wife of P8 puts the device in its bag if she finds time, and when she does not find time, she covers it with a cloth because of the ‘mess’ it creates with it cables and hose.

Figure 3.8 Device storage during daytime - P1, P2, P3 and P4

Positioning and Placement

P1 stated that, he wanted to put the device above his bed but he had to position it at the same level of his bed because the distributor said so. P4 and P6 said that they had to remove their bedside lamp to open a space for their devices. Also P6 had to change bed spots with his wife to be close to the electrical outlet.

P5 has a plug near his husband's side of the bed, and also she unplugs the device after every time she uses it. Therefore, she has to turn around the bed every time to plug and unplug the device. Also P5 said that her distributor told her to put the device on a lower level than her in order for the humidifier's drop of steams to return back into the device. Therefore she had to put a small coffee table near her bed.

Figure 3.9 Device storage during daytime - P5, P6, P7 and P8

P7 positioned his device on the floor under the bed in the first weeks of his device usage because they did not know where to put it and they did not want it to be seen by their guests. Later on, they put it on his bedside after they got used to it and after they understood that it gathers less dust by doing so.

The children of P8 were doing their homework on their parents bed, therefore the device was surrounded by books and sheets of papers. At the same time, the extension cord for the device of P8 was hanging between the bed and the wall due to being too short, which may pull somebody's leg.

Two of the devices (P6 and P7) were positioned backwards, because their hose socket was at the top of the device. When the device is placed in order to keep the hose towards participants, the icons of the buttons were facing the other side. These two devices were from the same brand but not the same model.

3.3.5.2 Electrical infrastructure

P1, P2, P3, P4, P5, P6 and P8 stated their concerns about the unstable voltage in their neighborhood. P1 wants to buy a protective multi socket in order to not to pull the plug every day with the intention of protecting the device from high or low voltages. P2 and P8 have already bought a protective socket for the changes in voltage. Also both P1 and P2 said that they are considering buying an electricity back-up device, just in case. Lastly, it was observed that, P1, P4, P5, and P8 was using an extension cord.

3.3.5.3 Temperature

P1, P2, P3, P5, and P7 stated their concerns about the temperature of their room. P1 complained about the mold in the bedroom which makes him harder to breathe, and makes him feel much colder. Also he stated that, their home is heated by a heating stove and his bedroom does not have a heating; as a result he and his wife are feeling much colder because of the leakage of cold air pressure that the device

produces. Also as he had pneumonia before, he was afraid to catch a cold because of both the cold air pressure and the cold temperature of the bedroom.

P2 stated that he uses his heated humidifier when it is winter because of the need of heating the cold air pressure. Even though the humidifier is generally used for humidifying the dry summer air, P2 said that he does not use his heated humidifier during summers.

P3 said that she is decreasing the temperature level of their central heating because she does not feel cold anymore. She stated that, before her CPAP device, she was sleeping with an open mouth therefore she was feeling cold.

P5 stated that she has arthritis, which is why she keeps the room well-heated every time. Also she has a humidifier component and that is why she says that the device usage is not affected by the temperature of the room in terms of the coldness of air pressure.

Even though P7 said that he does not experience any temperature related effects, he mentioned the importance of a well-heated room while using a CPAP device due to the fact that, CPAP devices apply cold air through the user's airway and out into the bedroom environment. He also emphasized the need for a humidifier component, especially in well-heated environments.

It was observed that the bedroom of P8 did not have a heating system but he did not mention any temperature related effects.

3.3.5.4 Lighting

P1, P2, P4, P5, P6, P7, and P8 are affected by the lighting conditions of their bedrooms. It was observed that, the bedrooms of P5, P6, and P8 were dark due to dim lighting choices. Three out of eight participants (P5, P6, and P7) had a night lamp in their bedroom, and P1, P4 and P7 stated that they feel the need of a lamp when they are putting on their mask during night time. P4 stated that there was a

night lamp where the CPAP device is plugged, but he had to remove it to plug the device. He said that, now he turns the lights on to wear the mask in the middle of the night and therefore he wakes up his wife.

P3 and P8 turn the lights on when they put on the device but they are not affected by it. P2 stated that, he can put on his mask and find the power button in the dark.

P1 was squinting while checking the display. Even though he does not have any visual impairment, as an explanation he said that, he was casting a shadow on the device due to the lamp's position. Also, P1 stated that he is considering marking the power button by gluing a glass bead on it, because he said that he cannot see the power button at night with a sleepy head. In addition, he said that he would cover the buttons other than the power button, to prevent pressing on them at night. The reason behind these ideas was, he does not like to use a night lamp and he does not want to press other buttons in the dark; also, by doing so, he said that he would not wake his wife by taking the mask off without turning off the device by mistake (when the mask is removed, air pressure noise increases). Lastly he said that it would be better if the device had a lamp on itself.

When waking up at night, P5 stated that she finds the buttons and wears the masks with the help of a night lamp and a little torch which was kept in her drawer. When it was asked if she can see the display, she took her small torch from drawer and said that she can only see it with that torch.

> *"(...) I keep a torch in the drawer here, it would be better if the display was bigger, like people for us, you cannot put on glasses every time, for that reason I have to use a LED torch. We do not put on glasses when going to sleep, of course (...)"* **(P5)**

Also, P6 was keeping a torch near the device, but he said that he does not care and know what the display shows, therefore he uses it only he feels the need for looking at the display if something feels wrong (e.g. higher pressure than it should be).

3.3.5.5 Users' solutions for adapting the environment to the device usage

It is observed that, some participants wanted to make changes in their environment of use in order to cope with the challenges which their CPAP usage constitutes. Changing pillow, fitting a hose hanger and bringing extra furniture into the bedroom were their solutions.

Pillow change

Three participants (P1, P4, and P7) stated that, they feel the need of changing their pillow because of their device usage is affected by it. The reasons are stated as having headaches because of the straps, being too stiff to move freely with a mask, and being too low to overcome high pressure that that the device applies.

Figure 3.10 Reflux pillow - P7

"(...) I am considering changing my pillow with a soft one because my pillow is too stiff for sleeping with a mask. When I sleep on my right and left

sides, the pillow pushes up my mask, dislocates it; the air flees from the gap caused by dislocation, and makes a loud noise which wakes me and my wife up. Also the flowing air disturbs my eyes, if my mask is dislocated." **(P1)**

*"(...) your mask's straps are too stiff, that's why you have headaches, so maybe a neck hernia pillow may ease it. "(***Wife of P1)**

"(...) I am having headaches because I have neck hernia, and in addition because of the pressure that the straps of the mask apply. Also I can't turn right and left easily because it dislocates the mask. So I want to change my pillow with a neck hernia pillow. I think it will help me sleep better with my head pushed back and my neck supported." **(P4)**

"(...) I feel like I am being suffocated by the continuous air flow. The pressure makes it difficult to breathe. So I bought a reflux pillow [wedge support], it helps me to overcome the high pressure." **(P7 - Figure 3.10)**

Also, the wife of P7 stated that, the reflux pillow is disturbing because of the height difference between her and her husband while they are sleeping. She expressed this situation as;

"(...) Now he is sleeping while sitting, like I am in somewhere different. He already has hoses and cables on his side; with this reflux pillow, now his side is a different neighborhood than mine." **(Wife of P7)**

Hanger

P1 stated that, he gets entangled with the hose of the device when he turns right and left during sleep; therefore he found the solution of hanging the hose to the wall behind his sleeping spot. His solution can be seen in Figure 3.11. Also, it should be mentioned that, the wife of P1 reflected her disturbance related with the idea of drilling the wall of the bedroom, which she thinks spoiled the decoration of the environment.

"(...) I did something like this [pointing the hanger on the wall] and now it is fine, I turn this side, I turn that side, the hose always comes from the above, now I can turn easily ... I had to make a hole in the wall, I wish I had used a hanger or something different." **(P1)**

Figure 3.11 Solution for entangling with the hose - P1

Figure 3.12 Device stand - P5

Stand and protection

P1 stated that he was considering preparing a foam stand for the vibration of the device to prevent the scratches on the furniture. P5 said that her distributor told her to put the device on a lower level than her in order for the humidifier's drop of steams to collect in the device. Therefore she had to put a small coffee table near her bed (Figure 3.12).

3.3.6 Assistance

Participants were asked about who they would contact if there is a need for assistance, and also they were asked about the conditions in which they would contact their doctors that prescribed their CPAP therapy. Also participants stated some concerns or thoughts about their health insurances in relation to their CPAP devices. It is observed that, participants rely on their distributors in time of need, and there are some economic concerns in relation to the National Health Insurance.

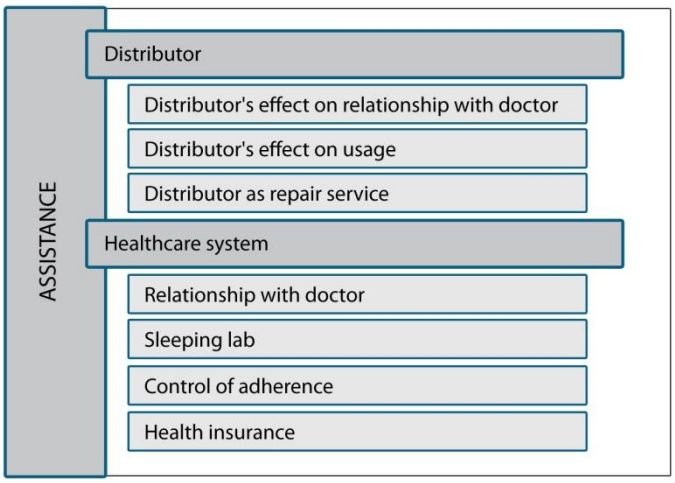

Figure 3.13 Assistance

3.3.6.1 Distributor

In need of an assistance, all of the users stated that they would contact with their distributor. All of them were confident that their distributor will take good care of the device and will provide a good assistance. P1 and P6 stated that they would contact their doctor as well. Distributor' effects as assistance providers are summarized in Table 3.13.

Table 3.13: Distributors as Assistance Providers

Distributor's effect on relationship with doctor	P1, P2, P3
Distributor's effect on usage	P1, P2, P3, P4, P6, P7, P8
Distributor as repair service	P1, P2, P3, P5, P6, P7, P8

Distributor's effect on relationship with doctor

P1, P2 and P3 make their distributor to readjust their devices, without the knowledge of their doctors. They both decreased their devices' pressure level until they feel comfortable.P1 and P2 stated that they consult the distributor about their CPAP therapy instead of their doctors.

P1 stated that, the distributor knows better than doctors; doctors only know how to look at the computer, distributor is an expert of the devices. According to P1, distributor gathers every customer's demands and claims; therefore he is better at dealing with his problems. P2 stated that he never went to his doctor after he received the device; he said that only keeping in touch with his distributor is enough.

Distributor's effect on usage

All of the participants stated that they learned to use the device from their distributors. Also, three of them (P5, P6, P8) are trained in the sleep laboratory by the hospital personnel as well. Seven of the participants (except P5) stated that, the distributor adjusted their device and showed only how to turn it on and off it by the power button. They said that the distributor did not teach what other buttons do and what information the display shows. Also, P1, P3 and P8 were really afraid of touching other buttons to not to change its settings.

P1 was prescribed for a CPAP device seven years ago but he abandoned his device after the first night's usage. He emphasized that, the distributor of his first device did not care to help him with his problems at that time. He said that they did not call or return his calls, and they did not adjust applied pressure properly, and they did not teach how to use the device. But he appreciated that his current distributor was helpful and caring, therefore he stated that he did not struggle with his device related problems alone.

> *"(...) He [current distributor] called and asked me if I am doing well with the device within my first month after I purchased it. He gave me his card and asked me to call whenever I encounter a problem with the device."* **(P1)**

Distributor as repair service

Seven of the participants (except P4) stated that they would call the distributor if their device does not work well. They considered their distributors as the device's repair service as well. P4 stated that, if his device has problems he would check if there is any repair service before handing the device to the distributor.

3.3.6.2 Healthcare system

Relationship with doctor

P1, P2, P3, P4, and P7 stated that they did not see their doctor after their CPAP therapy prescription. P5 stated that, she will consult to her doctor about the re-adjustment of her device. Distributor's effect on the relationship of participants with their doctors was significant when the participants were asked about the assistance they received.

Sleeping lab

P1, P3, P4, P5, P6, P7 and P8 mentioned their experiences in the sleeping lab, where their devices' titration (air pressure level) is determined and prescribed. P4, P5, and P6 stated that, it was a good introduction to CPAP therapy in terms of knowing what they will deal with. P1, P3, and P7 mentioned the state of sleeping in a sleeping lab with all kinds of cables and hoses around their body. P5, P6 and P8 stated that they had a basic training at the sleeping lab.

Control of adherence

Four participants (P1, P3, P5, and P8) stated their concerns about the control of their CPAP therapy adherence. P1 stated that, ten years ago no one called or asked about the device and his problems with it, therefore no one knew that he abandoned his CPAP therapy. Also, P1 said he heard that, Ministry of Health will call to check once a year whether he uses his device so he should inform his doctor about the problems that he experiences with his device. P3 was anxious about the debit (insurance warranty) which the National Health Insurance will ask for if something happens to the device that they rented. P5 stated that the National Health Insurance will check if he is using his device. P8 stated that his adherence is determined by the report of his doctor who will control it.

Health insurance

Six participants (P1, P3, P4, P5, P6, and P8) stated their concerns about the affordability of the devices. P1 stated that the National Health Insurance does not

provide a humidifier therefore he cannot afford one, and he feels abandoned and helpless. He also stated that the European Social Healthcare is better than Turkey in terms of these kinds of conditions. P3 was pleased about the speed of the National Health Insurance in terms of refunding her deposit on time. P4 mentioned that, his first mask did not fit to his face dimensions and the National Health Insurance did not provide a second one, which he paid for himself. P5 said that even though his doctor prescribed her a humidifier with her CPAP therapy, she had to pay for it herself, because the National Health Insurance did not provide one. P6 had a private health insurance, therefore he said that he could buy a relatively expensive device, for which he got a full refund. P8 stated that he cannot afford an auto-CPAP and a humidifier, and the National Health Insurance does not provide them. P1 and P8 stated that, the humidifier is provided in the south and the east parts of Turkey where the air is drier than Bursa (northwest of Turkey).

3.3.7 Factors Affecting Purchase Decisions

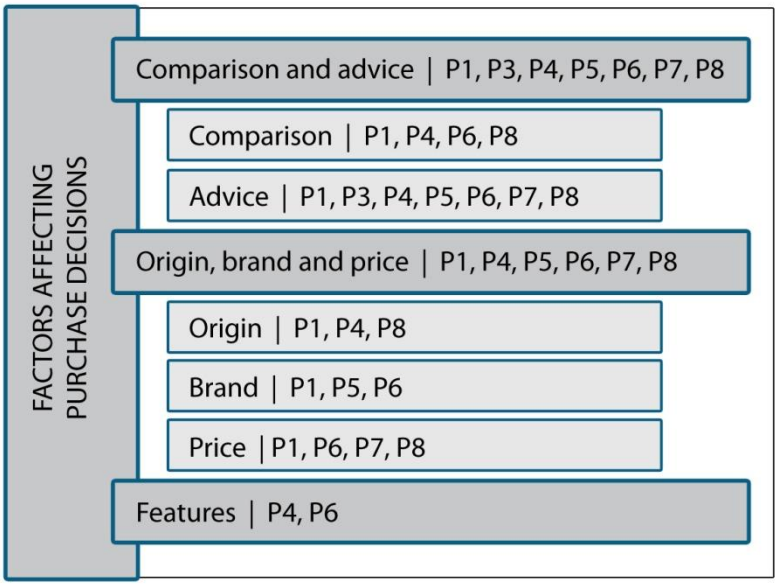

Figure 3.14 Factors Affecting Purchase Decisions

Participants were asked how they chose their CPAP devices from among other ones on the market. According to the participants, brand, origin, price and the advice of the doctors were the most effective factors while selecting their CPAP devices (Figure 3.14).

3.3.7.1 Comparison and advice

P1, P4, P6, and P8 stated that they have seen the other CPAP devices on the market before deciding on theirs. The others were introduced to other brands and models by various distributors that they have visited. P4 stated that, he chose his mask's dimensions by himself by trying on the three versions on the market. On the other hand, P2, P3, P5, and P7 did not find an opportunity to compare their chosen devices with the others properly. P1 said that he bought what he saw and he stated that even if he had the opportunity to see other options, he could not choose from among them because he has to try them for several nights at first. Also P3 got upset when she learned that there is a vast amount of different brands, models and sizes on the market. She stated that nobody showed her CPAP devices other than hers.

Seven participants stated that, they chose their model of devices considering the advice from their doctors (P3, P4, P5, P6, and P7), staff of sleeping lab (P1) or distributors (P8). P2 stated that he does not remember who advised his device model since he has been using his CPAP device for 10 years.

P6 and P8 mentioned that doctors are prohibited from advising certain brands and distributors. On the other hand, the doctors of P3 and P4 advised a specific distributor, and the doctors of P5, P6, and P7 advised a specific brand for them.

3.3.7.2 Origin, brand and price

P1, P4, and P8 were strongly affected by the origin of their CPAP devices. They repeatedly pointed out that their device is a German product which is referred to as durable and assuring. Also, P1, P5 and P6 mentioned that the brand of their device

is a well-known one, which is better than the others in terms of durability, quality, and availability of repair service. P6 strongly mentioned that, the availability of a repair service and replacement parts were significant factors while choosing a brand of a product.

P1, P6, P7, and P8 stated that, the price of their device was a significant factor during deciding phase. P1 said that even if his device is a German product, if the distributor offered a higher price, he would not buy it. P7 mentioned that, he bought what his doctor prescribed and advised, but there were expensive and therefore better ones on the market which he would have preferred if he had known before. P8 said that he favored another brand's device but he had to buy the device which he can afford. P6 stated that he bought his device even though it was notably expensive than others, which is an indicator of quality according to him.

3.3.7.3 Features

P6 mentioned the appearance features of his device as an affecting factor on his decision. He stated that, the other devices on the market were much bigger and rougher than his device. Roughness was described as having a bigger size and having an unpleasant color. He was pleased that his device has a dark navy color which is suitable for his bedroom furniture. P4 and P6 mentioned that their devices have a ramp feature which helps them to fall asleep without having to struggle with high air pressure.

3.3.8 Preferences for a new CPAP device

Participants were asked what would be the most significant feature or requirement if they would look for another device after their experiences with their current device. In this section the participants' answers for this question are presented (Figure 3.15). Their answers varied according to their problems in general. Some of the participants wanted to eliminate the factors which constitute problems while using their devices.

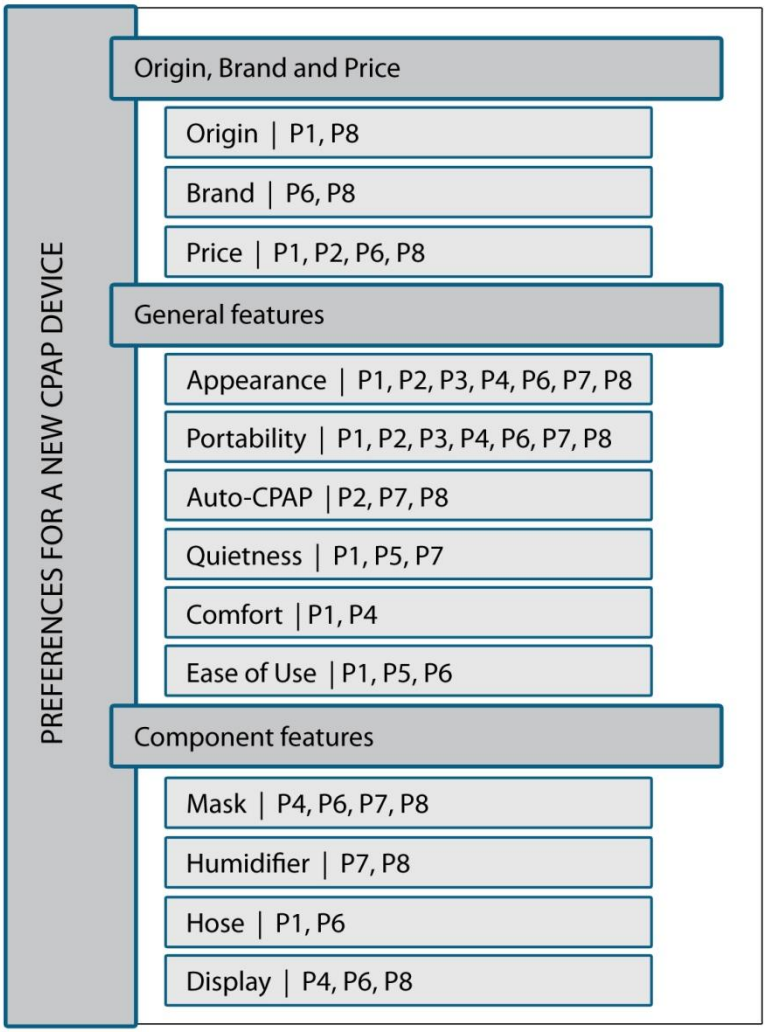

Figure 3.15 Preferences for a new CPAP device

3.3.8.1 Origin, Brand and Price

P1 and P8 were the participants who mentioned the ***origin*** of product as a requirement to consider while purchasing a CPAP device. P1 stated that, he may choose a Turkish product because of its lower price and availability of replacement parts. Even though P8 did not mention an origin of product that he may prefer, he

stated that he would avoid Chinese products due to their reputation for being replication and having low-quality. P6 and P8 mentioned ***brand*** as an important factor in relation to the same concerns with the origin of products.

P1, P2, P6, and P8 mentioned the ***price*** of the device as a consideration. P1, P2, and P8 mentioned their desire to have an expensive brand and model which they would not afford. On the other hand, P6 said that, he would choose an expensive device since he thinks that price is an indication of better material, durability and quality.

> *"(...) There are other devices on the market which were better but they were expensive. My device was 1400 TL but better ones are 3000 TL. If I had better financial circumstances I would go and buy the device with the 3000 TL price tag, that expensive one will be much better than mine for sure (...)"***(P1)**

> *"(...) I will use this device for the rest of my life. Of course I will pay more to have a better device. I am using this everyday (...)"* **(P6)**

3.3.8.2 General features

Appearance is mentioned by P1, P2, P3, P4, P6, P7, and P8. Four participants (P2, P3, P4, and P8) specifically pointed out that, they would not pay attention to the appearance of the device as long as it works properly. While P4 was saying that the appearance of the product does not matter since he does not see the device while sleeping, his wife said that she would buy a white colored device instead of their dark colored one, and she would seek a device with a *designed cover* which would hide the device and its mask and hose.

P1, P6, and P7 stated that they would care for the color of the device. All of them wanted a bright colored device. Also they all stated that, they would not buy a rectangular and big sized device which is referred to as *rough*. P6 and P7 said that they would prefer a device that matches with their bedroom furniture. P7 wanted a

more *electronic-looking device* which may be related with his current device that does not feature a display.

Portability is mentioned by seven participants (P1, P2, P3, P4, P6, P7, and P8). They all preferred a smaller device instead of their current one, in order to carry it easily. At the same time P1, P6, P7 and P8 added that, small sized devices will be more pleasing in terms of appearance.

Auto-CPAP was another desired feature, which was mentioned by P2, P7, and P8.All of the participants that are using non-automated CPAP devices stated that they would like to buy an automated one if they had a second chance. P2 said that he would not have to go to a doctor or to his distributor for pressure adjustment if he buys an auto-CPAP. P7 mentioned that auto-CPAPs are quieter because they have a *technological superiority*. P8 stated that he would prefer an automated device in order to breathe easily with the help of self-adjusting pressure feature of auto-CPAPs.

> *"(...) I would want it to be an Auto-CPAP. You don't have to go to a doctor; it has an electronic chip which adjusts everything itself instead of a doctor. (...) Those devices are like a doctor. You don't have to go a sleeping lab; it doesn't matter if you sleep at the home or at a sleeping lab."* **(P2)**

Quietness is mentioned as a desired feature by P1, P5 and P7. All three of them stated that, they would put quietness in the first place while buying a new CPAP device if they would have a second change.

Comfort is mentioned by P1 and P4. Comfort was referred to as having nothing disturbing (P1) and not creating problems (P4) while they are using the device.

Ease of use is pointed out by P1, P5, and P6, and it is referred to as being *more understandable to use*.

3.3.8.3 Component features

This section describes the component related desires specifically mentioned by participants.

Mask is mentioned by P4, P6, P7, and P8. All of them said that they would buy a mask which does not leak air. P6 and P7 stated that they would buy a mask which is more adjustable and easy to put on. It should be noted that, P6 and P7 were using same brand of mask, which is completely different than other participants' brand of masks.

Humidifier is mentioned by P7 and P8. But it should be noted that, all of the participants who do not have a humidifier mentioned that as a problem before. But only P7 and P8 said that they would buy a device with a humidifier if they were given a second change.

Hose is mentioned by P1 and P6. P6 said that he would buy a device with a softer material of hose, and P1 stated that he would buy a device which holds its hose higher than his head (which helps him to turn to his sides without entangling himself with the hose).

Display is mentioned by P4, P6, and P8. P4 wanted a bigger display. P6 wanted the display to show a digital clock which would interest him more than some information that he does not understand. P8 wanted a display that shows the devices' own settings and memory clearly.

3.4 Results of the Field Study

In this section, the findings of the field study are arranged and summarized in reference to the field research questions. Contextual factors that have an effect on the use of home use CPAP devices are examined according to the findings initially, and factors that play a positive role on the use of home use CPAP devices and handling problems regarding use error and maintenance are explored further.

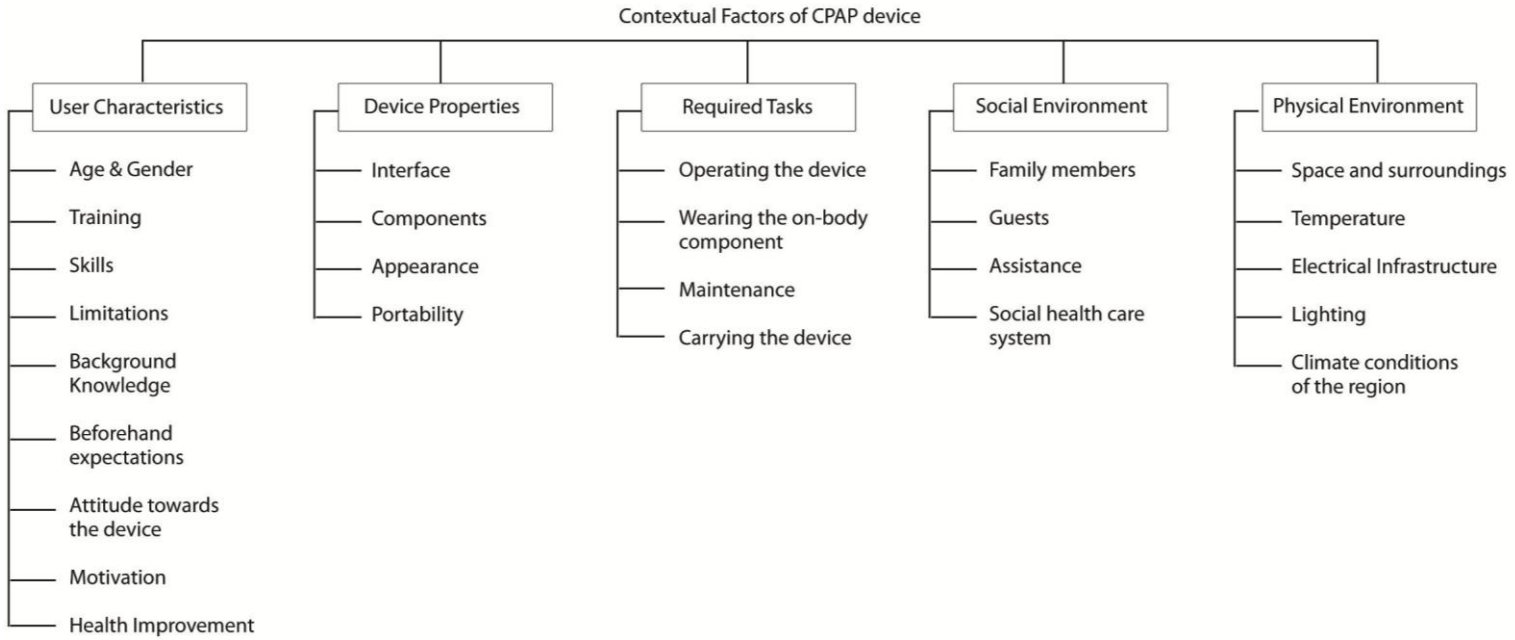

Figure 3.16 Contextual factors of CPAP Device

3.4.1 Contextual Factors Affecting the Use of CPAP devices

The answer to this question is sought for, both in the literature review on home use medical devices, and in the field study focusing on CPAP device usage, which is selected for its being used specifically in the home environment and for the absolute necessity of device adherence. According to the results of the field study, conducted with eight CPAP device users, the usage affecting factors are collated under the following titles: User Characteristics, Device Properties, Required Tasks, Social Environment, Physical Environment, and Health Improvement (Figure 3.16).

3.4.1.1 User Characteristics

Table 3.14 User Characteristics as contextual factors

User Characteristics	
1	Age and gender
2	Training
3	Skills
4	Limitations (Physical and mental conditions)
5	Background knowledge
6	Beforehand expectations
7	Attitude towards the device
8	Motivation
9	Health improvement

Age and gender: Even though there were no age related findings, it should be considered that, the age range of the sample size was similar due to the conditions of sleep apnea. On the other hand, males were found to be more sensible about

feeling in need of a device and more concerned about their spouses' ideas in terms of whether their spouses view about them are changed or whether they are disturbing them with their device usage. On the other hand, females were more relaxed about their spouses, since they were more concerned about their snoring before CPAP therapy. In addition, female participants had some difficulties while attaching and detaching device components, which requires more strength.

Training: Users were strongly affected by the beforehand training they got on the usage and the maintenance of their devices. A confident device use is found related with the proper knowledge on the device usage. Also, it is found that, reading the user manual has a positive effect on the proper knowledge on the device usage.

Skills: It was seen that the users did not learn or explore device controls and features adequately, although six of them reported that they are in good terms with electronic devices and computers. Therefore it can be said that, users were not able to relate any previous knowledge and experience with such devices to the medical device that they were using. Also, considering that the device labels, display information, and display information units were in English, and not in the local language, it can be said that, language played a sharing role on this situation.

Limitations: Physical and mental limitations are effective factors on the use of home use medical devices and on the users itself, according to the findings. Patient illness history, visual impairments, and psychological concerns were the effecting limitations in this study.

Background knowledge: It was seen that, previous knowledge about the prescribed therapy could cause prejudice for the device, provide a prepared state of mind, or create an opportunity to discover one's need for it.

Beforehand expectations: Expectations were mostly affected by background knowledge or assumptions. They may result in anxiety or becoming overly

concerned about the device usage. On the other hand, it was reported that, once the improvements in health were recognized, the negative expectations were overcome.

Attitude towards device: According to the findings of the study, attitude towards the device affected users in terms of keeping up with their adherence. Again, improvements in the health affected the attitudes of the users. Also, negative attitudes, such as feeling obliged to use a device in order to sleep better, were overcome by the recognition of the positive changes in health.

Motivation: Motivation of the users was found effective on the keeping up with the device adherence, and was found affected mostly by realizing the recovering health and life conditions, appreciated appearance features of the device, appreciated features of the components, and acceptance of the device by the social environment.

Health Improvement: According to the findings, users and their social circle were motivated to use the device after they recognized the improvements in their health. Therefore, health improvement is considered as a factor, which affects the device usage.

3.4.1.2 Device properties

Table 3.15 Device properties as contextual factors

Device Properties	
1	Interface
2	Components
3	Appearance
4	Portability

Interface: According to the findings of the study, what the display shows was effective on the usage. If the displayed information is not comprehensible for the users, displays are ignored. Also, readability was affected by lighting of the environment, display angle, having a backlight and the size of the display. Controls and display of a device were found to be important in terms of learnability. An easy to learn device will enhance the usage of the home use medical device. Also, an interface which allows the user to explore itself, which does not make the user concerned about making mistakes and which allows the user to return to its previous settings, will provide a better usage.

Components: Components, which are detachable or extend beyond the main device were found to be effective on the usage of such devices. These components may be more appreciable if they are designed to be easier to tidy up when not in use, and easier to clean and maintain. Also, on-body parts had a significant effect on the usage. Fitting to the dimensions of the body part, wearing or attaching easily on the body, and allowing free movement were the appreciable component features. Also, chosen materials of the components affected the usage and the user in terms of appearance, maintaining, and body contact.

Appearance: According to the findings, the devices can be found pleasing or disturbing depending on their appearances. Not fitting to the usage environment's decoration and furniture, and turning the environment to a hospital, were mentioned as problems. On the other hand, brighter colors, curvature forms and small size for the devices were appreciated.

Portability: Portability was found effective for carrying the device while travelling, and appreciated for its compact appearance. Smaller sizes and providing special cases for the devices were found more motivating to carry the device.

3.4.1.3 Required Tasks

Table 3.16 Required tasks

Tasks	
1	Operating the device
2	Wearing the on-body component
3	Maintenance
4	Carrying the device

Operating the device: Operating the device was carried out with the user's knowledge which is obtained through training or from the user manual. It was seen that, users, who do not have an adequate knowledge on the controls and display information of the device, when encountering with a problem, prefer to restart the device by its power button.

Wearing the on-body component: Putting on the on-body component was problematic, when the strapping and clipping parts were not easily manageable. It is useful to have easily adjustable strapping and clipping parts of the on-body components which do not require adjusting every time it is worn; otherwise, users tend to remove it without releasing these parts, which results in damaging them. Also, it was observed that, a fast release clip is found useful when the user needs to take a break while using the device.

Maintenance: Maintaining the device and its components was affected by the knowledge and training of the user. According to the findings, each user adapted different maintenance terms, but in general they were taking good care of their devices. It was seen that, cleaning the device was facilitated with easily detachable and washable parts of the devices.

Carrying the device: Carrying the device is required when users are travelling. Carrying the device is affected positively, if the device is small in size and if a special case is provided.

3.4.1.4 Social Environment

Family members: It is found that, family members could have both positive and negative effects on the usage and the users. Thought of disturbing the family members and receiving much attention from them while using the device, could result in feeling embarrassed or alienated. And, these feelings and thoughts in return, could result in disturbance while using, or abandonment of the device. At the same time appreciation and showing acceptance could motivate the users to keep up using the device.

Table 3.17 Social Environment as contextual factors

Social Environment	
1	Family members / People living in the same household
2	Guests
3	Assistance
4	Social health care system

Guests: Curiosity of the house guests was found affecting the users negatively. It was found that, users avoided guests who asked questions. Therefore, they preferred to hide their devices, or not using them in the presence of guests.

Assistance: Assistance was found to be related with the distributors, and doctors. According to the findings, users relied on the distributors, from which they bought their devices, when faced with a problem. It was found that, users lost contact with

their doctors in time, if they had been using their devices for a long time. Meantime, a caring distributor affects usage positively in terms of keeping up with the adherence, since in case of a device problem, it is solved by them. Also, the institution that the device is prescribed by, or who the user is trained by, has an effect on the usage, such as the example of sleeping lab for this study.

Social health care system: Social health care system was found effective since most of the time it is the provider of the device or care. It is found that, economical concerns and control of adherences are related with the social health care system. Users chose their devices according to the funding that the national health care provides for them, therefore a pleasing or a disturbing device experience is affected by it.

3.4.1.5 Physical Environment

Table 3.18 Physical Environment as contextual factors

Physical Environment	
1	Space and surroundings
2	Temperature
3	Electrical Infrastructure
4	Lighting
5	Climate conditions of the region

Space and surroundings: The space and the surrounding of a device affected the device usage positively or negatively. The space that the device occupied and the required storage conditions were effective on the positioning and placement of the device.

Temperature: It is found that, the temperature of the environment could have an effect on device usage. The heating system of the house was also found to be effective.

Electrical Infrastructure: The places of the electrical outlets and voltage of the environment that the device is used in were found to be effective on the usage, positioning and placement of the device.

Lighting: Lighting conditions, such as dim or bright lighting choices, and having the need of a light source while performing tasks were found to have an effect on the device usage. Not having to use a light source while using a device at night was important according to the study.

Climate conditions of the region: For this study, it was found that, climate conditions of the region where the device is used, affected the users and the device usage. Since a component, the humidifier, was provided by the national health insurance only for specific regions that have dry weather conditions, users who could not afford this component were experiencing difficulties.

3.4.2 Factors that play a positive role on the use of CPAP devices

According to the findings of the study, the most effective factor that plays a positive role on the use of CPAP devices is recognizing the improvements of one's health. Increasing quality of life due to decreasing symptoms and other related disturbances play a great role on the acceptance of the usage of devices and keeping up with its adherence. According to the participants' reactions and attitudes, it seems like even though they are having tough problems with the usage of the device, in the end, the recognized improvement in the health by time compensates for the difficulties they experience.

At the same time, features of the devices that provide comfort and ease of use, and appreciated appearance features such as color and curvature form of the device,

motivate users. Even though nearly every participant was lacking knowledge on the purpose of device controls, handling the device with just the power button resulted in the device to be evaluated as easy to use.

Lastly, acceptance and positive feedback of the users' social circle result in a positive approach to the device usage. Support from family members, especially spouses, motivates users in terms of keeping up with the device adherence.

3.4.3 Handling problems regarding use error and maintenance

It is observed that, users tend to ignore or bypass problems regarding errors and maintenance. For instance, users were restarting the device when they think that they made a mistake. Also, it appeared that they were not searching for a solution even when they thought they changed the device settings by mistake. They were significantly reliant to their distributor, confident that the distributor would fix the device in case of a serious error. When it comes to maintenance, some of the users stated that they did not know some terms of maintenance. Also, they were adapting different habits for cleaning the device. None of them thought that they were making a mistake regarding maintenance. It is seen that, some of the users just ignored or bypassed component fails without taking care of the problem.

3.4.4 Choosing home use medical devices

Based on the findings, users choose their devices mostly according to their price, country of origin and brand. Also, advice of the doctor was among the significant considerations of the users. Not knowing the other brands and models on the market and not having the opportunity to try other brands and models of devices limited half of the users while choosing their devices. On the other hand, the other half of users who reported that they have purchased their devices after a research on the market stated more preferences if they had the opportunity to buy a new device.

CHAPTER 4

CONCLUSION

In this chapter, the research questions will be revisited according to the findings of the literature review and the conducted field research that is presented in the previous chapter. Limitations of the conducted study and suggestions for further researches will be presented afterwards.

4.1 Research Questions Revisited

4.1.1 Driving Factors behind the Current Trend of Home Use Medical Devices

The driving factors behind the current trend of home care are explored in the literature review. It is found out that, the most significant factors behind the emergence of home care and home use medical devices are demographic changes and the constant development of the technology. Also, the other reasons behind this trend, which are investigated in Section 2.1.3, are found interrelated. With help of technology and scientific knowledge, quality of life is increasing and the human life span is extending. As a consequence, the older population of the world is increasing, and people's living standards are changing. While the living standards are changing, family structures are getting defragmented and female participation of educational life and labor force is increasing; which results in a shortage in the caregiver pool for the aging populations. At the same time, this changing life style of the era is affecting the current situation of non-communicable diseases, in a negative way. While non-communicable diseases are increasing and while the world population is aging, the governmental expenditure of the public health care is constantly increasing.

At the intersection of this chain of events, home care and home use medical devices constitute a solution for the problems that these events cause. With the help of developing technology and knowledge, more and more procedures and treatments can be migrated to the home with the help of home use medical devices. Therefore, caregiver shortage in the formal and informal care pool can mostly be overcome by these devices. Non-communicable diseases can be handled at the home instead of frequent or permanent admission to the hospitals. When the stress on the hospitals are decreased, burden on the public funding of healthcare can be overcome in terms of easing the burden of escalating number of non-communicable diseases and of the elder population, with the help of the distribution of healthcare between home care and hospital care.

To conclude, considering all of the mentioned changes in demographics and their economic and social outcomes, there will be an increasing need and demand for alternative solutions to conventional methods of care. It is evident that home use medical devices are becoming more important for today and the future. In the future, more people will need home care, and the medical device market will address not just hospital equipment buyers but also private customers, who are the home use medical device users and their caregivers.

4.1.2 Contextual Factors Affecting the Use of Home Use Medical Devices in reference to CPAP devices

As it was explored in the literature review, contextual factors that affect the use of home use medical device consist of factors of user characteristics (such as strength, vision, hearing, conditions or diseases, literacy, language skills, knowledge, experience, training, motivation), factors of device and its required tasks to operate it (such as ease of operation, ease of maintenance, error potential, complexity, learnability), factors of physical environment (such as location, temperature, humidity, contaminants, water supply) and factors of social environment (such as presence of family members, guests, children, caregivers, neighbors, colleagues and

their cultural beliefs, values and attitudes). In the literature, it is found evident that, these contextual factors have strong influence on usability. Enhancing usability eliminates use errors, provides ease of use and an enhanced experience and thereby motivates users to use the product.

The field study of this thesis spotted corresponding contextual factors that have effects on the use of home use CPAP devices, with a detailed insight in the light of the self-reports of the CPAP device users. Instead of putting out the situation of a home use medical device's environmental factors, contextual factors are sought among the expressions of users who are using an *absolute home use* medical device. At the same time, by doing so, factors leading to certain problems and factors resulting in motivation are also gathered, which are presented separately in Sections 3.3.2 and 3.3.3.

There may be contextual factors which are common for both leading to problems or motivation. For instance, social environment, appearance of the device, and some component features of the device can both cause disturbance or motivation. Also, users may not spot some contextual factors related problems they experience such as insufficient lighting or their lack of training. Moreover, required tasks may not be carried out properly, or some task may be skipped by mistake or completely ignored which might be affected by other contextual factors such as training, attitudes, assistance, and interface. Therefore, contextual factors of home use medical device may be interrelated in several ways.

In Figure 4.1, interrelation of contextual factors of CPAP devices is illustrated in the light of the findings of the field study. These relations of context of use factors may change from device to device, but the figure shows those that may be affecting each other and the importance of considering each factor according to this situation.

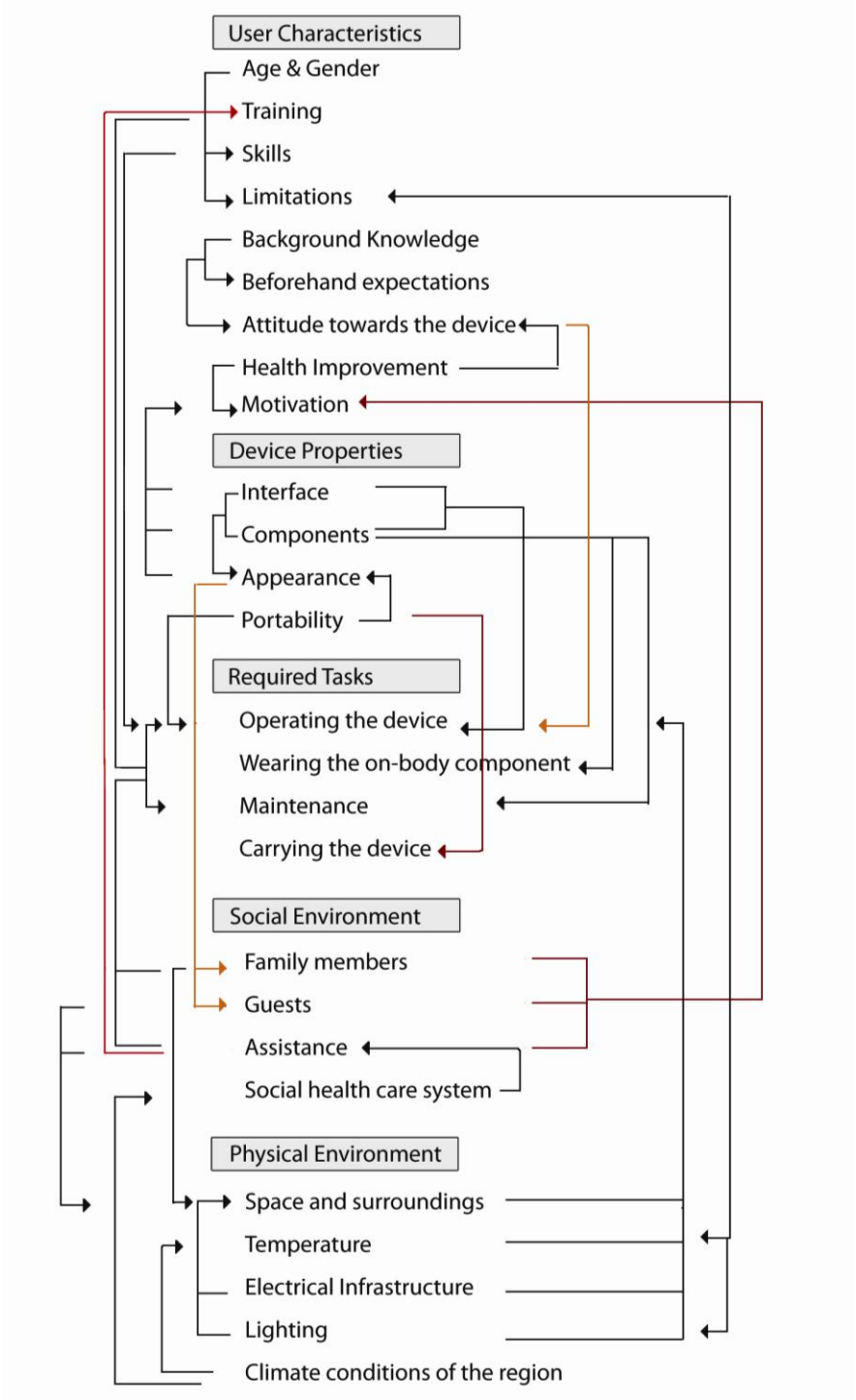

Figure 4.1 Spotted relationships between contextual factors of CPAP device

For example, training of the users is provided by assistance providers such as distributors and sleeping lab staff. Therefore, operating the device and the maintenance tasks are affected by training level of the user that his/her assistance provider provided. At the same time, operating the device and maintenance tasks are affected by family members since there were users who use their device carefully to not to disturb his/her family members, and there were users whose device maintenance was provided by their spouses.

As it was emphasized in the literature review as well, when medical devices migrate from the hands of professionals to the hands of lay users with diverse characteristics and to the uncontrolled environment of home, real life usage scenarios may vary according to the interrelated and converging context of use factors.

4.1.3 Needs of Home use Medical Device Users

Design of device

It can be said that, users need silent, easy to learn, easy to operate, easy to maintain, portable, and small size devices which do not disturb the people around them while they are using it. Readable display and understandable display information was among the other needs of the users. Also, devices with easily detachable and replaceable components could be helpful for the users.

Design of on-body components

First of all, one of the main needs of the users was a well-fitting mask, which does not leave sores and marks on their faces, which does not require tightening the straps to fix it to their head, which does not require extra effort to put on, and which does not obstruct their movements during sleep. Therefore, especially the home use medical devices which are used on-body or have a component that is worn on a body part need to be designed considering ergonomic dimensions of users, suitable materials for body contact, easy to adjust straps or clips, and plugs and joints which allow free movement.

Effective medical assistance

It is observed that, users are in need of better medical assistance. Within the circle of manufacturer, distributor, doctor and public health care institutions, it was seen in this study that the most easily reachable assistance was provided by the distributors. Distributors are at the convergence point between the relationships of manufacturer-distributor-user, and doctor-user-distributor. Also, meeting face-to-face with distributors does not require making an appointment beforehand; therefore in time they are considered as being the main assistance provider. It appears that users start to approach distributors for medical decisions too. For instance, in this study, three out of eight participants dodged around their prescribed pressure level that their doctors agreed to, with the help and opinion of their distributors.

Training of device usage

It was evident that, users need better training on the usage and the maintenance of their devices. In this study, all of the users were trained by their distributors; therefore their knowledge is within the boundaries of what their distributors provided for them.

Tracking of device adherence

It was observed that, users need an official adherence track. This was carried out by distributors for this study's case, but not all the distributors may be that concerning. When a user abandons a device without a notice to the related health care provider, or has problems which he/she does not care as much as he/she should, a scheduled track of adherence may help to solve the problems and get user back to his/her therapy.

Devices adaptable to diverse environmental conditions

Users need devices which are more adaptable to different physical environments. Problems related with the physical environment could have been eliminated with

the consideration of diverse environmental conditions. For instance, all of the devices' electric cords were fairly short and half of the participants were using an extension cord, considering that every wall of the rooms does not have an electrical outlet. As another example, only one of the devices had buttons which lit up when the device is on, considering that seven out of eight users were affected by the lighting conditions of their bedroom one way or another. Therefore, physical surroundings such as surrounding furniture, location of the electrical outlets, heating and lighting systems of the houses, contacting water, mould, dust, etc. should be considered in order to eliminate related problems and needs of the users.

Support of social circle

Lastly, as a significant need, users are in need of a supporting social circle, especially noteworthy for this study, more supporting spouse. Their support and consideration may be enhanced by the training with the spouse/family and providing better information on the expected improvements on patient's health before the device usage. For instance, after experiencing some difficulties with their social circle, some of the participants stated that, their social circle appreciated their device usage after recognizing the improvements in their health.

4.1.4 Attitudes and preferences of users towards home use medical devices

It can be said that, users have positive attitudes when their health is improving during or after the device usage. Also, approaching the home use medical device as a companion makes it easier to adapt to the adherence. On the other hand, feeling of mastery, and assuming him/herself as an expert of the device causes the user to be more reckless in terms of keeping up with the advices of the doctor. Lastly, feeling of the obligation of using a device may be depressing but at the same time this feeling may be overcome with an attitude of "health is more important", like most of the participants of this study have.

When it comes to preferences, low price, reputable country of origin and well-known brand are among the primary preferences of the users. Portability, quietness, ease of use and comfort are among the following preferences. Also, appearance related factors such as color and form are found effective on the preferences.

4.2 Recommendations for the Stakeholders

4.2.1 Recommendations for Designers and Manufacturers

Fitting in environment

To suggest a solution for one of the significant problems, the noise level and vibration of a device should be optimized in relation to the environment which the device will be used in. For example, for a home use medical device which is used in a bedroom while sleeping, attention should be paid for the noise that the device causes.

For electronic home use medical devices, providing a long power cord which reaches possibly far electrical outlets, an adapter which prevents high voltages and a switch which cuts the electric permanently might be useful. It is observed that, most of the users were afraid of leaving the device on stand-by because of the unstable voltage of their neighborhoods; therefore they were unplugging it every time after the usage or they were feeling in need of a protective multi socket.

When a home use medical device is used permanently as a part of their everyday life, some users may seek additional functions. In CPAP's case, featuring everyday life needs such as an alarm clock, a night lamp and a radio were additional functions that were desired.

On-body components

Home use medical devices which are used on-body, or which have a wearable component should have joints and straps which allow users to move freely. This

may be achieved by lose and easily rotating joints, and choosing proper materials which are endurable and soft enough to bend but hard enough to function. Also, strapping and clipping parts of the on-body components should be adjusted easily. For this study, cotton straps with clips are found more useful compared to hook and loop fasteners, considering they are used for fixing the mask on the head. In addition, a fast release clip may be useful when the user needs to take a break while using the device or when there is a case of emergency. Lastly, on-body /wearable components should be designed to be adjustable for different sizes of bodies easily and fittingly.

Interface

In the study, there was a CPAP device of a user which does not feature a display. It is observed that that the user did not know about a device feature, the ramp feature, which would have been useful to eliminate his problem of high air pressure while drifting into sleep. Therefore, it would be useful to feature a display if a home use medical device has features which are adjusted or turned on and off, to understand what kind of changes are done to the device.

If a home use medical device features a display, readability of it poses a significant effect on its usage. Readability is found related with the size and the angle of the display, size of the fonts, backlight brightness and color, and the lighting conditions of the use environment.

The information that the display of the device shows, is found important as well. Findings of the study revealed that, if the displayed information is not comprehensible for the users, displays are ignored, and when the displays are ignored, users tend to ignore learning and discovering the features of the device.

An easy to learn interface will enhance the usage of the home use medical device. Also, an interface which allows the user to explore itself, which does not make the user concerned about making mistakes and which allows the user to return to its

previous settings, will provide a better usage. Therefore, interface of a home use medical device should be paid great attention to, in terms of learnability. In CPAPs' case, users were mostly concerned about changing the adjustments of the device, which their distributor made for them, by pressing a wrong button by mistake. So, they had been hesitating to use device controls since the beginning of their device usage. Considering this, in addition to the factory reset, a reset to previous settings might be useful to ease this anxiety. Also, in addition to the icons on the buttons, labeling the buttons with their corresponding function will enhance usability.

It is revealed that, the controls of the device may be used without looking, especially for the devices which are used at night while sleeping. In CPAPs' case, users had to turn the device on and off in the middle of the night when it is needed, with the aim of not disturbing their spouses by turning the lights on. In that case, different sizes and different placements and grouping of the buttons according to their functions might be helpful in order to spot them by the guidance of touching, and without looking. This may also be helpful for users with visual impairments. Also, as another suggestion, providing backlight for the buttons would be useful for such devices, just as one user pointed out that he does not need a night lamp thanks to button backlights.

It is observed that, interface language and display information units were in English and some of the users were interpreting the display information in a wrong way. For that reason, showing the display information in users' local language may enhance the comprehensibility of the device.

During the study, it was seen that some of the devices had displays, which only showed the values of the changed setting. For instance, one user pressed the information button (labeled as "i"), and the display only showed "3xx h", which caused the user to think that he changed the pressure level that the device applies. Also that user pressed humidifier steam level buttons (labeled as "<" and ">" placed both sides of the steam icon), but he feared that he changed some previously

adjusted settings again. Therefore, showing what kind of setting is changed on the display as a title, instead of only showing numbers of values, would be helpful in order to prevent this kind of confusions.

Storage and maintenance

If a home use medical device consists of extending components and cables, the storage of this device should be considered. If a device is not used for periods of times, a specific case or cover should be provided to store it tidily, not just for carrying but also while it is standing. This may also help to keep the device safe from children and clean from dust. Also, occupying a smaller space may be useful if a device has to be kept in a specific place standing permanently and if a device has to be carried while travelling. Since a home environment should provide a cozy and comfortable living environment, considering the device appearance and size in relation to the decoration concerns, may be useful.

It is found that, having washable parts is effective in terms of ease of maintenance. This may be useful for other home use medical devices. Also, it is observed that, components which do not require muscle power to detach may be useful, especially for female users.

Hose of the CPAP devices are found aesthetically displeasing and hard to wash because of their ribbed plastic body. Therefore, for such kind of components, covering them with washable cloths may be useful in order to cover and maintain them.

It is observed that, there were some failing components such as the forehead pillow of the mask and the hose between the humidifier and device. While a user changed that forehead pillow only without changing the mask itself, the other user who experienced the problem was afraid of having to change the entire mask and therefore he was using his mask without that component. The other user, who had a torn hose, covered it with aluminum foil. Therefore, providing replacement for that

kind of small components might be useful instead of changing bigger components that smaller ones are attached to.

4.2.2 Recommendations for the Healthcare System

Assistance

It is found that, users tend to skip reading the user manual. This may be related with its instructiveness or just the users' habits. Stated by a user, a Multilanguage user manual is found to be complicated and hard to understand. On the other hand the same user appreciated the little booklet which is in her local language and said she is keeping it close to her device. Therefore, a small and easy to handle user manual may be useful in order to be perceived as easy to read and kept near the device.

Providing a more efficient medical feedback and control assistance for home use medical device users might be useful in order to control and help to keep up their adherence, find solutions for their medical problems, and prevent changing prescribed therapy in their terms.

Training

If the home use medical device is purchased from a distributor, the distributor may be the only source of training. Also, the internet provides home use medical devices without demanding a prescription and without an interaction with the users. Therefore, users are mostly learning to use and maintain their devices through user's manuals and/or distributors. As a result, users may not have a clear understanding of how to use the device properly and how to deal with the problems and errors.

As a suggestion, detailed demonstration by the doctors and the other health care staff may enhance the training of the users. Providing a reachable contact number might help users in feeling safe and confident, as well. Again, a secondary less technical but more practical guidance booklet may be provided with the devices. If

the training is provided by the distributors, it can be recommended that all device features can be covered during training, the degree of detail varying according to the users' capabilities and background knowledge, in order for users not to feel anxiety when interacting with the device. Forbidding the users from some features other than those mostly used, might impose stress upon the users. Also, this may result in using the device without its full functions, and not being able to intervene when some problem occurs, even though users may have the capability of solving it on site..

Affordability and health insurance

It is observed that, auto-CPAPs provided a more comfortable usage for the users in terms of breathing and falling asleep easier. Since auto-CPAPs adjust the air pressure according to the breathing of the user during different phases of sleep all through the night, continuous and fixed air pressure affected users in a negative way. Prescribing an auto-CPAP or a CPAP is the doctors' decision, but most of the time the doctors' decision is related with the funding which is provided by the users' health insurance. Sometimes doctors prescribe directly an auto-CPAP or sometimes they prescribe a CPAP therapy, leaving the decision to their patients' financial conditions. Therefore, when it is medically possible, providing an auto-CPAP for users may be useful in order to motivate them to keep up with their adherence with a more comfortable device usage.

Acquiring a humidifier component, which is offered optionally, is found effective on the usage and motivations of CPAP device users. In Turkey, a humidifier component is provided by the National Health Insurance, only for those users who live in specific regions that have dry weather conditions. On the other hand, it is seen that users with physical limitations could require such a device to warm and humidify the given air pressure, apart from the weather conditions of the region that they live in. For example, users with chronic throat or lung related diseases such as chronic bronchitis, sensible lungs and tonsils, or chronic pharyngitis, reported that,

they feel the need of a humidifier but their health insurance does not provide one. Therefore, it would be useful to take into consideration the physical limitations of the users while providing a humidifier component.

4.3 Limitations of the Study

There were some limitations which may have an effect on the results of the study. First of all, recruiting participants who would allow the researcher in their private use environment (i.e. bedroom) was a difficulty. Also, having to recruit participants independent from institutions or funding was another difficulty. These limiting factors have affected the sample size. Therefore, the sample size makes it difficult to assess whether the responses reached saturation before deciding on to cease the interviews. However, the analysis of the collected data showed that, semi-structured in-depth interviews with eight participants provided fruitful insight for the study topic.

The other limitation of the study was the gender imbalance of the sample size. Males have higher risk of having sleep apnea than females; therefore most of the CPAP users are male. This situation had a reflection on the sample. Lastly, since half of the participants have been recruited through the same distributor, the findings of the study may be affected by this specific distributor's relationship with his customers.

4.4 Concluding Remarks

As it is mentioned previously in Section 2.3.2, designers and manufacturers tend to fall short in terms of predicting and including use environment factors and user characteristics. Designers are more focused on "how the design should be used" than "how it might be used" (Hale et al., 2007, p.314) and not considering real usage scenarios may result in misuse; because in reality, a product may be used in and out of designers' predicted safe limits. As stated by Hassenzahl (2003), "there is no guarantee that users will actually perceive and appreciate the product the way

designers wanted it to be perceived and appreciated" (p. 33) and designers may not even visit and observe actual conditions of where the product will be used and who the product will be used by (Hale et al., 2007). In case of medical devices, safety oriented trials and regulatory documents may eliminate serious hazards, but problems and related situations which affect device usability and user experience may not be discovered. On the other hand, on-site and face-to-face studies with users may reveal significant problems and opportunities that laboratory trials and regulatory guidance materials do not inquire.

Also, even though it was not among the questions that this study seeks to answer, it is observed that, all of the participants were extremely positive, appreciating and collaborative during the interviews. All of them approached the study as an opportunity of self-expression to make heard their problems, concerns and approvals related with their devices.

At the same time, there were some difficulties while conducting the field study with the users in their homes. First of all, the warm up phase of the interviews required a long time to break the ice between the interviewer and the interviewees, since the interviewer is approached as a stranger guest, naturally. At first, there happened to be some doubts of the interviewees about privacy, which were later on eliminated by a detailed introduction of the interviewer and detailed explanations about the purpose and the method of the study. Also, sometimes family members other than the interviewee were curious about the interview, which resulted in gathering at the door of the interview site. Therefore, a second request had to be made politely by repeating the requirement of interviewing only the device users, in order to start the interview face to face. Another difficulty was the ambient noises (chatting family members and TV sound), which requires a good recording device. Even though a good recording device was used during the interviews, transcription of the recorded data required extra effort due to these ambient noises. Lastly, even though the spouses of the main interviewees were requested to be interviewed after the main user of the device, some of the spouses attended the last minutes of the interviews

while they were offering tea as an act of traditional Turkish hospitality. Although this situation did not affect the interviews negatively, the order of the closing questions has changed accordingly. Other spouses were interviewed during the tea-talks in the living rooms; therefore these interviews lasted longer and were more relaxed with the help of the living room ambience. It should be noted that, every interview ended up with tea-talks, and with the help of these more relaxed tea-talks, more insightful everyday stories about the CPAP usage were shared during these chitchats.

4.5 Suggestions for Further Study

To begin with, it should be mentioned that, this study does not cover all of the contextual factors of the home use medical devices in general. The chosen device for the study, the CPAP device, is a home use medical device which has specific environment and conditions to use. There is a vast range of home use medical devices which are used in different conditions. Therefore, an overall generalization may not be achieved by the findings of this study. For further studies, contextual analysis of different home use medical devices may be carried out in order to gather common and differentiating contextual factors of such devices.

Also, conducting studies with larger sample groups may be useful in order to make more certain assumptions. This may be carried out with the help of institutions such as hospitals and governmental institutions of health care, in order to reach the sample size more easily and to have a well-balanced age and gender groups.

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APPENDIX A

CHANGE IN THE LIFE EXPECTANCY

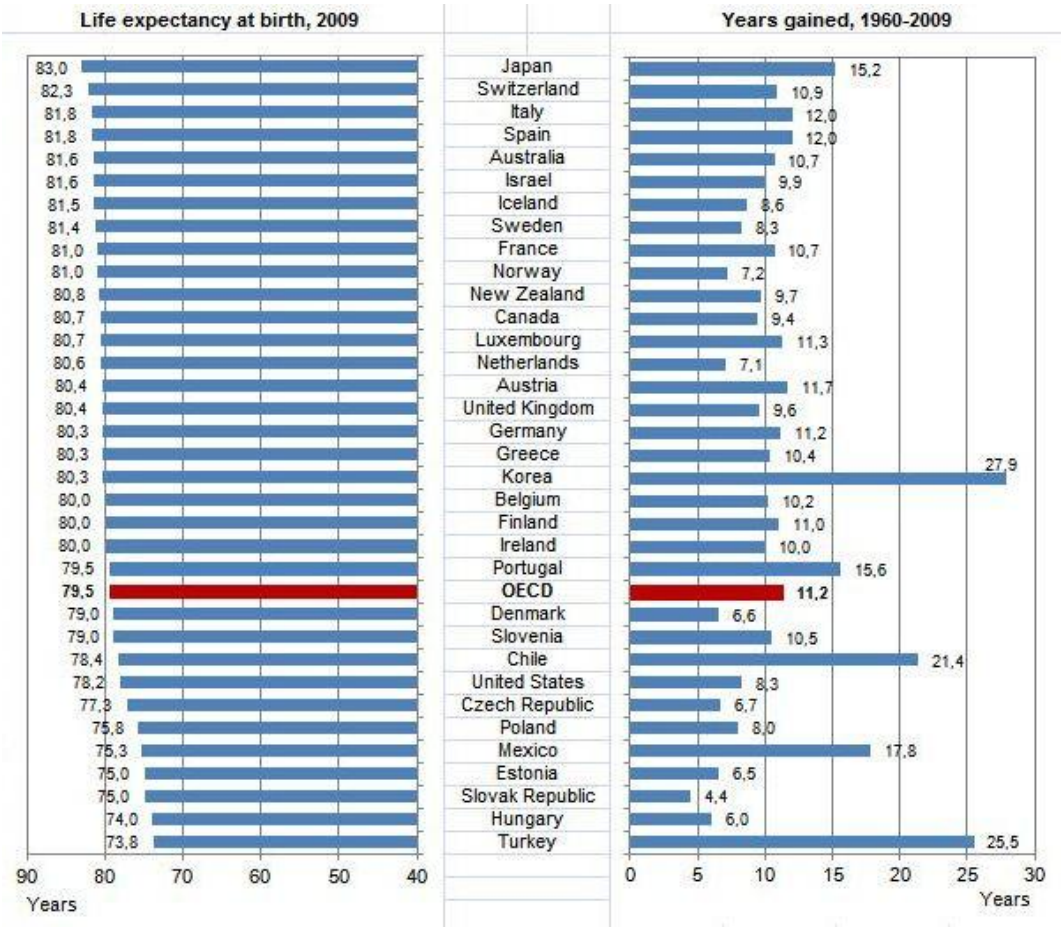


Figure A.1 Life expectancy at birth 2009 and years gained since 1960 (retrieved on April 05, 2013, from: http://dx.doi.org/10.1787/888932523177)

APPENDIX B

CONTEXT ANALYSIS GUIDE BY THOMAS AND BEVAN (1996)

USER CHARACTERISTICS	**User Types**	*User types being considered*
		Secondary or indirect users
	Skills&Knowledge	*Experience*
		Training
		Qualifications
		Relevant Input skills
		Linguistic Ability
		Background knowledge
	Physical Attributes	*Age Range*
		Typical Age
		Gender
		Physical limitations and disabilities
	Mental Attributes	*Intellectual attributes*
		Motivations
	Job Characteristics	*Job information*

TASK CHARACTERISTICS	**Task Goal**	*Main objective to perform task*
	Choice	*Can users choose whether or not to use the product to achieve their goals?*
	Task Output	*What are the outputs from the task?*
	Side Effects	*Are there any adverse side effects that may occur as a result of carrying out this task?*
	Task Frequency	*How frequently is the task normally carried out?*
	Task Duration	*How long does the task generally take the user?*
	Task Flexibility	*Do users have to follow a pre-defined order when carrying out the task?*
	Physical & Mental Demands	*any factors that may make the task physically or mentally demanding*
	Task Dependencies	*What information or resources are required by the users in order to perform the task?*
	Linked Tasks	*Does the user normally carry out the task as part of a set procedure?*
	Safety	*To what extent is this task hazardous to the health or lives of the user or other individuals?*
	Criticality of the task output	*How critical is the output of the task?*

PHYSICAL ENVIRONMENT	**Environmental Conditions**	*Atmospheric conditions*
		Auditory environment
		Thermal environment
		Visual environment
		Environmental instability
	Workplace Design	*Space and furniture*
		User posture
		Location
	Health &Safety	*Health hazards*
		Protective clothing and equipment

ORGANISATIONAL ENVIRONMENT	**Structure**	*Group Working*
		Assistance
		Interruptions
		Management Structure
		Communications Structure
	Attitudes & Culture (If the product is being used by an individual for his or her own purposes, this section is not relevant)	*IT Policy* (This question will not be relevant for non - IT products)
		Organisational aims
		Industrial relations (What is the status of industrial relations within the company?)
	Worker/User Control (This subsection is concerned with the factors which affect productivity and quality. If the product is being used by an individual for his or her own purposes, this subsection may not be relevant)	*Performance & Mentoring*
		Performance Feedback
		Pacing

TECHNICAL ENVIRONMENT	**Hardware**	*What hardware is needed to run the product?*
	Software	*What software is needed to run the product?*
	Referance Materials	*Please note, this does not refer to the instructional materials for the product.*

APPENDIX C

C.1 CONSENT FORM (English Version)

This study is being carried out for my Master's Thesis research which is going on in Middle East Technical University, Department of Industrial Design. I will ask some questions about your opinions on and experiences with the usage of your own CPAP device, which will take an hour or a little less.

There is no right or wrong answers for the questions. Your personal information will be kept confidential and your opinions will only be used for research purposes.

Thank you for your valuable time and consideration.

Do you agree to participate for this study?

Name Surname
Signature

Merve Aydın | 0505 --- -- -- | merve.aydin@metu.edu.tr

C.2 CONSENT FORM (Turkish Version)

Bu çalışma, Orta Doğu Teknik Üniversitesi, Endüstri Ürünleri Tasarımı Bölümü, Yüksek Lisans programı dahilindeki tez çalışmam kapsamında yaptığım bir araştırma için yürütülmektedir. Sizinle kırk beş dakika - bir saat arası sürecek olan bir mülakat yapacağız. Kullandığınız CPAP cihazlarının kullanımıyla ilgili görüşleriniz ve deneyimleriniz hakkında sorular soracağım.

Soruların doğru ve yanlış cevapları yoktur. Kişisel bilgilileriniz gizli tutulacak, görüşleriniz ise sadece arastırma amacıyla kullanılacaktır.

Değerli zamanınızı ayırdığınız için teşekkür ederim.

Bu çalışmaya katılmak istiyor musunuz?

İsim Soyisim
İmza

Merve Aydın | 0505 --- -- -- | merve.aydin@metu.edu.tr

APPENDIX D

D.1 INTERVIEW GUIDE (English Version)

User

Demographics

Age :

Gender :

Occupation :

Computer / electronic devices level:

General History of Illness (Warm up)

- How did you understand that you have a sleep apnea problem? Is there anyone with the same sleep problem in your family?
  Did you have any knowledge about CPAP devices before you were prescribed for one?
- Is there any other medical device that you use in your home?

Knowledge & Training

- How long have you been using a CPAP device?
- Did you ever use another model/brand of CPAP, other than yours?
  If yes: Diferences? Why did you change it?
  How long have you been using this one?
- How did you learn to use the device? (From who?)
- Did you read the user manual?
  If no: Why?
- Do you get any help from others while using the device? From whom?

Purchase Decision

- Where did you get your CPAP device ?
  Who chose its model and brand? (yourself, doctor, distributor, etc)
- Why did you buy this one?
- Did you make any research before buying yours?

Task

Usage

- Can you introduce your device? How does it work? How do you turn it on? How do you put it on? Could you demonstrate it?
- What can you tell about the display and the buttons? What do these buttons do? What does the display show?
  Which ones do you use more?
  Are there any buttons/features that you do not use?

Ease of Use & Related problems

- In your opinion, do you think that you are using the device as it should be used?
- About the device, is there anything that you want to do but you cannot?
  Is / Was there anything that you don't understand about the device usage?
  If so: How did you handle it? Did you get any help? From whom?
- Did you experience any problem? (While putting it on / While sleeping with it, etc)
- What do you think about the use of this device in general? Is it easy to use, difficult to use?

Error & Handling

- Did you encounter any device error? Did it ever fail? How did you understand that?
- What did you do in that case? Did you get any help? Who did you take the device to?

Maintenance & Service

- Did you ever contact the technical service or the distributor? Why?
- Does your device or its components (cables, hose, mask, humidifier...) need any periodic maintenance? Did you ever do something in terms of maintenance?
- Are there any replaced parts? Why?

Product Appearance/Features - Suggestions

- What do you think about the appearance of your device?
- Which features would you change if you have a chance?

ADL

Adaptation

- What were you expecting before the CPAP therapy? What did you feel at first? Were there any concerns?
- What were your thoughts when the device first arrived at your home?
- How was it, when you first started to use the device? For example what did you experience in your first week? ->How is it now? What did change since then?

Social Environment

- In your opinion, what does your family, for example your wife, think about your device?
  -> Did they get used to it?
  ->Did they encounter any difficulties?
  -> What did they think when the device arrived at home?

Coping

- Did you ever experience a situation in which you could not use the device? What was it?
- Did you ever discard or forget to use the device? Why?
  -> If yes: Do you have any precausion to not to forget?
- Did you ever take off your mask in the middle of the night? Why? (Was it an emergency case? Did the device stop by itself?)
- In you opinion, does this device make life easier, or harder?-> Why? In which cases?
- Are there any changes in your daily life or in your sleeping habits?

Relationship with Doctor

- How often do you meet with your doctor? Did you ever meet with your doctor since the beginning of your device usage?
- Did you ever contact your doctor, about anything that is related with the device or therapy?
- (if so) Did you share your device related problems with your doctor?

Home

Physical Environment

- How do you keep the device in daytime, while it is not in use? Are there any specific storage conditions? Why?
- Did you make any changes in your home or bedroom, after the device arrived?
- Did you ever experience anything in particular in relation to the surroundings of the device?

Outside Home

- Did you take your device with you, outside home? / Do you take your device while you are travelling?

  If yes:
  Did you experience any problems while doing so?
  Did you ever forget to take it with you? Did you ever forget a component?

  If no:
  Why?
  -> What do you think your device should be like for you to take it with you during travel?
- What do you think about the carrying conditions of the device?

Conclusion

- Assume that you are going to buy a CPAP device again, do you have any requirements or necessities that you want in that product? What will be the most important thing that you will pay attention?

D.2 INTERVIEW GUIDE (Turkish Version)

Kullanıcı

Demografik

Yaş :

Cinsiyet :

Meslek :

Bilgisayar/elektronik cihaz kullanımı:

Rahatsızlık geçmişi (Isınma)

- Rahatsızlığınız nedir? Nasıl anladınız?
  Ailenizde var mı?
  Daha önce CPAP ccihazları hakkında bir bilginiz var mıydı?
- Bunun gibi evde, sağlığınız için kullandığınız başka bir medikal cihaz var mı?

Bilgi ve eğitim

- Ne kadar süredir CPAP cihazı kullanıyorsunuz?
- Daha önce başka bir model/marka kullandınız mı? Varsa: Farklar? Neden değiştirdiniz? Bu cihazı ne kadar süredir kullanıyorsunuz?
- Cihazı kullanmayı kimden öğrendiniz?
- Kullanım klavuzunu okudunuz mu? Hayır: Neden?
- Kullanırken yardım aldığınız biri var mı? Kim?

Satın alma kararı

- CPAP cihazınızı nereden temin ettiniz? Kim seçti? (Doktor/kendisi vs)
- Niçin bu cihazı aldınız?
- Almadan önce herhangi bir araştırma yaptınız mı?

Görev

Kullanım

- Cihazınız hakkında kısa bir bilgi verir misiniz? Nasıl çalışıyor? Nasıl açılıyor? Nasıl takılıyor? Gösterir misiniz? (Demonstration)
- Tuşlar / Ekran hakkında bilgi verir misiniz? Şu tuş(lar) Ne işe yarıyor? Ekranda neler gösteriliyor? Hangilerini daha çok kullanıyorsunuz? Kullanmadığınız bir özellik var mı?

Kullanım kolaylığı ve problemler

- Sizce cihazınızı doğru kullanıyor musunuz? (Kullanıcıya göre)
- Cihaz ile alakalı yapamadığınız bir şey var mı? Anlamadığınız bir özellik var mı? Daha önce zorlandığınız bir şey oldu mu? Olduysa: Nası hallettiniz? Yardım aldınız mı? Kimden?
- Herhangi bir problemle karşılaştınız mı? (Cihazı takarken & cihaz ile uyurken)
- Sizce bu ürünün kullanımı nasıl? Sizce bu ürünün kullanımı kolay mı zor mu? (Cihazı takarken & cihaz ile uyurken)

Hatalar ve çözümler

- Cihazınız hiç hata verdi mi? Bozuldu mu? Nasıl anladınız?
- Cihaz hata verince ne naptınız? Birinden yardım aldınız mı? Kime başvurdunuz?

Bakım ve servis

- Kullanılan süre boyunca hiç teknik servisle/ alınan yerle iletişime geçtiniz mi? Neden?
- Cihazınızın ve parçalarının (kablo, hortum, filtre, maske, nemlendirici) herhangi bir periyodik bakıma ihtiyacı var mı?
- Hiç bakım uyguladınız mı? Ne yaptınız? Değiştirilen parça var mı? Hangisi?

Ürin görünümü/Özellikler ve öneriler

- Cihazın görüntüsü hakkında ne düşünüyorsunuz? Nasıl olsa daha çok beğenirdinız?
- Cihazınızda değiştirmek istediğiniz bir özellik var mı?

Günlük Hayat

Adaptasyon

- Cihazınızı kullanmaya başlamadan önce neler düşünüyordunuz? Ne hissettiniz? Çekindiğiniz bir şey var mıydı?
- Cihazınız eve ilk geldiğinde ne düşündünüz ?
- İlk kullanmaya başladığınızda nasıldı? Mesela ilk kulandığınız hafta neler yaşadınız? -> Şimdi nasıl? Değişen bir şey var mı?

Sosyal çevre

- Evdekiler (mesela eşiniz) ne düşünüyorlar sizce? -> Onlar alıştı mı ? ->Onlar için bir zorluk oldu mu? -> Ürün eve ilk geldiğinde ne düşündüler?
- Hiç herhangi birinden çekindiğiniz oldu mu?

günlük hayata uyum

- Hiç herhangi bir gece uyurken, cihazınızı kullanamayacağınız bir durum oldu mu? Neden? Ne oldu?
- Hiç uyumadan önce cihazınızı takmayı unuttuğunuz veya boşverdiğiniz oldu mu? Neden? -> Evet ise: bunun için bir önleminiz var mı?
- Hiç uykunuzun arasında cihazınızı çıkardınız mı? Neden? (acil bir durum mu vardı? Cihaza bir şey mi oldu?)
- Sizce Bu cihaz hayatı kolaylaştırıyor mu, zorlaştırıyor mu? -> Neden? Hangi durumlarda?
- Günlük hayatınız veya uykunuz ile ilgili bir değişiklik var mı?

Doktor ile ilişki

- Doktorunuzla ne sıklıkla görüşüyorsunuz? Ürünü kulanmaya başladığınızdan beri doktorunuzla hiç görüştünüz mü?
- Doktorunuza cihazla ilgili herhangi bir konuda danıştınız mı?
- (daha önce düzenli kullanmadığını söylediyse) Cihazı düzenli kullanmadığınızı doktorunuz ile paylaştınız mı?

Ev

Fiziksel çevre

- Cihazınızı kulanmıyor iken (gündüz) nasıl saklıyorsunuz? (Özel olarak bir saklama koşulu/biçimi var mı?) ->Neden?
- Cihazınızı eve getirdikten sonra evinizde veya yatak odanızda herhangi bir değişiklik yaptınız mı?
- Cihazın bulunduğu oda ve cihaz çevresi ile ilgili özel bir durum var mı?

Evin dışı

- Daha önce hiç cihazınızı evden başka bir yere götürdünüz oldu mu? Yatılı olarak bir yere giderken (Tatil, ziyaret, misafirlik vs..) cihazınızı götürüyor musunuz?

  Götürüyorum:
  Bu konuda bir sıkıntı yaşadınız mı?
  Unuttuğunuz oldu mu? Herhangibir parçasını unuttuğunuz oldu mu? (Meske, hortum, kablo...)

  Cihazınızı ev harici kullandığınız bir ortamda yaşadığınız bir sıkıntı oldu mu?

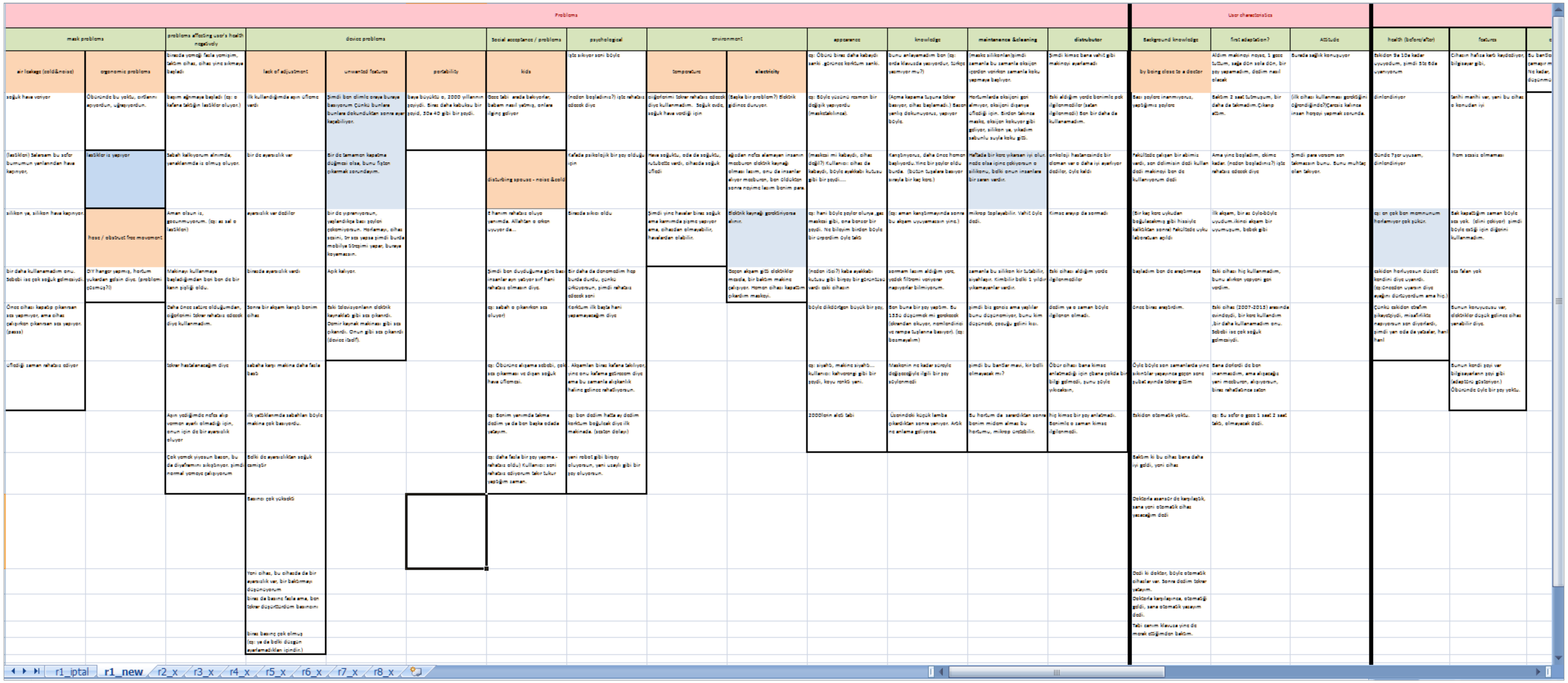
  Götürmüyorum:
  Neden?
  -> Sizce cihazınız nasıl olsaydı yatılı gittiğiniz yere cihazınızı da götürürdünüz?
- Ürünü toplaması, kurması, taşıması sizce nasıl?

Son

Şimdi tekrar bir CPAP cihazı alıcak olsanız, mutlaka şöyle olmalı dediğiniz bir özellik var mı? En dikkat edeceğiniz özellik ne olurdu? Bu tarz cihazları seçerken sizce en önemli kriter nedir?

APPENDIX E

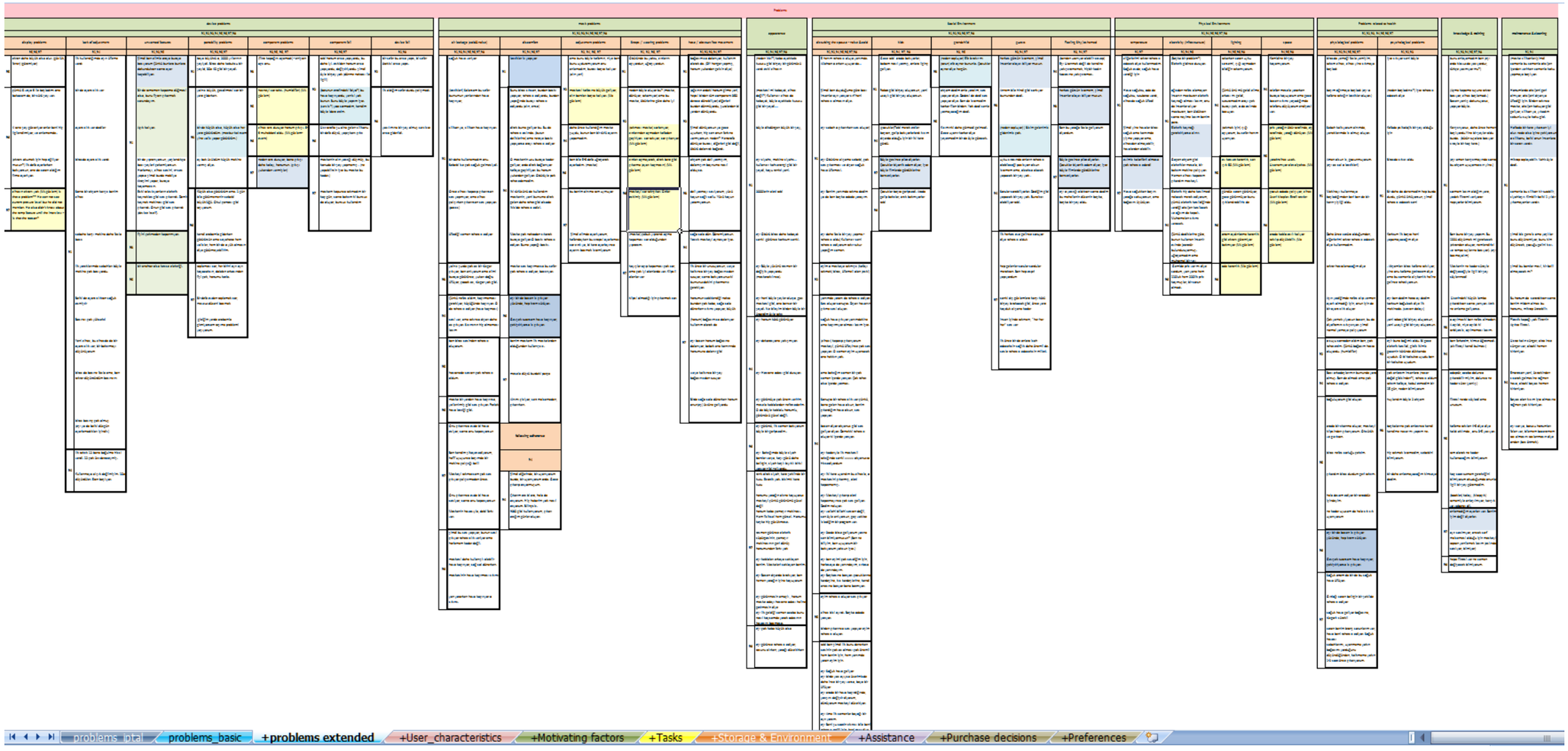
E1. EXAMPLE OF A DATA ANALYSIS DOCUMENT (Per Participant)



E2. CLOSE UP OF AN EXAMPLE OF A DATA ANALYSIS DOCUMENT (Per Participant)

				User characteristics			Motivating factors		Usage			
oblems	device problems	appearance	knowledge	Background knowledge	First adaptation	Attitude	Health (before/after)	Social acceptance / positive	Screen	Buttons	mask removal - midnight	
air leakage (cold&noise)	portability	renk olrak siyah, kare şeklinde bir kutu. Estetik yok. bizimki kara kutu	anlamadığım ayarları var. Benim işim değil diyorlar.	Kalp doktorum bunu önerdi	önce eyvah dedik, ilk duyumdan etkiden dolayı.	su hava gibi lazım. Bir nefes gibi ihtiyacın oluyor	Soğuk algınlığım varken cihazsız bir yere gitmem.	Sonra sonra eş- dost cihazı görmek istediler	ekranı yok!	önce maskeyi takıyorum sonra burdan açıyorum.	ben maskeyi full çıkarmıyorum, maske üzerimde gidiyorum. Hortumu ağzımın ordan çıkarıyorum, makinadan	yaln dedi
Onu çıkarınca evde bi hava esiyor, sonra onu kapatıyorsun	toplaması zor, her birini ayrı ayrı koyacaksın, dolabın arkasından fişi çek, hortumu katla.	hortumu yatağın altına koyuyoruz maskeyi çünkü görünümü güzel değil	ayrı satılmıyor, ancak sarf malzemesi olduğu için maskeyi toptan yenilemek lazım (aslında satılıyor, bilmiyor)	by family member	Biz de öyle çok zahmet çekeceğiz zannettik.	hiç unutmuyorum onu, çünkü faydalı olduğunu biliyorsun.	Ama kalp doktorum fark olduğunu söylüyor	eve gelenler, nagatif bakarken pozitif bakmaya başladı inceleyince		powera basınca açılıyor	uykuda takmak çok zor o yüzden açmıyorum cırtları çıkarmıyorum	kışın kere
Ben kendim şikayet ediyorum, hafif uyuyunca başımda bir makina çalıştığı belli	Bir defa evden toplamak zor, mevcut düzeni bozmak	hortum kaba çamaşır makinası. Hem fiziksel hem görsel. Hortumu keşke hiç gözükmese.		Daha önce bu cihazdan haberim vardı.	Fakat biz aldıktan hiç öyle bir şey olmadığını gördük.	kolay niye diyorum faydasından dolayı. Sağlıklı insan için zor da bizim için kolay.	eş: eskiden çok koltukta uyuyakalırdı, şimdi hiç yapmıyor	sonra gerçi onlarında eşleri almaya başladı, herkesin negatif fikri pozitife döndü aslında sayemde.		diğer tuş, içindeki ölçümleri ayarlamak için.	(maske) çabuk yıprandı açma kapaması zor olduğundan yıprattım.	Çünk geli yıka
Maskeyi takmazsam çok ses çıkıyor çalıştırmadan önce.	gittiğim yerde arabamla gitmiyorsam taşıma problemi yaşıyorum.	resmen görünce elektrik süpürgesinin, çamaşır makinasının geri dönüş hortumundan farkı yok		Hanımın amcasının eşi bahsetmişti.	Merakımdan kullanım klavuzunu okudum.		hayatı kolaylaştırıyor, öle olmasa takmam, faydalı olduğunu bilerek takıyorum.	artık alıştılar, etrafıma toplanıp gülüşüyorlardı, resim bile çektiler. Şimdi ben gidiyorum maskeyle bakmıyorlardı bile. Şimdi iki maskeyi üstüste taksam dönüp		anlamadığım ayarları var. Benim işim değil diyorlar.	kayışlar açıp kapaması çok zor, ama çok iyi olanlarda var. Klipsli olanlar var	
Onu çıkarınca evde bi hava sesiyor, sonra onu kapatıyorsun	unwanted features	eş: kabloları arkaya saklayan benim. Maskeleri saklayan benim.		O zaman bize çok acaip gelmişti	eş: acaba nasıl kullanacak dedim. Tuvalete filan kalkarken nasıl çıkaacak acaba dedim.					Yanlışlıkla basınca hiç bir şey olmuyor.	Alnımı çiziyor, sert malzemeden, çıkarırken.	mas süre lasti kom
Maskenin havasıyla, debi farkı var.	neden ters duruyor, bana çıkışı daha kolay, hortumun. (çıkışı yukarıdan vermişler)	eş: Bazen dışarda bırakıyor, ben hemen yatağın içine koyuyorum		O çok zor dedi kullanımı.	eş: Ama zaman içinde kullanırken alıştık.					(interview esnasında keşfetti rampa tuşunu.) Onu kulanmıyorum.	klipsi olmadığı için çıkarmak zor.	mas bağl
hose / obstruct free movement	component fail	eş: görünmesin amaçlı , hortum maske odayı hastene odası haline getirmesin diye		Onun bahsettiği cihazları hiç böyle tahayyül edememiştik							Şimdi elimde ayarlıyorum, kafandayken bu strapsi ayarlamaz zor cırtlı ya, bi kere	eş: n yıkıy
İlk önce bir unutuyorsun, wcye kalkınca bir şey boğazınızdan tutuyor, sanra bakıyorsunuz ki burnunuzdakini çıkarmanız gerekiyor.	maskenin alın yastığı düşmüş, bu konuda bir şey yapmamış . (ne yapabilirsin işte bu maske bu kadar.)	eş: ilk geldiği zaman acaba bunu nasıl koysamda yatak odasının havasını bozmasa dedim.										
hortumun sabitlendiği nokta bundan çok kaba, sağa sola dönerken sıkıntı	maskem kopunca takmadım bir kaç gün, sonra baktım ki bunsuz da											

E3. EXAMPLE OF A DATA ANALYSIS DOCUMENT (Problems Theme and Subthemes)



APPENDIX F

THEMES AND SUBTHEMES AS A RESULT OF THE ANALYSIS

User Characteristics
1. Age & Gender
2. Training
3. Skills
4. Limitations
5. Background knowledge
No knowledge
Being close to a doctor
By family member
6. Adaptation phase
Not easy/worried
Easy/not worried
7. Attitude towards the device
Health is important
Companion
Obligation
Mastery

Motivating Factors
1. Health improvement (before & after)
Life quality
Sleep quality
Physiological effects
CPAP loyalty
2. Social acceptance
3. Appearance of the device
4. Usage of device and its components
Ease of use
Extra features
Comfort

Problems
1. Problems related with the device
Display problems
Lack of adjustment
Unwanted features
Portability problems
Component problems
Component fail
Device fail
2. Problems related with the mask
Air leakage (Cold & noise)
Discomfort
Adjustment problems
Wearing the mask (Straps)
Obstructing free movement (Hose)
3. Appearance of the device and its components
4. Problems related with the social environment
Disturbing the spouse
Children
Grandchild
Guests
Feeling ashamed
5. Problems related with the physical environment
Temperature
Electrical infrastructure
Lighting
Space
6. Problems related to health
Physiological problems
Psychological problems
7. Lack of knowledge & training
8. Problems related to maintenance

Storage & Environment
1. Space and surroundings
Storage
Positioning & Placement
2. Electrical infrastructure
3. Temperature
4. Lighting

Assistance
1. Distributor
Distributor's effect on relationship with doctor
Distributor's effect on usage
Distributor as repair service
2. Healthcare system
Relationship with doctor
Sleeping lab
Control of adherence
Health insurance

Tasks
1. Usage
Display
Controls
Mask
Humidifier
Portability
2. Maintenance
Mask
Filter

Factors Affecting Purchase Decisions
1. Comparison and advice
Comparison
Advice
2. Origin, brand and price
Origin
Brand
Price
3. Features

Preferences for a new CPAP device
1. Origin, Brand and Price
Origin
Brand
Price
2. General features
Appearance
Portability
Auto-CPAP
Quietness
Comfort
Ease of use
3. Component features
Mask
Humidifier
Hose
Display