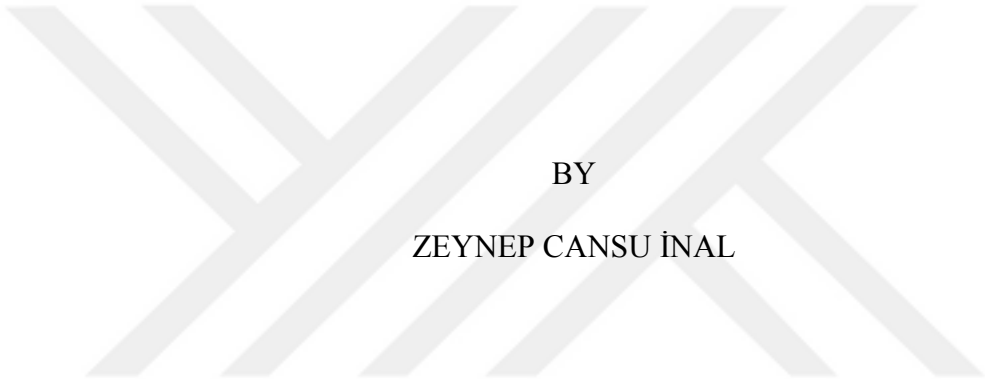


UNDERSTANDING USER PRODUCT INTERACTION: A STUDY ON HOME
MEDICAL DEVICES FOR THE ELDERLY

A THESIS SUBMITTED TO
THE GRADUATE SCHOOL OF NATURAL AND APPLIED SCIENCES
OF
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ZEYNEP CANSU İNAL

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR
THE DEGREE OF MASTER OF SCIENCE
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INDUSTRIAL DESIGN

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Approval of the thesis:

**UNDERSTANDING USER PRODUCT INTERACTION: A STUDY ON
HOME MEDICAL DEVICES FOR THE ELDERLY**

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ABSTRACT

UNDERSTANDING USER PRODUCT INTERACTION: A STUDY ON HOME MEDICAL DEVICES FOR THE ELDERLY

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In the field of healthcare, advancements in technology lead to a migration from hospitals to nonclinical settings. This alteration can be seen in both basic monitoring systems and complicated treatment systems. Concurrently, these technological developments increase the quality and existence of life. The aging population displays these enhancements supplied by the advanced medical devices of today's world. Before this giant leap, medical devices used to be designed and manufactured for only the professionals in the area. Today, patients as end-users are a consideration in these processes as well, with the introduction of home medical devices. These fast paced advancements in medical devices also force the elderly to adapt, although limitations on cognitive and physical abilities may cause an obstacle. Thus, it generates a working space for a design field study upon home medical device usage of the elderly. This study aims to comprehend the elderly's experiences and concerns on their usage of home medical devices and gain insights for the design process. The thesis is formed in two phases. In the first phase, a literature review regarding home medical devices and the elderly were analyzed. The second phase includes interviews and observations conducted with the elderly who use home medical devices. The

thesis concludes with the presentation of the findings focusing on difficulties and conveniences experienced during the usage home medical devices.

Keywords: Home use medical device, Medical device interaction, Design for elderly



ÖZ

KULLANICI ÜRÜN ETKİLEŞİMİNİ ANLAMAK: YAŞLILAR İÇİN EV TİPİ MEDİKAL CİHAZLAR HAKKINDA BİR ÇALIŞMA

İnal, Zeynep Cansu
Yüksek Lisans, Endüstri Ürünleri Tasarımı
Tez Yöneticisi: Doç. Dr. Naz A.G.Z. Börekçi

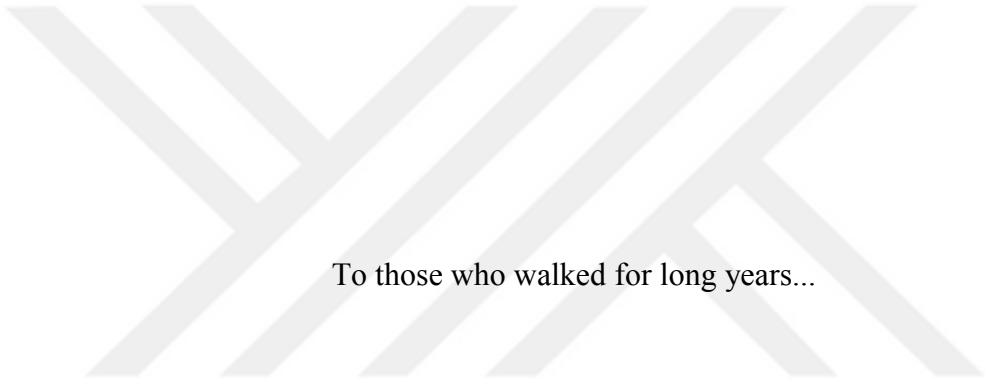
Eylül 2021, 116 sayfa

Sağlık alanında, teknolojiye yaşanan gelişmeler sayesinde, hastanelerden medikal özelliği olmayan ortamlara bir geçiş başlamıştır. Bu geçiş, hem basit hasta izleme sistemlerinde hem de karmaşık tedavi sistemlerinde görülmektedir. Ayrıca teknolojiye yaşanan bu gelişmeler, insan ömrünün uzamasını ve hayat kalitesinin artmasını da sağlamıştır. Uzayan ömür süreleri ile artan yaşlı insan nüfusu da bu ileri seviye cihazlarının yeterliliğini sergiler durumdadır. Medikal cihazlar bu büyük gelişme yaşanmadan önce sadece profesyoneller için tasarlanıp üretilmekte iken, günümüzde ev tipi medikal cihazların kullanıma girmesi ile birlikte, hastaların kendileri de bir son kullanıcı olarak addedilip bu süreçlere dahil edilmeye başlanmıştır. Yaşlı kullanıcılar tıbbi cihazlarda hızla devam eden bu sürece zoraki olarak uyum sağlamaya çalışıyor olsalar da, yaşadıkları bilişsel ve fiziksel sınırlamalar nedeniyle belirli sıkıntılar ile karşılaşabilmektedirler. Karşılaşılan bu durumlar, yaşlıların medikal cihaz kullanımı hakkında bir tasarım saha çalışması için alan oluşturmaktadır. Bu çalışma, yaşlı nüfusun medikal cihaz kullanımı sırasında yaşadığı tecrübeleri ve sıkıntıları kavramayı ve tasarım süreci sırasında kullanılabilecek fikirleri kazanmayı amaçlamaktadır. Tez iki kısımdan oluşmaktadır. İlk kısımda medikal cihazlar ve yaşlı nüfusa dair bir literatür çalışması

gerçekleştirilmiştir. Çalışmanın ikinci kısmı, medikal cihaz kullanan yaşlı insanlar ile gerçekleştirilen görüşmeleri ve görüşmeler sırasında yapılan gözlemleri içermektedir. Tez, evde medikal cihazların kullanımı sırasında yaşanan zorluklardan ve kolaylıklardan bahseden bulguların sunulmasıyla sona ermektedir.

Anahtar Kelimeler: Ev tipi medikal cihaz, Medikal cihaz etkileşimi, Yaşlılar için tasarım





To those who walked for long years...

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CHAPTER 1

INTRODUCTION

1.1 Background of the Study

Throughout the human history, medical instruments and devices have been invented and used to prolong and maintain our existence. In the stone age, there has been discoveries of our ancestors using a dentist drill approximately 9,000 years ago (Carmichael, 2007). Although in ancient times, tools were mostly invented to be used in hunting and food production, findings also indicate that there has been work done in the field of healthcare as well. Humankind's advancement with time helped more complex tools to be invented and in the last centuries, some of these tools have been evolved into medical devices.

The achievements reached also showed their effect on the functional capabilities of medical devices. These functions and the devices themselves dependent on the medical professionals, with their level of training and experience using the specific machine, designate the safe and effective operation of the device. On the other hand, these increasing capabilities on several essential devices had a significant effect. These essential devices became an element of home environment as well rather than being used exclusively in medical institutions. This migration has the positive effect on the cost of treatment since the patient visits the clinic less frequently (National Research Council, 2010). Additionally, quality of life increases with the treatment received in a home environment compared to a hospital-based environment (CDRH, FDA, 2010).

Developments in the field of healthcare and medical devices influenced the public's awareness of their own health and opinion on sustaining their condition. Increasing

effectiveness of treatments and the consciousness regarding selfcare led to lengthened life expectancy of human beings in the modern world. According to United Nations Report (UN Department of Economics and Social Affairs, 2019), in 2019 the population of humans over the age of 65 were 703 million and in the shade of statistics this number is expected to be over 1.5 billion in thirty years of time.

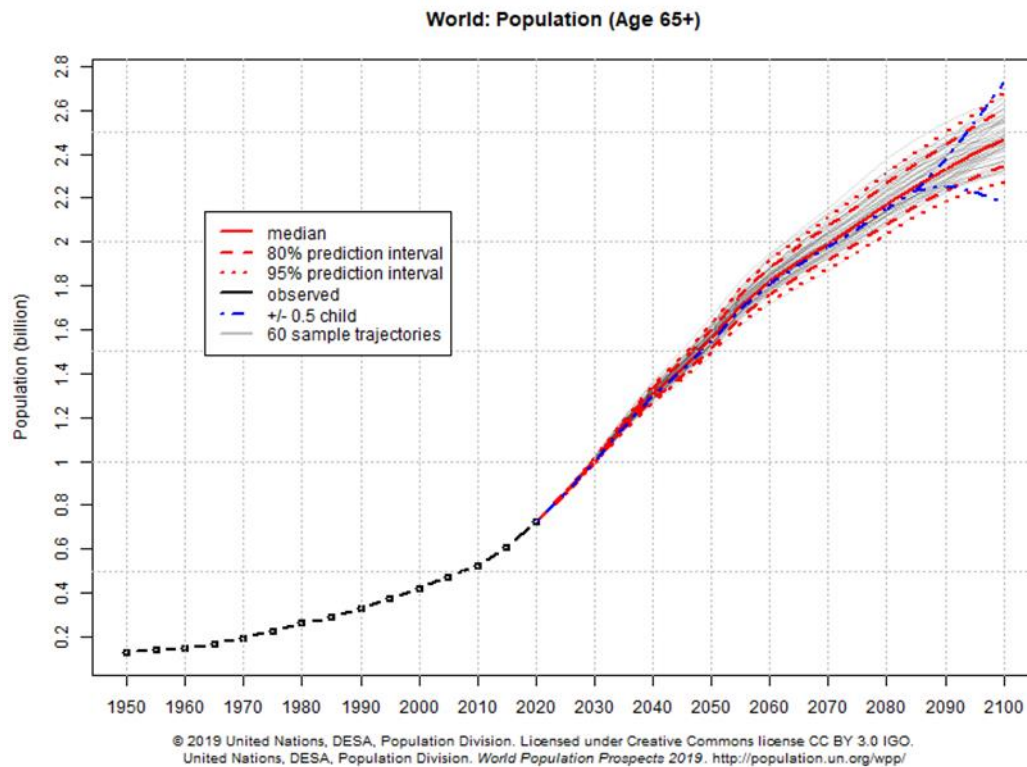


Figure 1.1 Population Projection of Elderly (UN Department of Economics and Social Affairs, 2019)

This currently high and expected to increase number of elderly, relies on the healthcare system more than any age group. This also leads to a raised volume of medical device users among the elderly. Impaired by cognitive and physical disorders, the elderly face with difficulties in their daily activities. Substantially more critical in terms of safety in comparison with routine tasks, misuse of medical devices becomes a significant risk at older ages. Hence, usability of medical devices presents itself as an important consideration due to the fact of high number of elderly users.

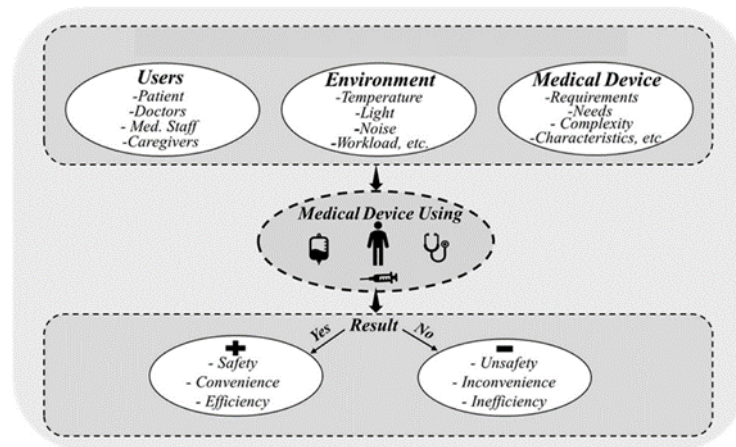


Figure 1.2 Elements for medical device design (Bitkina, Kim & Park, 2020, p. 2)

In the medical device design process, three main factors set the parameters for implementing usability guidelines. These factors are the medical device, the users and the environment where the device is being used (Figure 1.2) (National Research Council, 2010). The user as a consideration can show variety from being a professional in the field, being a medical staff or someone with less to none experience being the patient herself/himself. Environment is another parameter in usability depending on the surroundings such as clinics, nursing homes or residences. Medical device itself is a consideration as well since the requirements, complexity level depending on the features and the characteristics shape the device in terms of usage aspects.

A well-designed medical device incorporating usability ensures safety during usage and preserves functionality. Considering home medical devices are used in the home as a supplementary for the medical institutions, the usage and the respective result obtained are crucial both for the medical professionals and the patients. Hence, designing a user-friendly product in the medical field becomes a key consideration.

1.2 Aim, Scope and Research Questions

The aim of this study is to investigate the home medical device usage of the elderly. This thesis provides a detailed approach on the home medical devices and the elderly as a target group for the study. A field study is conducted in order to gather a set of data from the experiences of the participants during medical device usage, regarding the difficulties and conveniences originated during the usage. The study analyzes the qualitative data using selected methodologies, interviews and observations, and presents the findings to gain a perspective in the elderly's point of view. With these findings, it is hoped to form a guideline for those involved in the design and development of home medical devices for people aged 65 years or older. The main research question asked during the study is constituted as below.

- Which design criteria need to be considered for the elderly regarding their interaction with home medical devices?

The following questions focus to have a better understanding of the elderly using home medical devices. These sub-questions are listed below.

- Under which circumstances do the elderly use medical devices? (medical condition, rate of usage, setting, etc.)
- How do the elderly approach using medical devices?
- What are the problems that the elderly have while using medical devices?
- What are the positive experiences that the elderly have while using medical devices?

1.3 Structure of the Thesis

The thesis is formed of four chapters. In Chapter One, the background of the study is introduced, the aim of the thesis is stated and the research questions are given.

This chapter provides the foundation of the subject that it stands on, describing the purpose and context of the study.

Chapter Two includes a comprehensive literature review on medical devices, their classification and regulations in different perspectives. The chapter focuses on the elderly, detailing the features and constraints of this specific group. The following part of the review points to the home medical devices used by the aged population. Usability forms up the concluding part of this chapter, by discussing its principles and important considerations.

Chapter Three presents the methodology of the research conducted for this thesis, and the related research questions. The process followed throughout the field study and the formation of the procedure are presented. The final part of the chapter is constituted by the analysis of the data gathered during the field study and the chapter concludes with the findings of the field study.

In the concluding chapter, the outcomes of the thesis and the discussion formed around the findings of the field study are presented. A series of suggestions are made to be used during the design process of home medical devices for the elderly. The research questions of the thesis are answered. The limitations of the research are indicated and suggestions for further research are made.



CHAPTER 2

LITERATURE REVIEW

In this chapter, scholar publications and resources have been searched through in regards to medical devices, and the elderly as a part of a population and from a medical perspective. The literature review concludes with a section on usability and its harmonization with the medical devices and the elderly in general.

2.1 Medical Devices

In the field of medicine, a considerable amount of progress has taken over the centuries. The history of medical inventions goes further back to Ancient Egypt with diagnosis and treatment processes in healthcare (Xue, Yen, Boucharenc, & Choolani, 2008). In 1819, a French physician invented the stethoscope which is still a major medical instrument for healthcare providers (Roguin, 2006).

From a basic equipment such as the thermometer to complicated medical devices such as robotic assisted surgery systems, remarkable technological developments have been occurring progressively. In addition to that, this rapid development in the medical field expands the active area of healthcare in human lives. For instance, several medical devices are much more accessible for not only doctors and nurses, but for the general public as well. As Bitterman (2011) mentioned, a wide variety of medical devices and conditions show progress for both hospitals and communities. A transformation of health service areas from hospitals to home environment is inevitable.

Another perspective of behind the home healthcare system is the aging population. For instance, the CDRH and FDA reports in 2010 that, “The population of the United

States is aging, and people are living longer with chronic diseases that require daily medical care at home.” With time, quality of human life is increased and lifespan is lengthened. This is caused by great evolvments shown by the current healthcare systems. Hence, the purpose of the healthcare system is making improvements in life quality, human experience and ableness (Gilfillan, Tomcavage, Rosenthal, et al., 2010).

2.1.1 Definitions

Medical devices involve diverse products like equipment, drugs, materials, apparatus, etc.; considering the purpose of use, several definitions for the term of medical device are induced (Racchi, Govoni, Lucchelli, Capone, & Giovagnoni, 2016).

According to Federal Food, Drug, and Cosmetic Act (2019, p.2), medical devices are “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article that is (...) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease.”

Global Harmonization Task Force (2012, p. 6) defined the term of medical devices as follows.

“Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,

- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body,

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.”

These definitions have also been reinforced by the Directive 2007/47/EC (issued by the European Parliament and of the Council of 5 September 2007), and the Medicines and Healthcare Products Regulatory Agency (MHRA), which is an agency of the Department of Health and Social Care in the UK. As mentioned, these instruments are utilized for diagnosing, monitoring, preventing or treating illnesses considering the Medical Device Directive. MHRA (2016) emphasizes that medical devices should have a medical purpose, which means that products must have an intended use for them to be considered as medical devices.

2.1.2 Home Use Medical Devices

The term home medical device is defined as “a device intended for use in a nonclinical or transitory environment, managed partly or wholly by the user, that 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” (CDRH, FDA, 2010, p. 3). Additionally, FDA, CDRH, CBER (2014) presented a guidance named “Design Considerations for Devices Intended for Home Use”, to provide safety usage at home and to urge medical manufacturers. According to this document, a home medical device is a medical device identified for diverse environments such as

workplaces, schools, vehicles, etc., except medical institutions (FDA, CDRH, CBER, 2014).

While environment is an important factor for defining home medical device and its considerations, the term of user plays a crucial role in this respect especially for distinguishing from home health services. Examining the term of home health service, physician or professional healthcare personnel is the user that provides services that the patient needs. FDA (2010) defines the user of a home medical device as;

- a person who has a disease (the patient)
- a person who nurses the patient but is not a medical staff (relative, caregiver etc.).

In another perspective, users of home medical devices also can be therapists, nurses or physicians. They may work with home healthcare foundations or they may provide health services independently (National Research Council, 2010). According to this, both laypersons and professionals are considered as user groups of home medical devices. CDRH Home Health Care Committee (HHCC) also emphasizes the home medical device as a consumer product. Users of medical devices consume these products to improve their health conditions (FDA, 2018). Since these devices are used by untrained people, FDA provides documents such as instructions, precautions etc., to guarantee the safety of both patient and device.

2.1.3 Categorization of Medical Devices

In FDA's database, there are more than 1700 different types of medical devices. These are categorized into 16 groups, which are: anesthesiology; cardiovascular; chemistry; dental; ear, nose and throat; gastroenterology and urology; general and plastic surgery; general hospital; hematology; immunology; microbiology; neurology; obstetrical and gynecological; ophthalmic; orthopedic; pathology;

physical medicine; radiology; and toxicology. These categories given above have a specific product code for each (FDA, 2018).

Within the same context, Center for Devices and Radiological Health (CDRH), which is a sub institution of FDA, aims to assist and support the community regarding health issues. In order to provide users' safety and effectiveness of medical devices, CDRH classifies them from Class I to Class III according to the risk level of the device. Moreover, this classification includes critical descriptions, "intended use and indications for use", considering marketing processes of medical devices. Class I medical devices, such as elastic bandages or examination gloves, refer to a low risk. Thus, in a case of failure, misuse or accident, there may be a minimum harm potential for users. Class II medical devices, such as xxxx or/and xxxx, carry medium risk for users and a pre-educative process may be needed to minimize the possibility of injury. Class III medical devices, such as breast implants and heart valves, are essential for patient life. Therefore, these devices are included in the highest risk category (Johnson, 2016).

Medicine and Healthcare Products Regulatory Agency (MHRA, 2019) classifies medical devices into three categories covered by EU directives. The first group is active implantable medical devices that are powered by battery, and removable implants such as hearing aids, implantable cardioverters, etc., in regard to The Active Implantable Medical Devices Directive 90/385/EEC. These devices are considered in the highest risk group in the cases of device failure situations. Secondly, in vitro diagnostic medical devices are another class, which includes reagent devices, calibrators, test kits, etc. These in vitro diagnostic medical devices are covered in The In Vitro Diagnostic Medical Devices Directive 98/79/EC. The third group is named as general medical devices. These mainly consist of first aid equipment, dental apparatus, and specific monitors (e.g. ECG). General medical devices are regulated by The Medical Devices Directive 93/42/EEC. In addition, general and active implantable medical devices are separated into four classes, which are Class I, Class IIa, Class IIb and Class III considering risk levels.

(<https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements>)

- Class I - generally regarded as low risk
- Class IIa - generally regarded as medium risk
- Class IIb - generally regarded as medium risk
- Class III - generally regarded as high risk

2.1.3.1 Types of Home Medical Devices

Home medical devices are classified as a wide selection of products that can be considered as home medical devices, such as walkers, apnea monitors, air purifiers, hearing aids, glucose meters, and prosthetic devices. In 2010, a workshop has been conducted on “The Role of Human Factors in Home Healthcare”. The results and findings of this workshop are published by the National Research Council (NRC). According to the taxonomy provided (National Research Council, 2010), there are twelve main categories of home medical devices.

- Medication Administration Equipment: Devices that assist users to manage medication process by themselves. Droppers, Calibrated spoons, cups are several examples of this group.
- Test Kits: Devices that provide qualitative and quantitative data by means of measuring users’ samples such as allergy tests and pregnancy tests.
- First Aid Equipment: These equipment are used for treating injuries immediately, such as bandages, ice pack and tweezers.

- Assistive Technology: Devices that support and improve users' capabilities to cope with their limitations, such as walkers, prostheses, and visual aids.
- Durable Medical Equipment: Equipment are used to increase users' quality of life. Hospital beds, oxygen equipment and infusion pumps are included in this group.
- Meters/Monitors: Devices that measure parameters and provide data about health condition, such as thermometers, stethoscopes, and weight scales.
- Treatment Equipment: Devices that are used to treat a disease in subject, such as infusion pumps, dialysis machines, and transcutaneous electrical nerve simulation systems (TENS).
- Respiratory Equipment: Devices that provide gas mixture for respiration, such as air purifiers, nebulizers and compressors.
- Feeding Equipment: Devices that are used to satisfy the nutrient requirements of the patient by feeding them, such as feeding pumps and supplies.
- Voiding Equipment: Devices that are used for the voiding process of the urinary system.
- Infant Care: Devices and equipment used for 0 to 5-year-old infants' maintenance.
- Telehealth Equipment: Equipment that provide medical images and data about a patient's health condition, such as vital signs monitor, and medical cameras.

2.1.3.2 Product Survey

In this study, product survey aims to gather qualitative data from markets regarding medical devices that elderly use. Examples of products are given in Figure 2.1.

Harmony Home Medical Supply (n.d.) provides custom solutions with medical devices, accessories and home improvements. Medical Devices are presented under the name of Senior Medical Supplies which has is divided into five subcategories. Firstly, Home Aids and Assistive Devices for Elderly concerns mobility and safety of elder people. It contains wheelchairs, walkers and hoyer lifts. Health monitoring aides aim to monitor and manage specific health conditions such as glucometer, blood pressure monitor, portable oxygen tank etc. The company states that exercise equipment are essential for elderly even exhausting exercises are not necessary for them. Handheld exercise balls, floor pedals and bands are number of examples of this group. Bathroom is defined as the most dangerous place of the house and several safety equipment are presented such as grab bars, shower benches and raised toilet seats etc. bathroom safety, Last category is ADL (Activities of Daily Living) Aide. It aims to facilitate elderly's daily activities such as easy grip homeware, grab a stick for accessing higher places and etc.



Left: Portable Oxygen Tank

Center: Nebulizer

Right: Easy Grip Dinnerware

Figure 2.1 Examples of Medical Devices for Elderly

Caring Senior Service mentioned about increasing demand of durable medical equipment with age under the topic of Mobility and Medical Equipment for Seniors. Three types of equipment are presented which are portable toilet, cane and bathroom grab bars.

Another blog named Avacare Medical Blog, shares useful home medical equipment for seniors. Besides power wheelchairs, grab bars, shower chairs and mat, mobile-help medical alert system and smart pill dispenser system are mentioned. Medical alert system is set for emergency situations for who lives alone. Additionally, pill dispenser system works as a reminder for seniors in order to facilitate remembering their medications.



Figure 2.2 Medical Alert System

Alliance of Advanced Biomedical Engineering is a forum that informs about biomedical innovations and human health. Several improvements for elder care are mentioned. First one is telehealth system which consist of wearable monitoring device. It is a wristband that monitors users' daily routine and provide feedbacks. Another example is smart chair system which has sensors in itself. It helps to measure and inform about physiological conditions such as blood pressure, temperature and etc. Additionally, sensors may use to monitor senior's house in order to observe and interfere in the situation. Diabetes Management Device is placed around belly. Electrical stimulations activated heat shock protein and increase the physiological reaction. As mentioned above, smart pill dispensers are mentioned as an innovative medical device for seniors' medication process.

2.1.4 Benefits and Challenges of Home Medical Devices

The new age in healthcare system has changed the way of receiving a treatment, communicating with doctors and interacting with medical devices, and so on. Tracking current health situation, accessing past records and planning a treatment process for home are accomplished with the current emerging technologies. In the past years, the use of blood pressure measure device was only operated by healthcare professionals. Whereas in today's world, wrapping a device to a wrist and pushing a single button is sufficient to measure the blood pressure. In another perspective, complex devices, such as pulse oximeters, nebulizers, and dialysis machines, have found their way into homes. Unlike today, these devices were not available outside of health institutions in the past (National Research Council, 2010).

Home healthcare has an important role in increasing life quality and cost saving (CDRH, FDA, 2010). Medical services, institutions and professionals require a budget that is not completely supplied, therefore due to these limitations, medical devices show the trend of being used outside of the clinics and hospitals (National Research Council, 2010). Additionally, technology provides independency and allows health professionals to interact with the patient remotely. This remote approach has a significant difference in the cost of the treatment. A research conducted in 2008 compares monthly hospital and homecare costs and finds that there exists up to 50% decrease in expenditure in homecare (CDRH, FDA, 2010).

Home environment is associated with emotional and physical senses according to many people. It also correlates with memories and familiar feelings that create comfort in people. Home healthcare induces the healing process, and allows patients to be away from controlled spaces such as hospitals or clinics. People, during an illness prefer receiving assistive or nursing services at home, rather than going to hospital, which is described as an uncomfortable and depressive place (Tarricone & Tsouros, 2008).

On the other hand, using medical devices at home imposes great challenges. CDRH and FDA (2010) gathers these challenges under three categories, which are the knowledge of user, usability of devices, and environmental aspects. Considering the aspect of knowledge requirement from the user, quite a number of medical devices are designed for trained healthcare personnel due to the complex system of devices. The use of these medical devices may be too complicated to be operated safely and properly by the patient. National Research Council solidifies this statement in a workshop conducted, since the first category of the four, is user issues. It is shortly explained as; medical devices cannot be designed considering the patient as a user because of the diversity. Manufacturers cannot predict the end user who may be caregivers, distributors or patients (National Research Council, 2010). Therefore, capability, experience and the medical condition of the real user affects the safety issue of home medical devices directly.

Second aspect of home medical device problem is device usability. Although these devices are provided with instructions for use, whether they have a one or not, these labeling and documents supplied may not be sufficient in assuring safe operation (CDRH, FDA, 2010). According to the National Research Council (2010), this type of errors may cause instant consequences or it may be noticed too late. Moreover, while these devices are mostly suggested by a professional, the brand, model or type of the device suggested may not specified. The consideration must be taken into account from this perspective, and the home medical device that will be chosen should fit the socio-cultural level of the patient (CDRH, FDA, 2010). Another concern of this variety is that medical devices may differ greatly from the ones that are in use in medical facilities. For instance, unfamiliar features, different versions and models of the device that is available to the end-user, lead to inappropriate operation (National Research Council, 2010).

Lastly, unpredictable and non-clinical environments cause several challenges for providing safety of the medical devices. Physical obstacles, geographic location and general specialties of the home, existence of a child or pet, hygiene conditions, and so on, affect the quality of treatment and performance of the device (CDRH, FDA,

2010). Unlike professional medical personnel, the patient may not cope with the potential hazards. Therefore, environmental conditions should be taken into consideration while prescribing medical devices for nonclinical environments.

2.2 Elderly as a User Group

In the 21st century with the help of modern medicine and the current lifestyle, human life expectancy has increased significantly compared to the previous couple of centuries. User profile age average has moved drastically up, giving the elderly an important share in the total user population. Fisk and his colleagues (2018) support that a great amount of consumers are classified as elderly. According to World Health Organization's health report (2015), there needs to be a focus on a healthy and qualified lifetime in addition to longevity, and that older adults are not outdated stereotypes anymore. With aging population, demographic changes affect systems, services, products, etc. Moreover, these changes reorient functionality and capability of technology in order to meet evolving demands (Fisk et al., 2018).

2.2.1 Definition

According to Orimo et al. (2006) people 65 years and older are defined as elderly. In more detail, the term of elderly is divided into early and late elderly. Orimo et al. (2006) state that early elderly are the population age between 65-74, and the late elderly are above age 75. In another context, the distinction made among the elder population is divided into three different age groups. These are, young elderly aged between 65 to 74 with no major health issues, mid-old elderly aged 75 to 84 who show a variety from being well to experiencing deteriorating health conditions due to age-related diseases. The final age group is oldest-old aged 85 and above who are unable to sustain their daily activities caused by frailty (Chou et al., 2002).

On the other hand, old people cannot be classified sharply with numbers. As Fisk and his colleagues (2018) indicate, biological, social and psychological changes

show the level of senescence. When viewed from the biological aspect, increase in cellular damage and decrease in physical performance and mental stability cause aging in time. Additionally, with new developments in technology and healthcare, the human life span is prolonged. Until recent times, life expectancy was limited to around an average of 60 years. Today, the average of life expectancy is 83.7 in Japan (WHO, 2017a). According to the Global Health Observatory report (2012), worldwide population's average age in years was 72 in 2016. From different perspectives, there are several factors that affect longevity of human life. Historical, regional and social differences affect life expectancy (Orimo, Ito, Suzuki, Araki, Hosoi & Sawabe, 2006). Also, retirement, and changes in environment, such as friends and housing, correlate with aging. With these considerations, older people have individual constraints and the elderly cannot be generalized with quantitative values.

2.2.2 Constraints for Elderly

Cellular organisms in the human body start to show decay in some capabilities after some amount of time. For humans these losses of capabilities start to show around the ages of 60 to 65. These losses of capabilities, or also referred to as constraints, include but are not limited to sensation, perception, cognition and movement. Although knowledge and experience come with aging, several constraints are inevitable and need to be considered for a human-centered design process (Fisk, et al., 2018).

Auditory and Visual Sensory Constraints

Considering sensory abilities, decreases in vision and audition are correlated with aging (WHO Report, 2015). Hearing capacity has a significant role for interaction with a product or a service system. According to an epidemiologic study, hearing loss is mostly seen around the age of 75 and over (Ciorba, Bianchini, Pelucchi & Pastore, 2012). Most old people cannot follow a normal conversation due to lack of

hearing and this leads to the impairment of the quality of daily life. Additionally, several reactions may occur in return, such as emotional, behavioral and cognitive ones. For instance, hearing loss may cause social isolation because of feeling slow and inadequate. Another example is that focusing and distraction problems may affect the way of interaction. It can be said that auditory capabilities are an important consideration during the design process.

Another sensory ability that needs to be considered is vision. Quillen (1999) states that one of the essential health issues is impairment in vision. Vision losses which are decline in the acuity of vision, due to blurring, cataract, etc., have a significant effect in older adults' lives and visual capabilities vary from age to age. In fact, people older than 45 need to wear glasses for reading newspapers, driving at night, etc.; whereas people older than 65 generally do not have a healthy vision for daily activities. Decrease in acuity and sensitivity, problems in adaptation to luminous environments, and low speed in cognitive processing are associated with age (Fisk, et al., 2018). As it is mentioned in World Health Organization Report (2015), visual impairments have a negative impact on daily activities and interactions, and usage of technological devices, also leading to the possibility of accidents. Especially interacting with products needs visual searching and focusing. Considering warnings or pressing correct buttons in correct order leads us to visual capacity, which Fisk et al. (2018, p. 22) define as “dynamic visual attention”. It is related to being aware of the environmental changes and adapting to new situations. It happens slowly in the elderly in comparison to younger people. Thus, visual sensation is a critical design consideration to cope with limitations and capabilities.

Cognitive Constraints

There is a considerable amount of cognitive processing taking place during interaction with a product. Comprehension abilities, working memory and perception are the main cognitive functions for human beings (Fisk, 2018). There are also high level cognitive functions such as decision making, language processing and executive control. According to Glisky (2007), aging has the most influence on

cognitive domains, especially attention and memory. On the other hand, World Health Organization (2015) indicates that cognitive functions can be varied depending on education to years and this diversity of cognitive functions is affected by several environmental and social factors such as economical potential, cultural lifestyle, medications and health problems.

Memory: A primary cognitive constraint affected by age is memory. Working memory can be defined as a limited cognitive storage that maintains information for a short time. Working memory capacity declines with aging. Remembering and organizing information and representations are two main deficits for the elderly (Radvansky, 1999). For instance, old people can remember phone numbers which consist of 7 ± 2 digits if digits are repeated (Glisky, 2007). Remembering and retrieval of the information needs an active cognitive function. Besides remembering a phone number, deficiency in cognition can be seen in daily activities such as interacting with technological products,

Long-term memory is another cognitive domain that needs to be considered. In principle, it is an unlimited cognitive storage that keeps information for an ambiguous time. Long-term memory is divided into two categories, which are explicit and implicit memories, and these two aspects have several sub-categories. While explicit memory is known as declarative memory for which retrieval and remembering processes are practiced consciously, implicit memory is known as a non-declarative memory that leads to unconscious actions (Fisk et al., 2018). A category affected from aging is semantic memory. It is defined as a storage of general information about the world (Fisk et al., 2018). Remembering process may decline with aging, whereas the information does not disappear completely.

Another category is prospective memory which considers remembering planned actions (Fisk et al., 2018). It may be divided into two; time-based and event-based. Although there is a relationship between prospective memory and functional capacity showing decline with aging, the capacity of prospective memory can be affected by several factors such as motivation, environment, and context of the action

(Scullin et al., 2011). Procedural memory is another aspect. It includes knowledge of performing specific tasks such as reading, and riding a bicycle. These tasks are associated with automaticity and consist of actions without thinking. According to Fisk et al. (2018), elder people struggle in creating new automatic tasks and habits, while their prior automatic behaviours remain stable. Considering design aspect, providing consistent elements and natural tasks are critical for the elderly (Fisk et al., 2018). Also, it is important to take account of the previous habits and behaviours as well as the capability of learning new ones.

Perception: On a daily basis, humans interact with numerous objects. This interaction is made possible by receiving feedback using their perception (Faubert, 2002). Generally, perception is defined as "the consciousness of particular material things present to sense" (Angell, 1906, p. 122). In another definition made by Fisk et al. (2018), being aware of the events occurring around oneself and being able to deduce context construct perceptual function. For instance, smelling the atmosphere and distinguishing the smoke is an example of sensation, in addition relating the smoke with a burning process can be considered as perception. In short, perception is an act of interpretation sourced by environment using cognitive abilities.

Elder people show deterioration in their perceptual functions. This declination can be classified into several subjects such as auditory, visual or motion perception. It is stated that perceptual processes are directly related to sensorial abilities which are affected by several environmental features such as luminance and color (Faubert, 2002). Level of luminance sensitivity and photoreceptors wavelength show losses with age (Faubert, 2002). Moreover, hearing sensitivity is also affected negatively by aging. Studies show that elder people cannot organize the auditory information and eliminate inconvenient information (Tremblay & Ross, 2007). Thus, any amount of loss in sensorial functions can be linked with cognitive functions directly. Also, depending on the complexity level of the activity, need of cognitive abilities show variety.

Attention: During any interaction, attention is present. Being part of an environment, produced goods also require an amount of attention. These goods or products depending on their complexity, show a variety on the necessity of attention. In a simplified form, it can be defined as attention addresses all types of cognitive processes occurring in the state of consciousness (Shiffrin, 1988, p. 739). According to Mcdown and Shaw (2000), authors classify types of attention into four; selective, divided, switching and sustained attention. Selective attention is a cognitive process that is focusing on a specific task by eliminating other stimuli in the environment (Glisky, 2007). For instance, searching and detecting a symbol from a group of displays to select the right button needs selective attention. The process can turn into a complex task with similar shapes, colors or letters. On the other hand, divided attention refers to the multitasking process. It includes two or more processing at the same time. According to findings, elder people experience difficulties while performing multiple attentional tasks compared to young adults (Glisky, 2007). Similarly, aging causes a decline in the performance of switching attention processes, which is related to focusing on alternating tasks between different tasks (Glisky, 2007). Lastly, sustained attention can be associated with attaining and maintaining a particular task or activity, which is one of the major elements in cognitive processes (Staub et al., 2013). In contrast, aging shows no negative effect on sustained attention (Glisky, 2007).

As stated above, with increasing age, cognitive and perceptual abilities show a decline (Fisk, et al. 2018). This declination causes limitations due to the lack of attention.

High-Level Cognitive Functions

High-level cognitive functions get formed by a combination of the analyzing, planning and achieving of a desired result. These functions are used in the case of an event or facing a problem (Paz-Alonso et al., 2014).

Another perspective is that higher-level cognitive functions include several thinking capabilities such as adapting to current situation, judgmental call and evaluating

opinions (Levine, 2009). Glisky (2007) analyses the issue in three categories which are; speech and language processing, decision making, and executive control.

Speech and Language: As a part of daily life, humans express themselves using their voice forming an explicable group of sounds. In another statement, speech and language have always been there, as a tool of interaction.

The quality of the interaction is set by how well the language is spoken. Although having a rich word repertory formed by plenty of experience, older adults every once in a while, struggle with remembering proper words in required situations (Glisky, 2007). Fisk et al. (2018) support that with aging, constraints on working memory occur. These constraints emerge in linguistic aspects during a speech. Not only limited with memory capacities, hearing impairment may also affect the quality of the interaction (Glisky, 2007).

Decision Making: Every single action made by a human is a consequence of a decision. Decision making, a working memory process, works differently with age. The declination of working memory shows its effect when comparing different options (Carpenter & Yoon, 2015). Though, older adults have the capacity to relate a current situation with a similar one by using their long-term memory and experiences (Glisky, 2007). For instance, while making a similar decision; younger adults tend to research and assess trending information, whereas the elderly is more inclined to make use of their past experiences (Glisky, 2007).

Executive Control: Executive control refers to being able to process and manage multiple cognitive functions (Hart, 2015). It involves numerous cognitive processes for a singular task requiring planning, organizing, evaluating, etc. Also called executive function, it is related to top-down processing in order to deduct the desired result (Halligan & Wade, 2005).

Human brain is not always dependent upon extrinsic excitation. Interpreting the input from the environment and matching the information with past attempts or situations are involved (Kveraga et al., 2007). A known example of executive control and top-

down processing is the Stroop Effect. In this specific case, participants are shown words that are colors, but the words themselves are printed in a different color than what they mean. In research conducted by West and Alain (2000), the Stroop Effect is more prominent in elderly than younger adults. It can be concluded as such since cognitive abilities show a decline in elderly.

Movement Constraints

Elderly people exhibit movement constraints depending on various factors; movements take more time, they become unpredictable and uncontrollable (Ketcham & Stelmach, 2004). Ketcham et al. (2004) analyze movement constraints in several categories.

One aspect related to movement constraint is reaction time. The time span of starting the action constitutes response length. Research indicates that elderly show a delayed response compared to younger people (Ketcham & Stelmach, 2004). Fisk and his colleagues (2018) explain this deterioration with loss of perceptual ability.

A movement consists of the initiation, action and conclusion phases. Summing the total amount of duration of these three phases results with movement time. Though, the movement duration shows variety depending on the task complexity, the elderly performs tasks in an increased manner of time independent of difficulty (Ketcham & Stelmach, 2004).

Another aspect of the movement constraint is the accuracy of the action. Accuracy can be defined with two outputs; positioning of the final result, and pathway from initiation to conclusion (Ketcham & Stelmach, 2004). According to research, magnitude and duration of muscular performance show undesired variety in elderly (Ketcham & Stelmach, 2004).

An essential factor of movement is force control since well-timed and pointed movements are in need of sufficient control mechanism. Older adults struggle performing a task precisely due to irregular force control and insufficient force output (Ketcham & Stelmach, 2004). These deficits may be caused by alteration in

skin features, sensitivity of skin, and partially due to neural system as well with aging (Kinoshita & Francis, 1996).

Coordination ability is another concern for executing a movement. Many factors give shape to coordination skills, ranging from the response time of movement to perceptual abilities. Overcoming bimanual movements, and managing multiple tasks simultaneously become compelling activities for the elderly (Ketcham & Stelmach, 2004).

As mentioned above, aging brings several constraints related to both cognitive and physical aspects, and it affects the performance of the movement and the interaction. While designing a product or a system for elder people sensorial, perceptual, cognitive and motion capabilities need to be considered.

2.3 Usability

Bevan et al. (1991) state that the word of usability has been mentioned for a few years in the place of user-friendly which came to surface in the 1980s. Usability is related to ease of use which also leads to user-friendly products in a simplified form (Jordan, 2002). In this context, the definition contains several perspectives such as product-centeredness, user-centeredness, user performance and user interaction, and includes the terms of ease of use and acceptability (Bevan et al., 1991). These statements are utilized from International Standards Organizations (ISO). According to ISO's definition, usability is a measurement of users' interaction with a product, service or system in order to complete tasks successfully in terms of effectiveness, efficiency and satisfaction (ISO 9241-11, 2018). Similarly, Interaction Design Foundation also remarks an effective, efficient and satisfying design or a product in the context of usability measurement. In this regard, effectiveness measures the level of completeness of a task. Meanwhile, efficiency covers several factors such as effort required, duration of the achievement and cost (ISO 9241-11, 2018). In ISO Standards, satisfaction is defined as physical, cognitive and emotional reactions

induced by system interaction (ISO 9241-11, 2018). Whereas, Jordan (2002) states that satisfaction is a subjective matter because the term is in connection with comfort. NN Group indicates that usability can be used as a method for the conduct of the design process (Nielsen, 2012).

2.3.1 Usability for Elderly

Medical developments increase their influence on daily device interactions and exchange the methods and the devices with current ones. Among the people, especially the elderly approach these new methods and devices with hesitations albeit they are to increase life and health service quality (Abbate, Avvenuti & Light, 2014). While the elderly is hesitant against new technologies, using these technologies for the sake of them is a struggle as well. Elderly as a user group creates this struggle since they differ from the general public with their limitations as discussed in Section 2.2 Elderly as a User Group. Considering these limitations, designing for the elderly creates a challenge for the experts on the subject. Advancement of the technology can be expected as a beneficial factor although the outcome is not consistent with the anticipation. This statement is supported by research (Wildenbos et al., 2018) showing that on some certain aspects older adults can be affected negatively with newly developed devices.

Devices require to be designed thinking of cognitive considerations in addition to physical aspects to induce safe and convenient usage (Akatsu & Miki, 2004). These considerations are needed to be examined due to limitations caused by aging. The elder community shows a variety of abilities and disabilities imposed by aging; besides these, people may have temporal or permanent limitations due to environmental or situational aspects as well (Presier & Smith, 2011). In this context, universal design provides opportunities to users of diverse age groups, abilities and characteristics to experience the products, services or systems conveniently (Mustaquim, 2015). Universal Design has seven principles created for the design process in order to achieve usability solutions (Presier & Smith, 2011).

- Principle 1: Equitable Use
The design of the device is to provide the same level of availability and functions to any user group.
- Principle 2: Flexibility in Use
The device enables a variety of personal choices to be made during the usage according to the abilities and characteristics of the user.
- Principle 3: Simple and Intuitive Use
Using the device is effortless and convenient in regard to the background of the user.
- Principle 4: Perceptible Information
The data provided and results of the interaction made can be easily comprehended, independent of users' sensorial potential and environmental conditions.
- Principle 5: Tolerance for Error
The device ensures a safe usage experience avoiding chance of mishaps.
- Principle 6: Low Physical Effort
The device minimizes the amount of effort put by user to support efficient usage.
- Principle 7: Size and Space for Approach and Use
The device adapts to the environment and the user related to different aspects such as user's ergonomics or interaction.

Although the elderly show diverse limitations, universal design can be utilized to overcome disadvantages of aging and aims to remove isolation of the elderly from the general public in order to promote quality of life throughout (Carr et al., 2013).

This evolution of design strategies has born with the aim of encapsulating the elderly into the society, and the devices designed, using these strategies, are efficient tools for better accessibility. After mentioning about *universal design*, this evolution of strategies leads to *design for all*, which is a similar approach commonly used across the EU instead of universal design (Coleman & Lebbon, 1999). Initially adapted in

the UK, *inclusive design* is another design approach serving a broader spectrum of users while protecting the economic goals and users' fulfillment (Clarkson et al., 2013).

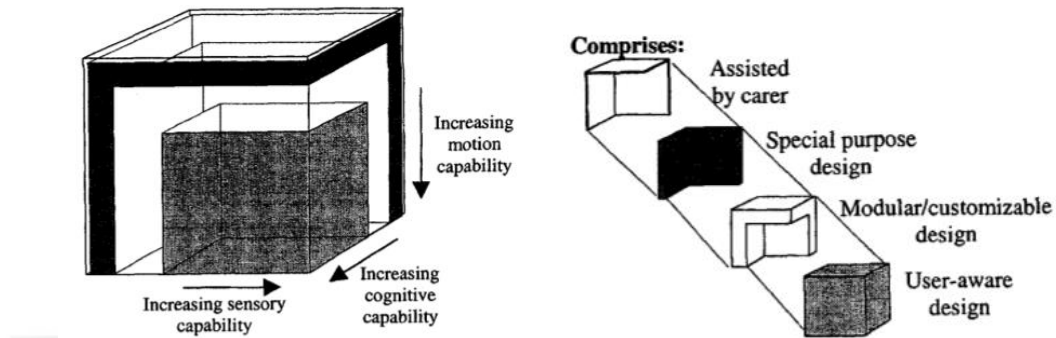


Figure 2.3 Left: Inclusive Design Cube; Right: Comprise Block (Keates et al., 2000, p. 47)

Inclusive design can be visualized with a cube approach. The volume of the cube can be defined as the amount and variety of users from a disabled person to a healthy individual. The size of the cube depends on three main aspects of the user, these are motion, sensory and cognitive capabilities. Higher volume of the cube indicates the higher amount of accessibility and a wider user demographic. The cube approach can also be complemented with *comprise* blocks, such as modular/customizable design, shown in Figure 2.3. During the design process, applying inclusive design strategies broadens the focus group and enables a device to have better usability (Keates et al., 2000).

2.3.2 Usability in Medical Devices

Innovations are emerging in order to satisfy the demand of human well-being by increasing the potential of human interaction (Tosi & Rinaldi, 2017). These ongoing developments in technology improve the medical field greatly, providing an opportunity for the patients to use these devices at their home environment on their own. This fact brings the “usability” issue to the forefront considering the healthcare field. While a wide range of user characteristics and behaviors are critical for the

interaction with medical devices, devices themselves also include safety considerations to decrease medical error. Bitkina and her colleagues (2020) state that, the structure and creation of device components are significant in order to provide an effective and safe usage since patients interact with these devices at first hand. In this context, the consequence of using a medical device involves a chance of error occurrence caused by both device and user (Vincent & Blanford, 2011). These errors can be exemplified under manufacturing and usage processes as misconducting operational process of the system or miscomprehending the information that the device provides (Tosi & Rinaldi, 2017).

Usability signifies the ease of use with which a user interacts with an instrument or a device in order to perform a task successfully (Mchome, Sachdeva & Bhalla, 2010). Nielsen (2012) defines usability under five principles, which are *learnability*, *efficiency*, *memorability*, *errors* and *satisfaction*.

- Learnability: Attributes that can be comprehended easily in regard to the targeted user group.
- Efficiency: Attributes related to proper and quick operation of various functions conducted by trained users.
- Memorability: Attributes of a device that relate to how well a seasoned user remembers the functions after a taking a long break.
- Errors: Attributes that affect the function aimed to be accomplished by the user negatively, or the intensity and frequency of an error.
- Satisfaction: Attributes that play a role on the pleasantness and positivity of the device during the usage.

Another perspective can also be given as, usability commonly defined with *simplicity* and *comprehensibility* of device functions and their respective conducts done by the user. The definition by means of device functions covers the apparatus, and the physical and virtual interfaces (Tosi & Rinaldi, 2017).

Alexandra and her colleagues (2013) mark five factors to enhance the usability of medical devices according to their case study. These are *engagement*, *information*

during and after use, confidence in clinical effectiveness, aesthetics and compatibility with life style.

- Engagement: Responses fed by the device to the user during a function and comprehension of the active operation.
- Information during and after use: Comprehensible data and facts displayed on the user interface during and after the usage period.
- Confidence in clinical effectiveness: Assuring the user in making a reliable assessment based on the output.
- Aesthetics: Appearance of the device, creating a bias on the user in both positive and negative ways.
- Compatibility with lifestyle: Characteristics of the device that define the mobility, sustainability, and environmental aspects that are significant for the user (Lang et al., 2013).

In order to achieve the ideal medical device, the design should encourage and ensure safe and proper usage from the beginning of the interaction to the final operational usage (Wiklund & Wilcox, 2005). This accomplishment can be reached by utilizing usability considerations.



CHAPTER 3

METHODOLOGY

In this chapter, medical devices for elderly and the categorization of the medical devices are explored, first with interviews conducted with experts for medical device categorization. Then the selection process of medical devices used in the study and the factors that have been accounted for, are presented. Furthermore, the methodology adopted for the field study carried out and the demographical information of the participants are given. The field study is a mixed-method research constituted for analyzing experiences in depth and gathering a high amount of data. In this study, observation and interviews are carried out by giving medical devices and assigning related tasks to participants.

3.1 Medical Devices for Elderly

A series of interviews with experts in the medical device field has been conducted. The subject of the interview and the questions directed were mainly about the medical device usage of the elderly. Based on their experiences, the experts expressed their opinions and provided real life examples on the subject.

In addition to the interviews made with the experts, a product survey has been conducted regarding which types of devices the elderly use, and the trend for the upcoming devices has been investigated.

3.1.1 Expert Group

Interviews were conducted with five experts in their own respective fields. These interviews were carried out in order to clarify interview questions for elderly as a user group and gain a direction for the field study.

Experts were chosen with Snowball Sampling method, to find experts of a specific field and gain general knowledge about the medical equipment commonly used by Elderly. While Expert E1 has years of experience in the subject the process of getting knowing was through different social networks. The rest of the experts except from E1, shown in Table 3.1, were suggested from previous interviews delving deeper into the subject by being more specific. The backgrounds of these experts as stated on Table 3.1, meet at a common point that four of them worked extensively in the sales of various medical device market and one of them; Expert E5 works as technical service personnel.

Pandemic conditions experienced during the study required the interviews to be completed via phone calls. Interview questions aimed at having a fundamental understanding of the expert on the subject. During the calls, the on-going plan had a semi-structured planning in order to understand and organize medical devices elderly use. This is conducted so in order to have the experts not limited to a condition but freely express their opinions having a room to think and understand the way they experience. Hence, questions asked in the later parts of the interviews were shaped with experts' thoughts, expressions and their responses.

Table 3.1 Expert Group

Expert Number	Gender	Field of Expertise
E1	Female	General Medical Devices
E2	Female	Orthopedy
E3	Male	Hearing Instrument
E4	Female	Respiratory Device
E5	Male	Personnel of Social Security Institution

3.1.2 Interview Analysis

Classification of the medical devices used by elderly, required expert views to gain an insight of the field and to have better understanding of the subject. These interviews included questions to achieve the aims stated. Beginning with the Expert E1, later on experts that has been interviewed are decided upon during the previous interviews.

The first interview conducted with expert E1; while the person's background is not affiliated directly with medical devices used by elderly, the overall knowledge of the medical equipment and devices and the broad social network expert has, made the dialogue beneficial for the subject. The interview started with, explaining the aim of the research and the possible positive findings for both the targeted users and the market itself. Expert E1 showed catalogues from various suppliers and, going more specific in these catalogues she mentioned firms that sell specific devices such as CPM, Pedal Exerciser etc. E1 also states opinions regarding which of these devices are used more commonly by the elderly.

The second interview were conducted with Expert E2, a salesperson in an orthopedics related medical market. During the dialogue, orthopedic medical devices and general medical equipment were discussed. It should also be mentioned that; one of the important aspects of supplying medical devices is, some specific medical

fields like hearing aids and dialysis devices need specific certifications to be provided in Turkish Ministry of Health Regulated Medical Market.

This led to a connection with Expert E3 who is a consultant and a salesperson specializes in hearing aid market. E3 has been trained and has necessary certificates in this specified field in order to supply these devices. During the interview, types of hearing devices and their expertise considerations for each case, such as number channels or tracks which is related to auditory discrimination has been discussed. It has been emphasized by the expert that user expectation, income, level of hearing impairment and using environment are essential factors for the elderly while choosing the proper device for themselves.

Another interview was conducted with E4 who is a highly experienced supplier in respiratory devices. According to E4's knowledge and experience; oxygen concentrators, ventilators, BPAP and nebulizers are used by elderly in general. Concentrators and ventilators, supply oxygen while breathing and muscular work done by lungs whereas BPAP devices provide bidirectional air flow to act like breath in and out as a lung. E4 also suggested a meeting with personnel from Social Security Institution in order to examine the problems and feedbacks received regarding respiration problems in Turkey.

Interview with Expert E5 has been conducted with the help of E4. E5 is a government official working active duty in Social Security Institution, responsible for technical servicing of medical devices. Though some questions directed, noteworthy responses were not achieved.

Table 3.2 Groups of Medical Devices

Group of Medical Device	Sample
General Medical Devices	Blood Pressure Measurement Device, Saccharometer, Wheelchair etc.
Orthopedic Medical Devices and Equipment	CPM, NMES, TENS, Pedal Exerciser
Hearing Instruments	Completely in Canal, In the Ear(ITE), Behind the Ear(BTE)
Respiratory Devices	Oxygen Concentrator, BPAP, CPAP, Ventilator, Nebulizer
Prosthesis and Orthosis	Dynamic and Static Orthosis, Lower and Upper Extremity Prosthesis
Dialysis Machine	

3.2 Selection of Medical Devices for the Study

Due to the study being carried out with the elderly, the selection of the medical devices was critical. Medical devices, as discussed in the literature review chapter of this thesis, are divided into several categories. These categories list these devices according to medical specialty they are designed for and the function they carry out.

In this study, three medical devices have been selected. These medical devices, belong to three different medical groups as given in Table 3.2 Group of Medical Devices. In addition to these devices belonging in different medical areas, their level of complexity is an essential factor in the selection process. This complexity level has been sorted with physical features such as number of buttons, existence of a digital screen and number of physical connections to the device. For instance, one of these medical devices is selected to have a digital screen, a high number of buttons and physical connections, whereas another device has been selected having a single button for operation, a digital screen and only one physical connection.

Table 3.3 Medical Devices Used in the Field Study

Device Number	Device Type
D1	Blood Pressure Measuring Device
D2	Nebulizer
D3	TENS
D3 Alternative (D3A)	Oxygen Concentrator

Device D1 (Figure 3.1) is a blood pressure measuring device. The measurement is done from upper forearm region with an armband apparatus. D1 has an ability for the user to start the measurement process with a single button. The measurement is conducted automatically and at the end of the process, the blood pressure measurement is displayed on the digital screen. D1 has a memory up to one-hundred measurements which can be divided for two users. In order to access the specific person's measurement results, the 1 and the 2 buttons are placed on the device. Additionally, D1 is operated by four batteries.

Device D2 (Figure 3.2) is a nebulizer. A Nebulizer dispenses a liquid medication in a vapor form so that it can be inhaled by lungs. D2 has a power outlet that connects to the electrical grid. It has a single on-off switch and has a storage compartment for apparatus. D2 has a two-piece plastic hose. In between these pieces, there is a conical vessel for liquid medication. One end of the hose connects to the device while the other end connects to the face mask.

Device D3 (Figure 3.3) is a transcutaneous electrical nerve stimulation (TENS) device. D3 sends electrical current to desired muscle groups and stimulates them for rehabilitation purposes. It has a high number of buttons in order to select program type, arrange the duration of stimulation and control the level of electrical output. D3 has a two-channel output. These channels can be controlled independently. For each channel, two pads are connected and according to the muscle group size, one or two channels can be utilized. The control of the device is done by five buttons and resulting output is shown on the digital screen.

During the field study, an alternative for Device D3, Device 3A (Figure 3.4), has been introduced. Having the same complexity level as D3, the alternative is an oxygen concentrator. This was coded Device D3 alternative in Table 3.3. An oxygen concentrator takes the atmospheric air, removes an amount of nitrogen, thus, enriching the air supplied in oxygen. Device D3 alternative incorporates three buttons in order to open/close device and arrange the treatment duration with +/- . In addition, the device has a knob for adjusting the flowrate of air. A single digital screen displays the treatment time and total hours of operation. The device provides the user feedback of the knob with a vertical float type flow meter.



Figure 3.1 Device D1

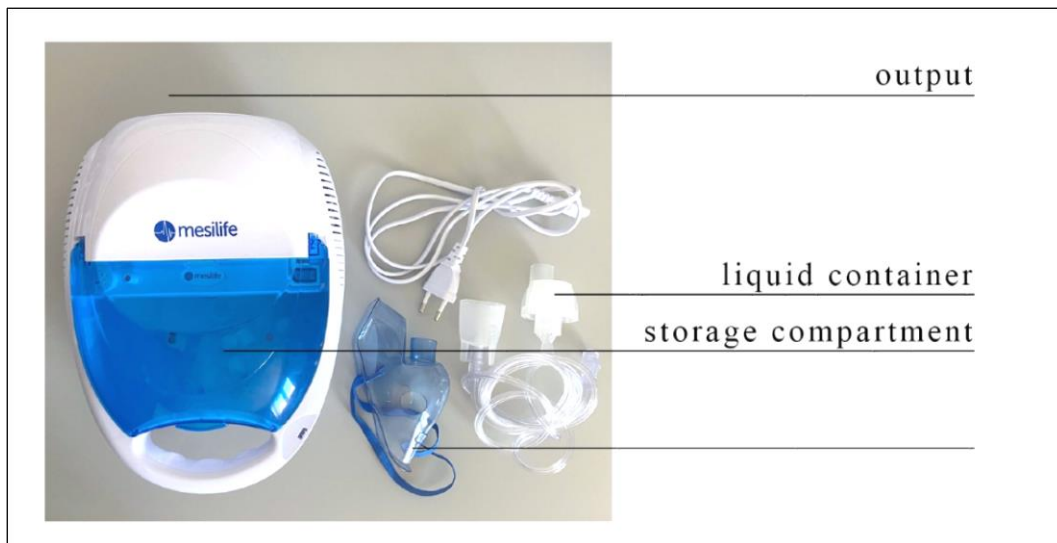


Figure 3.2 Device D2

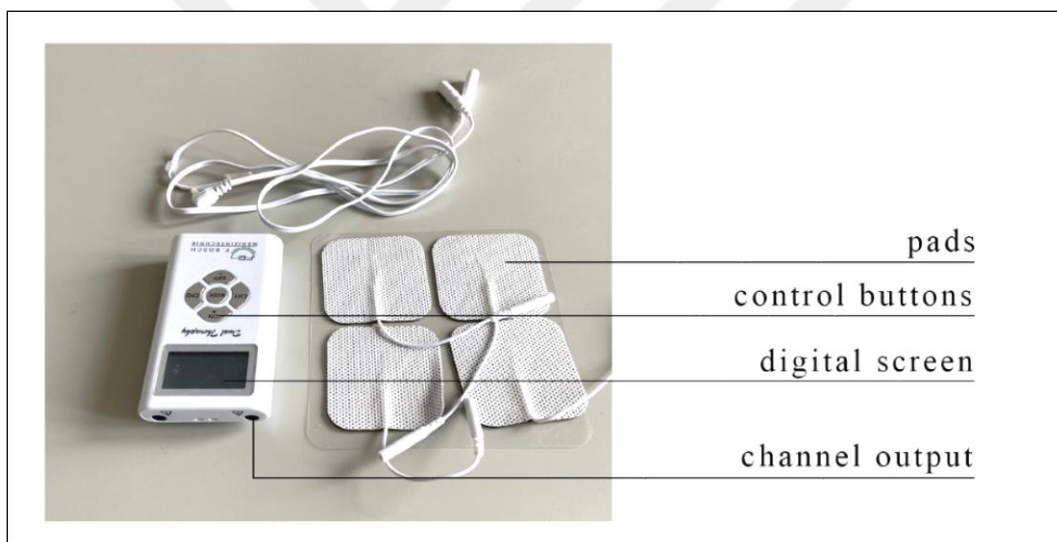


Figure 3.3. Device D3



Figure 3.4. Device D3A

3.3 Methodology of the Study

In the field study, the aim is to gather qualitative data. This qualitative data provides a better insight on gathering, analyzing and interpreting the information in the research process (Pathak et al., 2013). It is also crucial to comprehend users' actions and opinions in detail to make a development particularly in the medical field (Kelly et al., 2010). In order to obtain this data, a methodology has been chosen which involves in-depth interviews and observation. Interviewing is a data collection technique that aims to gain an understanding in regard to participants' point of view, thoughts and emotions (Holloway, 2005, p.39). Interview techniques have shown diversities from singular to collective interviews such as survey interview, qualitative interview, in-depth interviewing, life story interview and focus group interviewing (Gubrium & Hoistein, 2001). Among these, in-depth interview method gives the chance of thorough conversations with participants (Boyce and Neale, 2006). The correlation between Kelly's statement about requiring in-depth information in medical areas and Boyce and Neale's (2006) definition of in-depth interview, leads the field study to conduct this methodology. Additionally, in-depth interview is used not just for detecting the task completion, but for understanding

participants'' feelings, thoughts and reflections of their past experiences during the process. To support the in-depth interview method and to strengthen the data gathered, observation method is also chosen to be used. Observation is performed in an unconditioned environment where researcher investigates actions of the participants in detail (Cowie, 2009). In the observation method, while the task is underway, notes and observations are taken discretely. Mulhall (2003) states that in positive science related researches, observation emphasizes on noting the physical effort made by the participant. In another perspective, observation is not only made by seeing and hearing but also includes perceiving a taste, noticing scents and sensual stimuli (Ciesielska et al., 2018). Hence, this method has the advantage of analyzing the user behavior independently from the verbal feedback received by the user.

3.3.1 Task Description and Procedure

This field study has been conducted with elderly people in their own comfort zone. Before carry in out the interviews, the sessions were organized in four parts. The first part includes explanation of the field study and participants' contribution to the study. At the end of the first part, a consent form is presented to the participant and the study continues following their approval and submission of the filled consent form.

The second part consists of several questions to get demographic information regarding participants' background and past experiences. This experience questionnaire examines the participants' interaction with technological and medical devices.

For the third part, the main section of the study, a scenario is created in order to give participants various assignments. In each session, it is planned to give participants two medical devices. This enables a device being interacted by the participant more than once, thus creating the opportunity to have more data on a single device. In accordance with each device, a series of tasks are implemented. This can be

exemplified by opening and closing the device, executing the main function and maintaining it. Considering the devices have different complexity levels, this promotes distinctive challenges for participants.

The final part of the session compares the two devices presented to the participants, asking for distinguishable features among them by using probing technique. Researchers use the probes for exploring participants' perspectives and also facilitating the documentation process (Lucero et. al., 2007). The protocol used throughout the session including all four parts can be found in Appendix A.

3.3.2 Interview Questions

The interview questions followed a semi-structured manner in order to shape the dialogue with respect to participants' experiences and their emotions during the session. Semi-structured interviews were preferred, since Ryan, Coughlan and Cronin (2009) state that this methodology provides the space for a researcher to analyze further. These interviews are conducted one-to-one and give the participant the ability to divert the session in any direction (Ryan et al., 2009).

In a portion of the session, the participants are asked about their electronic device usage and related stories. Rather than scheduled and direct answers, the questions asked to the participants as stated above do require a background story in accordance with the semi-structured interview method.

A series of questions can be given as an example, "In a home environment, which electronic devices do you use often?" and "Among these which devices do you have the most trouble with?" These exemplified questions look for a why rather than what or which. By doing so, these types of questions enable the researcher to gain a better insight on the participant and obtain enriched data on the subject (Miles et al., 2005, p. 66). All the questions used throughout the sessions can be accessed from Appendix A2.

3.3.3 Sampling

The study aims to explore the usage of home medical devices by the elderly. Since the scope of this study focuses on the elderly, participants were selected as 65 years or older people. Although an age limit has been set for the research, no further limitations, e.g., sex, occupation, past experiences, have been required.

Selected participants have been interviewed in their home environment. The home specific environment of the interview has shown variety depending on the medical device operation requirements and participants' accustomedness.

The sessions were limited to nine participants, as discussed above, each participant was given two devices. In total, the number of device sessions were eighteen and six different data being gathered for each device. Participant/Device matrix is given in Table 3.4.

Table 3.4. Participant/ Device Matrix

Participant/Device	D1	D2	D3	D3-A
P1	x	x		
P2	x			x
P3	x		x	
P4		x	x	
P5	x	x		
P6		x	x	
P7	x		x	
P8	x		x	
P9		x	x	

The interviews were carried out between June 12 - June 26 2021. The duration of interviews mediated from 30 minutes to 56 minutes including the initial consent form procedure and end of session questions. During the interviews as per the participants' permission, data was gathered with video and audio recordings, and photographs have been taken.

Sampling methods can be categorized under two headings; probability (random) sampling and non-probability (non-random) sampling (Taherdoost, 2016, p. 20). Since the research conducted does impose an age limit on the participant, convenience sampling method has been selected under the title of non-random sampling. Convenience sampling facilitates to access specific participants efficiently in regard to requirements set by the researcher (Etikan et al., 2016). Throughout the research process, initial participants were chosen from the researcher's close circle. In the later phases of the research, participants have been reached out with the help of initial participants' networks.

At the beginning of the session, the participants, though no limitations imposed upon, were asked about their age, gender, occupation and past experiences regarding the research. The data gathered from the initial questions are presented in Table 3.5.

Table 3.5 Demographic Information of Participants

Participant Number	Age	Gender	Occupation	Relative in interview
P1	82	Female	Housewife	Her husband and her daughter
P2	88	Male	Retired (administrative staff)	His two daughters
P3	65	Female	Retired (teacher)	-
P4	67	Male	Retired (colonel)	-
P5	73	Female	Housewife	Her daughter
P6	77	Female	Retired (cleaning worker)	-
P7	83	Female	Housewife	-
P8	84	Female	Housewife	-
P9	75	Female	Housewife	Her grandchild

3.3.4 Data Analysis

Participants' input and the observation made during the interviews generate the research data. The outcome of this research requires the data gathered to be analyzed.

Considering qualitative research, data analysis methods show variety. It can be generalized with the most often used ones as; discourse analysis, thematic analysis, rhetorical analysis, conversation analysis, narrative analysis, critical incident analysis, semiotic analysis, cross case analysis, grounded theory analysis, ethnographic analysis, etc. (Gibson & Brown, 2009).

Among these methods, thematic analysis is used for this research as a data evaluation method. According to Braun and Clarke (2006), thematic analysis helps researchers to determine and examine the information gathered moreover, explore relevancies between data analyzed to obtain a meaningful outcome. To have an insight on the subject, thematic analysis aims to investigate similarities, associations and distinctions over a series of data (Gibson & Brown, 2009, p. 128). Thematic analysis has been selected for this research since it allows the researcher to maneuver over a great amount of complex data by providing space (Braun & Clarke, 2006, p. 78).



Figure 3.5. Data Gathering

The format of data gathered during sessions is audio recordings, video recordings and written notes taken by the researcher on the protocol sheets. Following the interviews, the researcher took further notes on the same sheets analyzing audio and video clips from the sessions. The notes gathered have been uploaded to a web-based platform (Miro) for better visualization of the processed data. On this platform, the

above-mentioned notes are formed into a table for each participant and for each device separately, according to the order of the sessions and tasks. The important points interpreted from visual table are written on sticky notes.

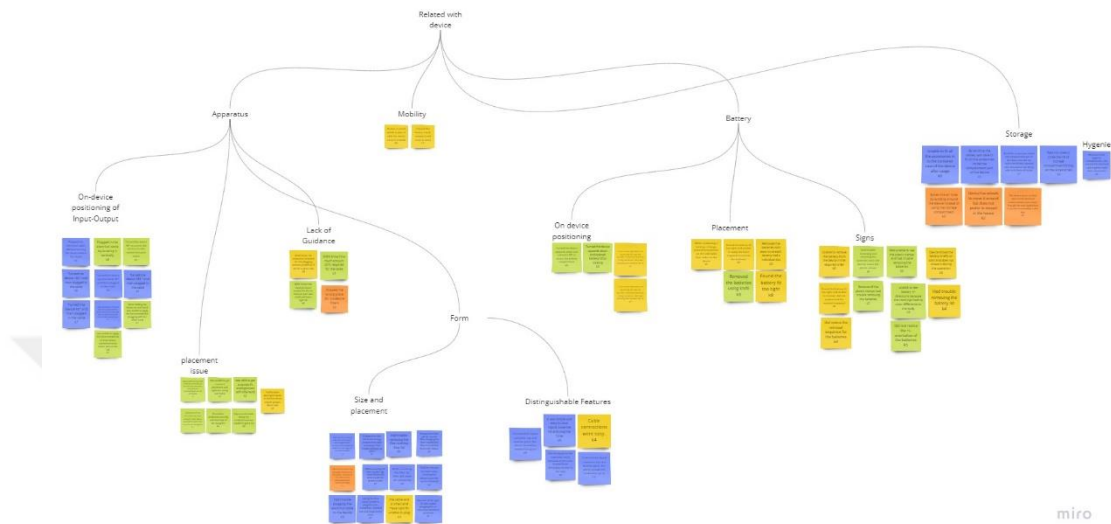


Figure 3.6. Web-based visualization

Each note with a single statement expressed the crucial situations and for each device sticky notes had a different color to ease categorization process. At the end of the analysis, notes have been distinguished under different themes like a branching tree for emphasizing on various subjects.



CHAPTER 4

FINDINGS

In this chapter, the main aim of this thesis, analyzing elderly users' interaction with medical devices, is explored. A mixed method research with interviews and observations was carried out with the elderly while using given medical devices.

The findings obtained from the data analysis are given in this chapter. This research aims to understand how the elderly use home medical devices in their home environment, and the experiences they have during this usage in a comparative way.

In the light of the research aim, the main question of this study is constructed as below.

- Which design criteria need to be considered for the elderly regarding their interaction with home medical devices?

The following questions focus to have a better understanding of elderly using home medical devices. These sub-questions are listed below.

- Under what circumstances do the elderly prefer to use medical devices? (medical condition, rate of usage, etc.)
- How do elderly people approach to using medical devices?
- In which ways do the elderly have problems while using medical devices?
- How do medical devices help the elderly in having positive experiences?

In consequence of the field study conducted, several criteria affect the use of home medical devices in both positive and negative directions, as obtained during the sessions. Considering the verbal and behavioral feedbacks, the data gathered were categorized under five main themes as factors related with: user, device, interaction,

environment, and operation. This categorization was studied on Miro, a web-based visualization platform and the final revision of the board can be found in Appendix C. The following subtitles present the themes obtained in the data analysis as the findings of the field study.

4.1 Factors Related with User

All four home medical devices used during the sessions, require some type of user input in order to obtain a feedback or output from them. This study does not investigate the users' history and past experiences related to medical device usage. The usability of these devices varies according to cognitive and physical abilities of the elderly and the way they approach and operate the devices. The range of categorization created for this study is under the subthemes of *limitations of the user* and *emotions & concerns*, detailed branching of the subthemes is visualized in Figure 4.1. The aim is to investigate limitations sourced by aging and emotions of the specific participant that affect the usability.

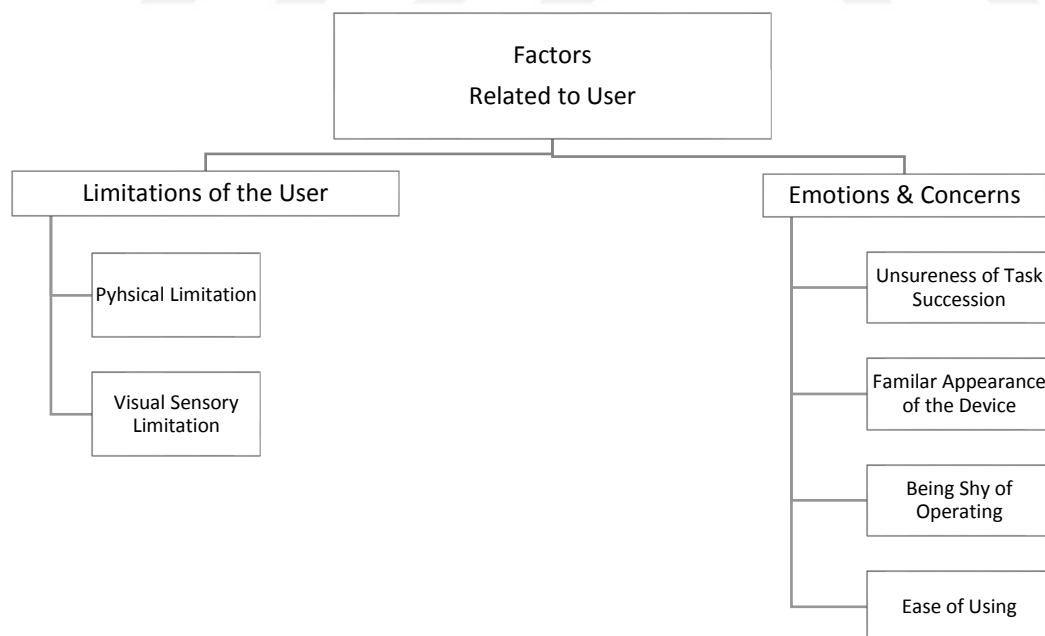


Figure 4.1 Factor Related to User Diagram

4.1.1 Limitations of the User

Aging shows decline on both physical and cognitive features as mentioned and analyzed in Section 2.2.2. Constraints for Elderly. In the field study, *physical limitations* and *visual sensory limitations* on some participants were detected as expected.

Two participants, P6 and P9 experienced difficulties on applying force for fitting cables due to having medically related physical conditions. Participant P6 had trouble plugging electrical cables to the devices D2 and D3, which have tightly fitting connections. This is caused by P6 having a finger rheumatism condition, debilitating her to apply force through fingers. In addition to that participant P9 struggled in a similar scenario with the apparatus' connections to D2 and D3 having a tight fit. The condition related to this issue is P9 experienced a finger bone loss caused by osteoporosis.



Figure 4.2 Examples of the physical limitations of the participants

Another constraint affecting the use of devices is *visual sensory limitation*. Unlike some participants, P4 had trouble seeing the values on the screen of device D3. This is because of the sight impairment based on aging. Participants P6 and P9 suffering from the same condition, were able to operate the device D3 using a pair of optical glasses.

4.1.2 Emotions and Concerns

Participants during the sessions, showed a great range of *emotions and concerns* from positive feelings of using the device easily to negative feelings about thinking they have not accomplished the task completely.

One of the main concerns experienced, is *unsureness of task succession*. Most of the unsureness feelings were towards the device D2, which has the highest amount of physical connections in comparison to the other devices. Five participants (P1, P5, P6, P7, P9) were observed checking an already assembled apparatus or connection twice or more. Participant P1 thought that a tight fit is required in order to seal the filter lid while assembling. Therefore, she felt the need to press the lid once again to seal and be sure of completing the task. Three participants (P5, P6 and P7) opened and closed the medication container of D2 several times to be sure of preventing spills and leakage. Also, participant P5 checked the fit between the face mask and the hose with pressing more. In another case, P9 wanted to be sure of the length of the electrical cable of device D2 due to need of electrical supply for operation. A sign of unsureness was observed during the use of device D1 by only participant P2. He checked the device for being able to open again after completing the task of battery changing.

Familiar appearance of the device is another subject observed. Two participants (P1, P9) expressed such type of emotion upon D1 and D2. P1 found D1 easier to use in comparison to D2 because of her past user experience on a different kind of D1. Participant P9 was not sure about operating D2 since she was unfamiliar with the device, stating “The device seemed unfamiliar, I thought for a second whether I may be able to operate it.”

Following, a concern related to user, while operating the device is *being shy of operating*. Two participants (P4 and P5) expressed their initial opinions with this feeling about D2 before using it. They thought that since the device has too many apparatus, it felt to them it probably has a complicated operation.

On contrary to the negative feelings, three participants (P5, P6 and P9) touched upon *the ease of using* three devices (D1, D2, D3) as their feedbacks. Participant P5 found D1 easier based on having less process to operate compared to D2. Both participants P6 and P9 thought that D2 was easier than D3 due to starting the operation with one single button.

4.2 Factors Related with Device

The analysis of the data collected during the study, is not all connected to the participant but the devices themselves also become a part of the enquiry. For all four devices, feedbacks received from participants and insights gained from observations can be categorized into four themes related with equipment. These subthemes can be listed as: *apparatus*, *battery*, *storage*, and *characteristic associated with mobility*. (Figure 4.3)

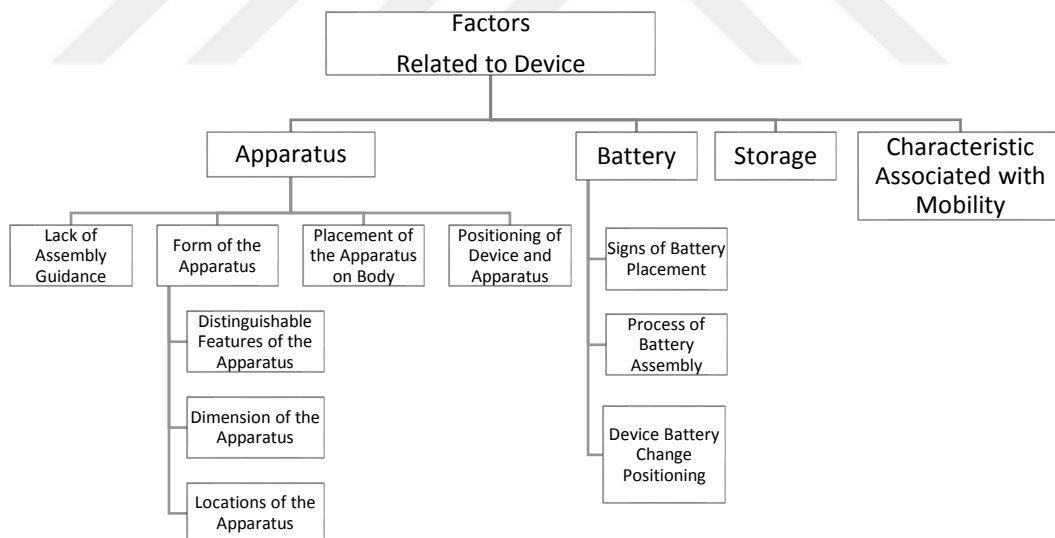


Figure 4.3 Factor Related to Device Diagram

4.2.1 Apparatus

Medical devices chosen for the study do not have unibody characteristics, rather they have one or more apparatus connected to the main section of the device. These apparatus requiring subtasks in addition to the operation of main body, cause several conditions.

Each input and output related connections challenge the user to find the correct fit for the assembly. Three participants (P2, P3 and P8) experienced issues due to *lack of assembly guidance*. P3 and P8 did not know how much amount of pressure and insertion needed for plugging the cables to the devices (D1 and D3). Considering D3A, P2 showed the wrong placement of the filters during the session.



Figure 4.4 Distinguishable Features of the Apparatus

Form of an apparatus belonging to a device is another subcategory in convenient usage for the elderly. This concern has been observed in seven different occasions with three different devices. The findings related to the form of the devices are divided into three subgroups; *distinguishable features of apparatus*, *dimensions of the apparatus* and *locations of the apparatus*. Considering the device D2, two participants (P4 and P9) had both negative and positive experiences. P4 and P9 confused which part of the medication container the liquid should be poured caused by top and bottom parts having similar form. On another perspective, P9 expressed that pouring the liquid in the container was easy with a cone shaped form of the

container. Unlike other participants, P4 found the cable connections of D3 were easy due to basic cylindrically shaped output cable.

Seven participants (P1, P2, P4, P5, P6, P7 and P9) had difficulties with D2, D3 and D3A during removing and fitting the apparatus. In detail, removing the D3A's water container was difficult for P2 because a short allowance for the connection of the hose is given, and assembly is forced to be made within a small volume.



Figure 4.5 Locations of the Apparatus

P1, P4, P6, P7 and P9 had similar experiences regarding removing the filter lid of D2. In these cases, issues experienced were, filter did come off partially and completely or in some cases was dropped by the participants into the storage compartment caused by the small form of the apparatus. Secondly, surrounding space of the filter is limited, which makes the process complicated and troublesome for some participants.



Figure 4.6 Dimensions and Locations of the Apparatus

Another perspective is obtained from P4 about changing the filter of D2. P4 suggested removing the filter with a pair of tweezers in order to protect the hygienic condition expressing the fact that the contents filtered is being inhaled by the user. Both D2 and D3, received feedbacks from the participants for having tight fit connections and generated some challenges to operate these devices. P1, P7 and P9 experienced trouble plugging the electrical cable to the wall socket and the hose to the port located on D2. P4 also was not able to achieve success for establishing the connections between cables and D3 itself.

Placement of apparatus on body was another subcategory related to the devices. Five participants (P1, P3, P5, P7 and P8) were observed failing to put on the armband and connect the cable to D1. P1 and P5 asked for help from their daughters to place the armband in the required correct position since attaching the armband with one hand was not easy to manage. P3, P7 and P8 did not notice the graphical representation in regards to the instruction of usage on the armband and thus they were not able to establish a correct placement and tightness using single hand. Contrary to the observations made, only P2 was able to place the armband by himself.



Figure 4.7 Placement of Apparatus on Body

Another finding regarding the subject has been discovered while device D3 was being used by P9. She experienced difficulties with reaching on her back side muscle groups to place the pads in order to get them stimulated by the device. Two devices, D1 and D2, have several output port locations positioned on different sides of the

devices, which brings up the need for participants to turn the devices in order to fit the apparatus.

Positioning of device and apparatus is another issue in general, related to the apparatus. Five participants (P1, P2, P5, P7 and P9) felt the need of turning and supporting the device using an object or a body part for several tasks they were given. For the task of plugging the electrical cable to the device D2; P1, P5, P7 and P9 preferred to turn the device in some manner to reach the electrical output port placed at the back of the device. Only P4 tried to reach the port and make the connection without turning the device to himself. Additionally, P2 and P8 wanted to turn the device D1 in order to access the electrical output position at the back, same with D2. Since D1 is more portable in comparison and can be used as a handheld device with no location restrictions, P1 and P2 have struggled to apply the demanded force for fitting the cable to the device, since they were holding the device with their one hand this has compelled them to do the task using a single hand.



Figure 4.8 Positioning of the Device and Apparatus

4.2.2 Battery

From all four devices, two devices D1 and D3 operate with battery. The other devices are sourced by the grid electricity using an electrical plug. For D1 and D3 since the battery is essential for the operation, changing the batteries has been given as a task in the sessions. During this task, participants had diverse experiences since it is

comprised of more than one step and requires multi-directional movements partnering with the need of cognitive abilities. *Sign of battery placement* is one of the critical issues for guiding the participants to change the batteries. Participants P3 and P5 were not able to see the +/- directions because there is no color difference to the main body of D1 in order to emphasize the orientation of the batteries. Additionally, six participants (P2, P3, P4, P6, P7 and P8) did not recognize the clamps of both D1 and D3 which generates a removal sequence, therefore they could not remove the batteries easily.



Figure 4.9 Sign of Battery Placement

Three participants P3, P8 and P9 had problems changing the battery subcategorized as *process of battery assembly* concerns. P3 was able to remove the batteries of D3 easily, since each battery had their individual slot. In contrast, she had to use a knife as a tool to remove the batteries of D1 because batteries were packed in a single slot and in the compartment, there was a tight fit. P8 and P9 were not able to apply the force required to remove the battery of D3, which has a tight fit slot. In addition, P9 placed the removed batteries on the table considering their order, so that she could replace them correctly.

Both D1 and D3 have battery compartment at the back of their body which leads the participants consider *device battery change positioning* in order to accomplish the task. Participant P6 and P9 after turning the device D3 upside down, as a natural position tried to remove the battery lid by pulling it. The amount of force they applied by pulling was not sufficient to open the lid. Seeing they had no success with pulling,

they turned the device around in order to open the lid by pushing. Considering D1, P5 and P8 turned the device upside down and rotated it 90 degrees to remove the battery lid easily.

4.2.3 Storage

Storage is another subtheme to be analyzed considering the device D2 and D3A. P1, P4, P7 and P9 weren't able to fit the apparatus in compartment of D2. This is caused by there no reference for how the packaging should be made or the required order in the storage compartment. This has led some participants not being able to understand the lid was still open or some required a few try out to close the lid successfully. In another point of view, P4 did not prefer to place the electrical cable into the compartment stating air hoses used by the patient should not be put together with the electrical cable. Because when the D2 is operating, electrical cables mostly placed on the ground and this creates a hygienic problem for the participant. In contrast, P2 prefers to store the air hose by winding around the deice D3A instead of using the storage compartment.

4.2.4 Mobility

All the devices featured during the sessions include various *characteristics associated with mobility*. This amount changes between fitting into a pocket or requiring wheels to be transferred. P3 and P6 gave comments about the mobility of the device D3. The statement made by P3 lies on previous experiences that she had to visit a rehabilitation center in order to get the same treatment with D3. Hence, the mobility and the efficiency came from compactness are praised by her. Although P6 regardless of previous experiences, mentioned about compactness and high-mobility characteristic of the device as well. P2 related with mobility of the device D3A, does not try to move the device around although there are wheels to ease the mobility. Hence, he locates the D3A in the most frequently used location, next to his bed.

4.3 Factors Related with Interaction

Devices used throughout the sessions with their screens, buttons and physical hardware required some type of interaction to be made by the participants. Analyzing participants' input to the devices, a series of subthemes were created according to which part of the interaction is in focus. These subthemes are *display*, *buttons* and *mapping*. Issues noted are explained in detail in the following sections. (Figure 4.10)

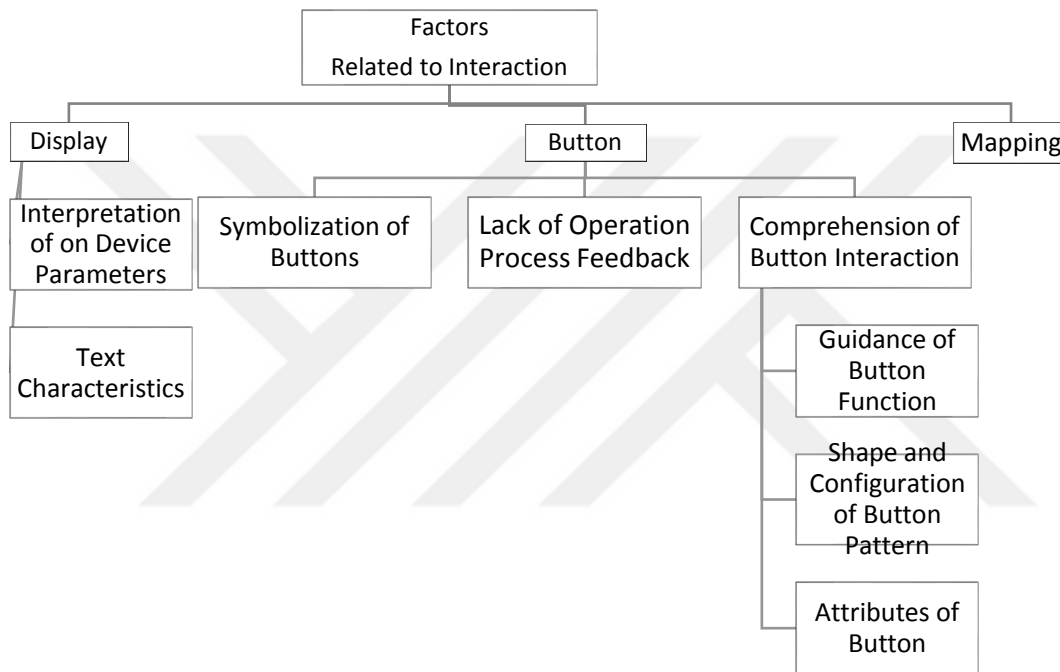


Figure 4.10 Factor Related to Interaction Diagram

4.3.1 Display

Three devices of the four in total incorporate a digital screen to display operation parameters or resulting output. In accordance with that during the sessions issues and conveniences are noted and recorded. These conditions recorded with relation to the display are distinguished in two subcategories, *interpretation of on device parameters* and *text characteristics*.

To begin with *interpretation of on device parameters*, participants P5 and P8 were not able to comprehend the measured results displayed on the screen of D1. In the case of P5, she did not correlate 95/56 for her blood pressure measurement with 10/6 which is a common expression used by both the professionals and the public. For the case of P8, she assumed that the first measurements included both higher and lower values. Her high blood pressure value was 126 and the lower measurement was 81. Neglecting the lower blood pressure value, she thought her measurement was 12 high and 6 low. Considering D1, P7 was not able to interpret the code E3 on the screen, a sign of an error in determining measurement data. Related with interpretation issues, P8 could not comprehend the value on the screen of D3A, stating “It always stays at 88” which actually displays the total time of operation in hours.



Figure 4.11 Interpretation of on Device Parameters

The second theme, text parameters, includes issues related with display size of the characters. Participants P1, P2, P5 and P8 were able to read the values on the screen of D1 without glasses, expressing they found the size of values adequate. In contrast, P4 and P7 needed optical glasses to read both screen values and the battery signs +/- directions.

4.3.2 Button

In consideration of interaction, all four devices have a single or a series of buttons in a sort of combination to operate the devices. These buttons' features, affect the users'

way of use and how they contemplate device operation. During sessions, several problems regarding the buttons were detected. These can be subcategorized as *symbolization of buttons*, *lack of operation process feedback* regarding informing users and *comprehension of button interaction* and the resulting interaction output.



Figure 4.12 Symbolization of Buttons

Issues in regard to *symbolization of buttons*, were observed in two devices D1 and D3. D1 does not incorporate an on/off button, instead there is a blue rectangular operation button and a white symbol placed in the center resembling the symbol of the common on/off button with 1 and 0. In result, all six participants using D1, P1, P2, P3, P5, P7 and P8 have misused the operation button as an on/off button and experienced issues considering tasks given. P1 and P7 tried to press the operation button long enough to turn off D1 but nonetheless the device started measuring again. P2 did not notice that the operation button can be interacted with and instead, he pressed the “1” button to start the measurement, which has a grey colored thin frame around it, used for browsing previous measurements. P3 tried to press the operation button to turn on D1, and started the measuring process of the device unintentionally. P5 also intended to press the operation button to check the previous measurements, also leading to measurement being started. In a similar case, P8 failing to identify the operation button and the memory buttons, tried to press the small colored rectangular graphics indicating safe to critical measurement values.

In relation with the symbolization issue of D3, the device has several buttons in a circular pattern and during the sessions, P9 pressed the “CH1” button, which is used

for setting the parameter of channel one, to start the operation before turning on the device.

Six participants (P1, P2, P3, P6, P7 and P9) experienced difficulties while using D1 and D3 related to another subtheme, *the lack of operation process feedback* in regard to informing the users. The task of browsing through the memories is a main concern observed for D1. P1, P2 and P3 did not comprehend the function of 1 and 2 buttons which show past values for two different users, and repeatedly pressed these buttons to shift among the values. Participant P1 did not know the way of checking her previous measurement, she asked whether the armband should be worn while searching the results. P2 decided to measure his blood pressure again after D1 was operated once because he checked the memory of the first measurement and could not find his corresponding value. Additionally, P3 felt the need of reopening the device once more to check her measurement. Failingly, pressing the operation button and conducting the measurement again, she was surprised and stated “Wow, it memorized my result under user 2”. Final observation made with D1 is that P7 pushed the operation button longer than necessary to start her measurement with the device due to missing feedback related with the duration of interaction.

Buttons used in devices are expected to divert and naturally instruct the users for appropriate usage scenarios. In correlation with appropriate usage, *comprehension of button interaction* is related with *guidance of button function, shape and configuration of the button pattern* and *attributes of the button* depending on the observations made during the sessions. Guiding the users both instinctively and in an apprehensible way is expected from the interactive hardware. In regard to *guidance of button function*, participants P3, P8 and P9 did not understand the mode button of D3, placed in the center of the circular combination made out of five buttons. Mode button used in D3 enable users to browse between different parameters. When a specific parameter is chosen, +/- buttons which are placed up and down, are used to change the value of these parameters.

In accordance with the same subtheme, four participants (P1, P5, P7 and P8) experienced difficulties for their tasks in D1. P1 did not understand that the blue rectangular button, which has a comparable size advantage to other buttons, can be used to start the device operation. P5 pressed the “1” button to access the past measurements though not receiving any feedback she proceeded to press the “2” button expecting to get the same output. In the end, she was not able to succeed. Similarly, P7 and P8 were not able to access the previous measurements by using the “1” and “2” buttons. P7 tried pressing the memory buttons once, not comprehending that pressing multiple times allows to browse among past measurements. In the case of P8, realizing not being able to complete the task given for accessing the previous measurements, she started to press each button on the device unknowingly.



Figure 4.13 Guidance of Button Function

During sessions, only the device D3 stood out for *shape and configuration of button pattern*. Five participants (P3, P4, P6, P8 and P9) are noted depending on this specific subtheme. P3 and P4 tried to turn on the device using the center button intuitively rather than pressing on the button labeled with “on”. P6 pressed the “off” labeled button, placed on the bottom of the pattern, to turn on the device and neglected the “on” button same as the other participants. She was observed to have the opinion that D3 has a single on/off button to turn on and off the device, whereas the device incorporates on and off buttons distinctively. The vice versa case has been observed for P9 thinking on button is used for both turning on and off the device. P8 while operating the device, used the off button as a back function between the menus. In

context, D3 does not have any back function or a button assigned to that specific action.



Figure 4.14 Shape and Configuration of Button Pattern

Attributes of the button placed on the devices can be analyzed under *text* and *color* sections. Selected devices D1 and D3 have several buttons with *text*, symbols or no indication leading to different features in their specification. P5 and P8 commented on the existence of text and its means of utilization in order to operate the devices successfully. P5 stated that “If there were any texts on the buttons of D1, it would have been easier for me to operate.” P8 giving feedback on the linguistic attribute of button text placed on D3, stated “It would have been easier to operate if the text were in Turkish,” commenting on the fact that the text on D3 is in English.

On the subtheme of *color*, D1 has different colored buttons exclusively. Two participants (P5 and P8) have been observed with button coloring in focus. P5 was not able to distinguish the operation button which has a dark blue coloring different from white device interface background and pressed the past memory button which has a grey colored thin bezel. P8 thought that the indicating graphics that have different colors to emphasize the level of measurement, are buttons and tried pressing on them.

4.3.3 Mapping

Establishing the connection between hardware and digital screen is another concern noticed during the field study. Two devices D3 and D3A showed mapping related problems both by observation and comments made by the participants. Considering D3, participants (P3, P4 and P6) faced with challenges comprehending the relation of hardware to display. P3 plugged the cable to the upper left port of D3 but she did not succeed in identifying that the CH1 button, placed on the left side of the interface, is used for stimuli parameter of the cable connected. In a similar manner, P4 tried to set the parameter of “CH2” by using the specific button while there has not been a cable connection made to the upper right port. In addition, P4 gave a feedback, stating that the relation between the screen, buttons and connection ports is complex and hard to conceive. Although P6 established the connection of upper left port and pressed the “CH1” button to control all the operational functions of D3, she failed to read the correlation between the digital display and the rest of the buttons. P2 did not succeed in using the timer function of D3A since he was not able to comprehend that pressing the +/- buttons result with changes in the digital display.

4.4 Factors Related with Environment

Environmental conditions had an effect on several sessions with examples as *device positioning* and *distance to energy source*. (Figure 4.15) Most of the participants (P1, P4, P5, P6, P7 and P9) placed the device D2 close to an electrical socket since the device requires grid electricity to be operated. Apart from the need of electrical supply, participant P2 needed a flat surface to achieve a convenient usage due to devices having mobile characteristics and a compact form. On the same subject, P2 was not able to press the on/off button of device D1 comfortably because it was placed on his lap. Although device D2 has a compact and portable design, participants (P1, P4, P5, P6, P7 and P9) who had experienced with D2 in the sessions, preferred to place D2 on a table in order to operate easily and properly.

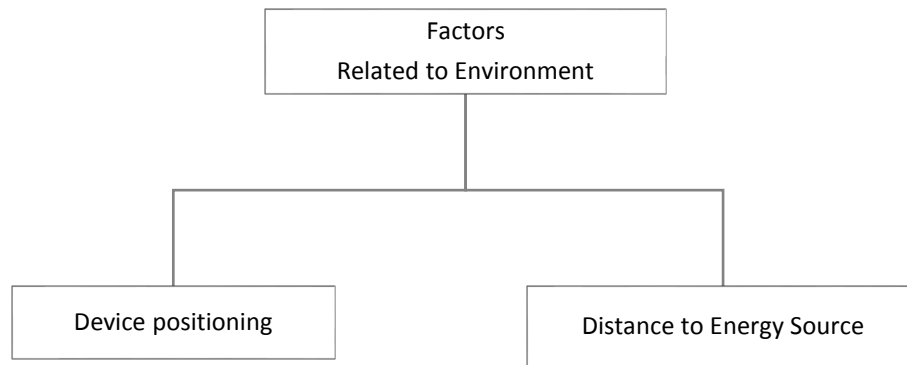


Figure 4.15. Factor Related to Environment Diagram

4.5 Factors Related with Operation

Tasks given during the sessions were performed diversely by participants depending on their perspective and past experiences. This diversity generates several concerns regarding *operation sequence*, *difficulties during usage* and *feedback provided by the device*. (Figure 4.16)

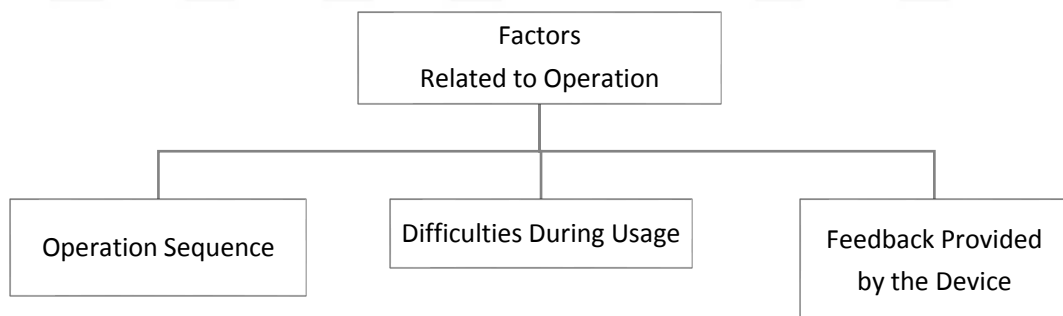


Figure 4.16 Factor Related to Operation Diagram

Five participants P1, P3, P4, P5 and P6 followed different *operation sequence* for D2 and D3. While P3 set the parameters on the screen before plugging in the cables of D3, P5 fit the air hose to D2, then plugged in the electrical cable.

These flexibilities in the operation sequence generate several *difficulties during usage* for participants. While P1 and P6 had to hold the liquid container vertically

with one hand in order to prevent spill, with the other hand they had to cope with cable connections for the operation. In a similar situation, P4 preferred to set the parameters before establishing the cable connections and this led the device to switch of because of the time spent. In consequence, he thought that he had lost the measurement arranged.

Three devices D1, D2 and D3 received mentions from the participants regarding their *feedback provided by the device*. P4 asked “How long should D2 be working?” pointing to an issue about the duration of operation feedback. P8 and P9 did not recognize D3 was working until they felt the electrical stimuli. This leads to undesired device operation caused by lack of feedback. P2 tried to access a previous measurement while D1 was conducting a measurement giving no feedback regarding menus cannot be accessed.

CHAPTER 5

CONCLUSION

In this concluding chapter, the research questions, for which an answer has been sought, will be revisited based on the literature review and findings of the field study. Insights from the research, suggestions for the design process of home medical devices, and recommendations for further research will be expressed.

5.1 Research Questions Revisited

This section hopes to answer the research questions set at the beginning of the thesis, in reference to the research findings, and literature review.

5.1.1 Design Considerations for Home Medical Devices for the Elderly

Observations and feedbacks received for all four devices used in the study by the nine participants are categorized in several themes and subthemes under Section 3.3. These findings in total are five themes, fourteen subthemes and eighteen subcategories and are related with the users' capacities, devices' physical features, ways of interaction, environment, and operations made during the tasks (Figure 5.1).

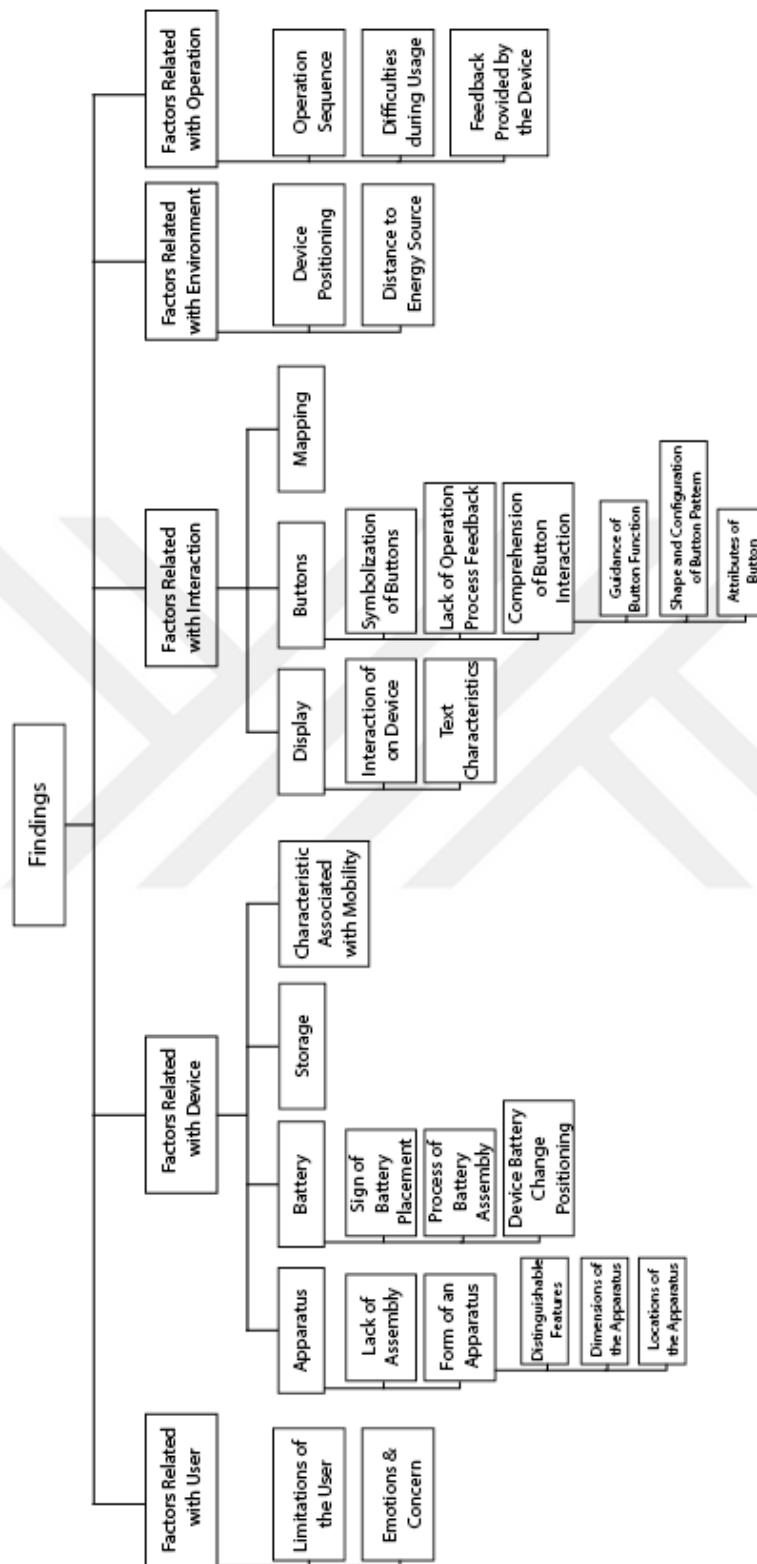


Figure 5.1 Findings Diagram

In the final chapter of the study, in order to summarize the analyzed findings five design considerations have been created in regard to themes explained in Chapter 3 Findings. Design considerations presented here after are visibility of structure, ease of use, comfort, feedback and perceptibility. The themes of findings, factors related with *device*, *interaction*, *environment* or *operation* can be used to show way for design criteria of home medical devices. These four themes during the categorization process for finalizing the study, when examined for their similarities and matching patterns, an involvement can be noticed. Factors related with device are included under design considerations of *visibility of structure*, *ease of use* and *comfort*. Related with interaction, the other design consideration affecting factor, includes displays, buttons and mapping issues. These subthemes partially overlap with considerations that include themes related with device such as *visibility of structure* and *ease of use*. Additionally, interaction theme is covered under *feedback* and *perceptibility* considerations. Findings related with operation theme are discussed under *ease of use* and *feedback* considerations. Related to environment the final theme of the findings is categorized under *comfort* consideration. These four main themes of findings are in junction with each other considering their placement under the design considerations and the correlation between themes can be emphasized by their repetition under several considerations.

5.1.1.1 Visibility

Visibility, one of the main principles followed by the notion of Don Norman, is the intuitiveness of the design allowing the users to get to know about the product and how to use it (Rodgers et al., 2019). In the field study, participants being handed the devices for the first time, enabled the visibility aspect of the design to be emphasized. All four devices include connections that needed to be assembled before an operation and disassembled after. This can be exemplified by D1 requiring the armband air hose connecting to the main body before the operation. D2 with the storing the apparatus after the operation is another example. Visibility considerations have been

detected under two themes including four subthemes in total. These are factors related with device and interaction and accordingly the subthemes are apparatus, battery, display and button.

Participants had struggled with apparatus connections regarding pressure and insertion needed for them leading up to lack of assembly guidance. This issue has been detected in three participants and three devices as discussed under section 3.3.2.1. All devices lacked visualizing the amount of insertion needed for the apparatus hence caused confusion for the pressure needed as well. This has been detected by users not being able to troubleshoot why the device has failed to start when a loose connection was present. Also, an indication of lack of assembly guidance was participants asking for a confirmation of the assembly to the researcher. Considering apparatus, form is another important aspect for the visibility considerations. Sessions indicated two participants coming up with issues related to apparatus form of D2. This has been caused by the container and the lid sharing the same form creating uncertainty for where the medication should be poured. In the light of visibility considerations and the observations made, the apparatus should indicate the amount of connection between the body and itself. This may help the elderly understand where to stop the assembly or how much further pressure is needed for an incomplete one. The apparatus should also provide the elderly to distinguish the specific task of the part with their form creating an intuitive guidance.

Two devices selected for the study are operated with batteries. On these devices, one of the tasks was changing the battery. Two participants were not able to insert the batteries in their correct positions. A more common issue observed with batteries was that six participants were not able to comprehend the removal sequence of batteries in both devices. The first issue was caused due to battery direction signs being hard to see. Removal sequence was in direct relation with clamps positioned in several places of the battery compartment restricting the free movement. Hence, in order to prevent the issues observed and stated by the participants, battery directions should not share the same color with the body or rather than embossed signs another way of indication should be investigated. For the common issue with

the battery clamps, the sequence of removal/assembly should be clearly indicated or clamps should be more striking for the user.

Two subthemes related with interaction raised concerns in terms of visibility considerations additionally. Participants had difficulties with the *interpretation of the device parameters* and *text characteristics* used on the display. Three participants were not able to give meaning to the parameters displayed on D1. Moreover, the same condition has been observed for a specific function of D3A. Text characteristics of D1 as observed from two participants' sessions required optical glasses to be read. Otherwise, without any sight aid the participants were not able to see the values displayed. To decrease the possibility of miscomprehensions, on-screen parameters should be incorporated with daily speech elements for easy understanding and they should be in adequate text size due to visual impairment with aging, considering the elderly as a user group.

Buttons as a way of interacting with the device are also analyzed named *symbolization of buttons* under visibility considerations. Problems observed in sessions related with buttons were in D1 and D3 by seven participants indicating a high number of misconducts. The operation/measure button used on D1 has a symbol in resemblance to common on/off sign. All six users of the specific device had experienced problems with this issue when they intended to turn on the device, it led to the measurement being started. A similar observation has been made in a single session of D3. The user with the lack of symbolization on on/off buttons, tried an irrelevant button to turn on the device. Related with buttons, texts and coloring attributes of them also raised visibility considerations. Participants commented on D1 and D3 having no explanatory texts placed on buttons. In the coloring subsection, as a way of habit users do not expect the dark blue button of D1 to operate the main function. Regarding button related issues, symbols used on the buttons should clearly identify the function they represent. The text of the buttons should be understandable and brief. The coloring used on buttons should separate them from each other and also the graphical components, in respect to their importance and frequency of usage.

5.1.1.2 Ease of Use

According to the Principles of Universal Design shared in Chapter 2.4 Usability, a number of considerations affect the devices' ease of use from the perspective of the user. The four devices selected for the study were chosen in the evaluation of the researcher with three devices having three different levels of complexity and the alternative of a device that shares the same level of complexity. Although results obtained from the field study indicated that the level of complexity in each device, evaluated by the researcher, are not linearly proportional with the number of issues observed considering the ease of use.

The data gathered during the sessions when analyzed with the consideration of *ease of use*, some subthemes are detected having a direct relation with the subject. The first subtheme concerning the consideration is factors related to apparatus. Two subcategories of the subtheme included under this section are, *dimension and location of the apparatus* and *placement of apparatus on body*. In regard to dimension and location, seven participants experienced difficulties on three devices. Participants struggled changing the filter and removing the filter lid of D2 caused by having small form to hold with hand but rather requiring to pinching with fingers. The filter was placed on a corner of the storage compartment with a restricted access. In another case, four participants faced the problem of connecting the cables of D2 and D3 since their connections were too tight and matching cable ends are small in comparison to be held by a hand and participants struggled to apply the required force for the assembly. In the session of D3A, the user as a task of maintenance was expected to remove the water containing filter unit. The container had its own space in the device with a closing lid. Since the location and the spacing of compartment are limited, the device caused problems when the container was attempted to be removed. When designing for the elderly, the spacing provided for the apparatus manipulation should enable accessing the specific body of the device and deliver the amount of volume a hand requires to move around the apparatus. Additionally, the apparatus should be adequate in size for the elderly to apply the force required.

One of the maintenance tasks given to the participants was related with battery changing analyzed under *process of battery assembly*. Three participants were observed with having trouble assembling the batteries of D1 and D3. On the case of D1, participants were not able to remove or assemble the batteries because a single slot holds all the batteries, which makes it harder for users to change them easily. For D3, while the batteries have their individual slots, the fit between them is excessively tight for the elderly. In a specific session, P3 preferred to use a knife to remove the batteries from slots. Hence, to achieve the ease of use in battery operated devices each battery should have its own slot and removing/assembly should be easy enough to do it by hand.

Characteristics associated with the *mobility* aspect of the devices used in the study received positive feedback from the participants for all devices. Especially for D3, P3 and P6 mentioned that, in the past, for the same treatment they had to visit a rehabilitation center, and now they can carry the device for the same function in their pockets. Although D3A has wheels to provide mobility for users, P2 stated that the location of the device is not needed to change frequently since the usage environment is mostly fixed. Having a high mobility specification enables the elderly to use devices easily, moreover, this feature has to be thought out within the context of environment of usage.

Tasks handed out to participants for using the devices conduct a sequence of actions to accomplish the desired output. The *operation sequence* to obtain the result is not strictly dictated by the devices, the sequence can be altered by the user according to their preferences. Three participants followed different paths to achieve their tasks though this has led to several difficulties for the operation. One of these difficulties can be exemplified as changing the course of actions caused the upcoming step needed to be performed concurrently with another step. Consequently, devices should clearly guide the elderly about the sequence of actions to prevent misconduct or overlapping of steps.

5.1.1.3 Comfort

While interacting with medical devices in a home environment during the sessions, in order to achieve a more comfortable experience of usage, several actions were carried out by the participants. Considering the factors related with the themes of device and environment, five subthemes of findings are involved with *comfort considerations*. The outputs of all four devices differ from each other and their ways of assembly are positioned diversely on them. This has led the participants to reposition the device and the apparatus in order to perform the operational tasks with convenience.

Achieving the desired amount of convenience during the usage, some participants preferred to position the device for the assembly of apparatus differently. Considering D1 and D2, five participants were observed turning the devices in some manner to access the ports and establish the connections. Although mobility aspect of the devices allows the users to rotate them easily, it also limits the users' range of motion. While participants held and rotated the device with one hand for convenience purposes, they had to conduct the connection operation with a single hand. Limited to one hand, this condition makes the process challenging for the elderly users. For instance, P1 and P2 have struggled in applying the force required and holding the device steady during assembling the connections of D1. Positioning the physical features on the device interface should prevent users' need of rotating the body or searching for another positioning in order to access and conduct the assembly. This condition also has a connection with the mobility aspect, since for a device having high mobility, the problem might not be the rotating process itself but the restriction of user's motion during the process.

Conducting maintenance of the devices has a relation with comfort consideration as well. Participants repositioned the devices (D1 and D3) in order to remove the battery lid. While some participants preferred to pull the lid, the others preferred to push depending on the amount of force they could apply. The lid and the accessibility of the batteries should be defined by the device clearly with the consideration of all

usage scenarios. Additionally, the physical limitations of the elderly should be a limiting factor to avoid excessive force requirements.

Two devices (D2 and D3A) include a storage compartment for their apparatus. A great majority of the participants could not manage to fit all parts of the apparatus in the compartment of D2 caused by the lack of information on how to position the apparatus inside the compartment. At the end of their tasks, participants preferred to store all apparatus in the compartment, where as an exception P4 did not want to place the electrical cable into the storage stating that hygienic conditions of the apparatus would be in risk. The user of D3A as another example, did not prefer to store the air hose apparatus in the compartment with the observation that he interacts with the cable every day and storing and removing from the compartment everyday becomes a nuisance for the user. In terms of the storage compartments, when the findings are analyzed with consideration of comfort, all the apparatus should be able to fit with ease or if a limited space is inevitable, guidance of the storage should be visually presented to the elderly. As for the electrical cables or parts that touch the ground or any place considered as non-hygienic, they should be separated from the other hygienic medically-related apparatus in their respective individual storage slots. Frequency of usage also should play a role in designing the storage compartment. Parts that are frequently used require a more convenient way of daily storage and removing process.

Two devices (D2 and D3A) require grid electricity to be energized and operated, thus this condition affects the *environment* aspect of the usage. Participants using the two devices observed to place the device close to an electrical socket in order to operate it. Besides electrical requirement, some participants needed a flat surface to obtain a comfortable usage, since P2 tried to use D2 placed on his lap ending up with some difficulties. If the devices need an electrical connection to be operated, the length of their electrical cable and the mobility aspect should be carefully thought for the elderly, since a short span of an electrical cable may bring up challenges in usage. Additionally, devices that need a specific surfacing for their operations should indicate this requirement clearly in the user handbook or visually on the device body.

5.1.1.4 Feedback

Feedback, another design consideration related with usage of home medical devices by the elderly, provides the amount of information to users about operation process and actions required to complete the task. Feedback should include the confirmation of action initiated by the user, operation processing and outcome of the action in order to indicate successful interaction to the user (Norman, 1992).

In the field study, difficulties caused by lack of feedback were observed and gathered under two themes, namely *interaction* and *operation*. Two devices D1 and D3 have a series of buttons to carry out operations and related functions. All six participants experienced miscomprehension of button function, due to lack of operation process feedback. The specific way of using memory buttons of D1 was not understood by any of the participants. Several participants were not able to associate 1 and 2 buttons with checking the measurement memory. This situation has been solidified with the observations such as participants confusing which button includes their measurement or not pressing the memory buttons more than once to shift among values. Also in which condition participants should interact with buttons, such as checking the memory while armband still on the users' body or during the measurement process, was another sign of lacking feedback during the process. In order to provide a "pleasurable experience", devices are expected to explain for themselves, what kind of a device they are, how they are used and what their functions are (Norman, 2013). In a brief statement, devices themselves and their interface (buttons) should represent their functions and their way of using to the elderly, who are the users, considering the findings.

Factors related with operation have also been detected to have a correlation with feedback considerations both in a positive and a negative way. Two subthemes, *operation sequence* and *lack of device operation feedback*, can be gathered under this topic. Two devices (D2 and D3) provide flexibilities in their respective task order of the preparation phase. For instance, while P3 arranged the parameters on display before making the cable assembly, P5 preferred to plug the cables first then

continued with the parameter set-up. However, these flexibilities caused difficulties during the operation process since they did not provide the user with feedback. Additionally, three devices received comments from participants regarding whether the devices they were using during the sessions were working or not. Devices failed to provide feedback on the ongoing operation to the users, hence the questions arose from the participants. During sessions, P4 did not understand how long the device should work to finish his task, P8 did not recognize the device was working until the muscle received the stimuli and P2 tried to access the memory of previous measurements while D1 was conducting a measurement. Examples obtained clearly indicate that, devices should be able to provide clear and distinguishable feedback to the elderly when a button is interacted with and during or after conducting their respective function. Also, the feedback should be intuitive providing signs as to how to use the device or a specific function in an explanatory way that can be carried out by means of text, color, shape or placement of elements on the interface.

5.1.1.5 Affordance

Affordance is another consideration essential for users' experiences. The definition of affordance is an associative mixture between the characteristics of the devices and the physical and cognitive capacities of the users to indicate a way of using (Norman, 2013). During the sessions, participants were not able to correlate the display parameters with the series of buttons, which leads to a subcategory *comprehension of button interaction*.

Two devices D1 and D3 showed issues in relation with affordance consideration. All the participants, while using D1, failed to access the previous measurements or save their finalized measurement under using the specific user "1" or user "2" buttons. This has been also supported with the observation of participants not being able to comprehend that pressing the memory buttons multiple times enables them to browse between measurements. In the case of D3, likewise, all the participants failed to perceive the buttons and their functional capabilities. D3 has buttons placed on a

circular pattern and most of the users expected the button placed on the center of the pattern to be used for turning on and off the device. On the contrary, the device has an individual on and off button, but they have been overlooked caused by the perceptual misconduct. In another case related with D3 is that while the participants were trying to set the parameters, they were not able to comprehend which parameter they have been setting up by just looking at the screen. The task of setting up the parameters also brought up the issue that participants tried to browse between the parameters by using outward buttons placed on the circular pattern thinking they were directional buttons for browsing. Considering the affordance, while designing the interface of the devices, past experiences, habits and general knowledge of the user groups should not be neglected. It seems that the elderly as a user group tend to use the devices with their experiences in focus rather than comprehending the new ways of operation. Additionally, interfaces should provide visual hints and instinctive elements in regard to device functions to be comprehended by the elderly easier.

5.1.2 Preferences of the Elderly Using Medical Devices

Findings presented from the sessions as stated in the above sections not only include observations made by the researcher but also include the comments and feedbacks made by the participants. Statements made by the elderly are valued precious and included in the study, because these allow the researcher to have an insight from their perspective. The perspective gained can also be used to determine the preferences of the elderly while using these home medical devices.

In order to investigate the preferences of the elderly, observations, feedback and comments received were analyzed in detail, concentrating on both the researcher's and the participants' points of view. In the findings, users were analyzed under two subthemes as *limitations* and *emotions & concerns*. Among the participants selected for the study, two of them have limited physical abilities in their hands caused by rheumatism and osteoporosis. These physical limitations affected assembling the

connections in a negative way during sessions which led to some failures in their tasks. Another limitation observed was losses in visual sensory capabilities in some of the participants. This limitation has been detected with participants requiring an optical glass to read the values displayed on the digital screen.

Participants according to the findings, showed a wide range of *emotions & concerns* to the three of the devices. The feelings have been found to be essential for the study since they affect the first approach and bias shown toward the devices. Emotions observed were *unsureness*, *familiarity* and *shyness* while concerns were *ease of use* considering these devices. Most of the *unsureness* feelings were directed to the physical connections and assembling parts causing participants to check the process repeatedly. *Familiarity* in correlation with appearance of the devices, was another feeling displayed. Users gave feedback about their familiarity feelings from their past experiences with the medical devices. While positivity has been observed when a participant had a previous experience with a similar device, the contrary has been detected, in cases where unfamiliar feelings shaped the participants' opinions on not being able to operate. Another feeling investigated was *shyness*. Shyness has been found out when the device has high number of apparatus leading users to think that the device is complex to operate. *Ease of use* relying on comments of the participants, has been considered as a concern as well. Participants compared the devices' features and themselves to one another, as a result, the number of buttons and the operations affected their opinion on ease of use.

According to the findings related to the elderly, the population shows a great variety of characteristics depending on their culture, life style, educational level and background in interactions with devices. Hence, during the design process of home medical devices for the elderly, emotions and limitations of the elderly as a comprehensive user group bring up a wide range of considerations.

5.2 Limitations of the Study

The Covid-19 pandemic has affected the study greatly since the disease poses major threat for the elderly more than any other population group. The schedule of the field study have been ambiguous due to unpredictable nature of the disease and colided with the vaccine development phases. The limitations imposed on the field study were not solely caused by the pandemic but searching for participants was also another problem faced with. Reaching out to nursing-homes only by mail or telephone because of the curfew, was not enough to get the staff's interest and consent for the study. Therefore, participants were reached out by the previous participants and their network. All the sessions to ensure the safety of the environment, were conducted with face masks and protective equipment against Covid-19.

Limitations in communicative aspects of the study were also a concern. Questions directed to the elderly, affected by the deterioration of hearing and comprehension skills, were required to be repeated several times. Some questions were altered in another direction or divided into parts to be more simple and understandable.

5.3 Recommendations for Further Research

The thesis and the field study concluded were to analyze the interaction between the elderly and the home medical devices. Based on the findings of both literature review and the results of the field study, the issues elderly had with the devices are in a noticeable pattern as the discussion part indicates.

This indication can be used as a guide and be utilized for upcoming device design phases in order to help the user to have a more user-friendly experience. The four devices provided for the sessions have different features and different complexity levels. Also the user interfaces on these devices included many type of involvement, from buttons, knobs, port connections and screens. This variety helped to examine different interface element and the perspective of the elderly against these elements.

Sessions carried out with just the researcher and the participants. The study can be extended including additional medical professionals, helping the observations be analyzed with a broader perspective. Also, the data gathered can be expanded by reaching out the nursing homes or medical institutions where elderly are accessible in greater numbers.





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APPENDICES

A. Ethical Committee Approval

UYGULAMALI ETİK ARAŞTIRMA MERKEZİ APPLIED ETHICS RESEARCH CENTER	 ORTA DOĞU TEKNİK ÜNİVERSİTESİ MIDDLE EAST TECHNICAL UNIVERSITY
DÜMLUPINAR BULVARI 06800 ÇANKAYA ANKARA/TURKEY T: +90 312 210 22 91 F: +90 312 210 79 59 ueam@metu.edu.tr www.ueam.metu.edu.tr	
Sayı: 28620816 /	20 Mayıs 2021
Konu : Değerlendirme Sonucu	
Gönderen: ODTÜ İnsan Araştırmaları Etik Kurulu (İAEK)	
İlgi : İnsan Araştırmaları Etik Kurulu Başvurusu	
Sayın Naz A.G.Z. Börekçi	
Danışmanlığını yürüttüğünüz Zeynep Cansu İnal'ın "Yaşlılar için ev tipi medikal cihazların kullanılabilirliğinin incelenmesi" başlıklı araştırması İnsan Araştırmaları Etik Kurulu tarafından uygun görülmüş ve 201-ODTU-2021 protokol numarası ile onaylanmıştır.	
Saygılarımızla bilgilerinize sunarız.	
	
	Dr. Öğretim Üyesi Şerife SEVİNÇ İAEK Başkan Vekili

B. Field Study Protocol (Tur)

TEZ ÇALIŞMA PROSEDÜRÜ

ODTÜ Endüstriyel Tasarım Anabilim Dalı Yüksek Lisans tez çalışması kapsamında, yaşlıların ev tipi medikal cihaz kullanım deneyimleri incelenerek, tasarım sürecinde dikkat edilmesi gereken kriterlerin tespit edilmesi amaçlanmıştır. Bu çalışma için belirli tasarım kriterleri göz önünde bulundurularak üç farklı kullanım zorluk seviyesi oluşturulmuş (a, b ve c) ve bu seviyelere bağlı olarak belirli medikal cihazlar seçilmiştir. Her katılımcıya üç kategoriden seçilmiş iki cihaz verilecek olup, katılımcılardan cihazlara ait kullanım senaryolarındaki görevleri tamamlamaları istenecektir. Kullanıcılara göre cihazlar değişkenlik göstermekle beraber medikal cihaz sunulmadığı veya tedarik edilemediği durumda çalışmanın maket üzerinden gerçekleşmesi planlanmıştır.

Tablo: Zorluk seviyelerine göre cihaz kategorileri

a.



Tansiyon Cihazı / Ateş Ölçüm Cihazı / Kan Oksijen Ölçüm Cihazı

b.



Nebülizatör / EpiPen / Yardım cihazı

c.



Oksijen Konsantratörü / Tens Cihazı

65 yaş üstü olmak koşuluyla katılımcılarla uygun örnekleme yöntemiyle iletişime geçilmesi planlanmıştır. Pandemi koşullarından dolayı katılımcıların isteğine bağlı olarak kendi ev ortamlarında veya zoom, skype gibi çevrimiçi platformlar üzerinden görüşmeler gerçekleştirilecektir. Planlanan çalışmada yarı yapılandırılmış görüşme, gözlem, ses kaydı ve görüntü kaydı yöntemleri kullanılacaktır. Görüşmelerde cinsiyet, yaş, eğitim durumu, medeni durumunu içeren demografik bilgileri, teknolojik ve medikal cihaz geçmiş deneyimleri sorularak demografik bilgi edinilmesi planlanmıştır. Yarı yapılandırılmış görüşmelerde katılımcılardan, belirlenen görüşme sorularına verdikleri cevapları ayrıca derinleştirmeleri istenecektir.

Görüşme Soruları

Kaç yaşındasınız?

Eğitim durumunuz nedir?

Medeni durumunuz nedir?

Hanenizde kaç kişiyle yaşıyorsunuz?

Daha önce medikal cihaz kullandınız mı? Kısaca hangi cihazları kullandığınızdan bahsedebilir misiniz?

Evde hangi teknolojik cihazlara sahipsiniz? Hangi cihazları daha çok kullanıyorsunuz?

Şu ana kadar kullandığınız hangi cihaz sizi kullanım açısından en çok zorladı? Bu cihaza ait tecrübenizi anlatır mısınız? Cihazın ne yönde değişmesi kullanımınızı kolaylaştırdı?

*Katılımcıya ilk cihaz verilir ve ön bilgilendirme yapılır. Bahsedilen görevleri yerine getirmesi beklenir.

(Açma/kapama, menüler arasında dolaşma, fonksiyonu yerine getirme, cihaz bakımı vb.)

Verilen tüm görevleri tamamladığınızı düşünüyor musunuz?

Görevler sırasında hangi zorlukları yaşadınız? Bu zorlukları düzeltmek amacıyla neler yapılabilir?

Bu görevleri tamamlarken kolaylık sağladığınızı düşündüğünüz unsurlar nelerdir?

Size hangi cihaz daha karmaşık geldi? Hangi açılardan karmaşık geldi? Bu karmaşıklık nasıl giderilebilir?

C. Field Study Protocol (Eng)

THESIS STUDY PROCEDURE

In the scope of Master of Science Thesis Study in Industrial Design Department at METU, it is aimed to determine the criteria that should be considered in the design process of home medical devices by examining the usage experiences of the elderly with them.

For this study, considering certain design criteria, three different usage difficulty levels (a, b and c) were created and certain medical devices were selected according to these levels. Each participant will be given two devices with different difficulty levels selected from these categories, and they will be asked to complete the tasks given to them during the usage scenarios of the devices. Although the devices show variety according to the users, it is planned to carry out the study on a mock-up model in case the medical device cannot be presented or supplied to the participant.

Table: Device Categories According to the Difficulty Levels

a.



Blood Pressure Monitor / Infrared Thermometer / Pulse Oximeter

b.



Nebulizer / EpiPen / Medical Alert System

c.



Oxygen Concentrator / TENS Unit (Muscle Stimulator)

It is planned to contact the participants with the appropriate sampling method, provided that they are over 65 years old. Due to the pandemic conditions, interviews will be held at the request of the participants either in their own home environments or online platforms such as Zoom or Skype. In the planned study, semi-structured interview, observation, audio and video recording methods will be used. Demographic information regarding to the participant is planned to be obtained by asking their gender, age, education level, marital status, past experiences of technological and medical devices during the interviews. Using In semi-structured interviews as a method, participants will be asked to further deepen their answers to the interview questions asked.

Interview Questions

How old are you?

What is your education status?

What is your marital status?

How many people do you live with in your household?

Have you ever used a medical device before? Can you briefly talk about which devices you have used?

What technological devices do you have at home? Among these, which devices do you use more frequently?

Which device you have used so far has been the most difficult for you in terms of use? Can you tell us about your experience with this device? What changes would make the device easier to use?

*The first device is given to the participant and brief information about it is given. It is expected from participant to accomplish the tasks given.

(Turning on/off, navigating through menus, performing functions, device maintenance, etc.)

Do you think you have accomplished all the given tasks?

What difficulties did you experience during the usage session? What can be done or changed to correct these difficulties?

What elements do you think helped you to complete the tasks?

Which device seemed more complex to you? In what ways did it seem more complicated? How can this complexity be eased?

D. Interview Guideline (Tur)

Araştırma Hakkında

Merhabalar, adım Zeynep Cansu Ünal. ODTÜ’de Endüstriyel Tasarım bölümünde yüksek lisans yapmaktayım. Tezimde 65 yaş üstü kullanıcıların medikal cihazlarla ev ortamındaki etkileşimini incelemeyi amaçlıyorum.

Öncelikle çalışma sırasında dilediğiniz zaman sebep vermeksizin görüşmeyi durdurabilirsiniz. Bu görüşmede elde edilecek bilgiler üçüncü kişilerle paylaşılmayacaktır.

Çalışmadan kısaca bahsedecek olursam tez konum kapsamında, belirlenmiş olan iki tane medikal cihazı kullanmanızı isteyeceğim. Bu kullanım sırasında size belirli görevler vererek bu görevleri tamamlamanızı isteyeceğim. Görev sonrasında deneyimlerinizi benimle paylaşmanızı rica edeceğim. Sizin içinde uygunsa görüşme süresince ses ve görüntü kaydı almak istiyorum.

Görüşme Tarihi:	
Görüşme Saati:	
Görüşme Yöntemi:	
Görüşülen Kişi (kod):	
Görüşme Bitiş Saati	

1. Bölüm	Demografik Sorular
Kaç yaşındasınız?	
Eğitim durumunuz nedir?	☐ İlköğretim ☐ Lise ☐ Üniversite ☐ Yüksek Lisans
Mesleğiniz nedir?	
Medeni durumunuz nedir?	
Halenizde kaç kişiyle yaşıyorsunuz?	
Herhangi kronik bir rahatsızlığınız var mı?	

2. Bölüm	Medikal ve Teknolojik Cihazlarla İlgili Deneyim
Daha önce medikal cihaz kullandınız mı?	
Kısaca hangi cihazları kullandığınızdan bahsedebilir misiniz?	
Ne zamandır kullanıyorsunuz? Ne sıklıkla kullanıyorsunuz?	
Evdeki elektronik cihazlarınızdan	

hangilerini sıklıkla kullanıyorsunuz?	
Şu ana kadar kullandığımız hangi cihaz sizi kullanım açısından en çok zorladı?	
Bu cihaza ait tecrübeyi anlatır mısınız?	
Cihazın ne yönde değişmesi kullanımınızı kolaylaştırırdı?	

Cihaz 1

3. Bölüm		Cihazlarla Etkileşimin İzlenmesi
Görevler		Lütfen belirttiğim görevleri cihazınızla gerçekleştiriniz
Açma/kapama		
Menüler arasında dolaşma		
Ana işlevi yerine getirme		
Cihaz Bakımı	Pil değişimi	
	Parçanın temizlenmesi	
	Parçanın değiştirilmesi	
Kullanım sonrası		Lütfen cihaz kullanımınızla ilgili aşağıdaki soruları yanıtlayınız
Verilen görevleri gerçekleştirdiğinizi düşünüyor musunuz? Neden?		
Deneyiminiz sırasında hangi zorlukları yaşadınız? Neden?		☐ Ağırlık ☐ Kinestetik His ☐ Biçim ☐ Renk ☐ Buton ☐ Font
Bu zorlukları düzeltmek amacıyla cihaz ve kullanım çevresiyle ilgili neler yapılabilir?		
Deneyiminiz sırasında cihazla ilgili kolaylık		

sağladığını düşündüğünüz unsurlar nelerdir?	
Cihazı kullanmadan önce neler düşündünüz? Çekindiğiniz bir şey var mıydı? Neden?	
Kullanım sonrasında sahip olduğunuz bu düşünceler ne şekilde etkilendi? Neden?	

Cihaz 2

3. Bölüm		Cihazlarla Etkileşimin İzlenmesi
Görevler		Lütfen belirttiğim görevleri cihazınızla gerçekleştiriniz
Açma/kapama		
Menüler arasında dolaşma		
Ana işlevi yerine getirme		
Cihaz Bakımı	Pil değişimi	
	Parçanın temizlenmesi	
	Parçanın değiştirilmesi	
Kullanım sonrası		Lütfen cihaz kullanımınızla ilgili aşağıdaki soruları yanıtlayınız
Verilen görevleri gerçekleştirdiğinizi düşünüyor musunuz? Neden?		
Deneyiminiz sırasında hangi zorlukları yaşadınız? Neden?		☐ Ağırlık ☐ Kinestetik His ☐ Biçim ☐ Renk ☐ Buton ☐ Font
Bu zorlukları düzeltmek amacıyla cihaz ve kullanım çevresiyle ilgili neler yapılabilir?		
Deneyiminiz sırasında cihazla ilgili kolaylık		

sağladığını düşündüğünüz unsurlar nelerdir?	
Cihazı kullanmadan önce neler düşündünüz? Çekindiğiniz bir şey var mıydı? Neden?	
Kullanım sonrasında sahip olduğunuz bu düşünceler ne şekilde etkilendi? Neden?	

4. Bölüm	Cihazlar Arası Kıyaslama
Sizce bu cihazlardan hangisi kullanım açısından diğerinden farklı? Neden? Nasıl geliştirilebilir?	☐ Kullanım yeri ☐ Kullanım şekli ☐ Biçim ☐ Görünüş ☐ Doku
Sizce bu cihazlardan hangisi arayüz açısından diğerinden farklı? Neden?	

E. Interview Guideline (Eng.)

About the Research

Greetings, my name is Zeynep Cansu Ünal. I am a Master's student in Industrial Design at Middle East Technical University. In my thesis, I aim to analyze the interaction of users over the age of 65 with medical devices in the home environment.

Before all else you are able to stop the session at any time without giving any reason. The information gathered in this meeting will not be shared with third parties and will be kept confidential.

As a brief explanation of the study, I will request you to use two medical devices for the session. During your usage period I will be giving you certain tasks and ask you to complete them. After this period I will ask you to share your experiences with me. As to your consent, I would like to record audio and video during the session

Interview Date:	
Interview Time:	
Way of Communication:	
Person Interviewed (Insignia):	
Interview End Time:	

1. Chapter	Demographic Questions
How old are you?	
What is your level of education?	☐ Primary School ☐ High School ☐ University ☐ Master's degree or higher
What is your occupation?	
What is your marital status?	
How many people do you live with in your household?	
Do you have a chronic condition?	

2. Chapter	Experience Related to Technological and Medical Devices
Have you ever used a medical device before?	
In a short manner can you talk about which devices you have used?	
How long have you been using them? In which frequency?	

Which of your electronic devices at home do you use frequently?	
Which device you have used so far has been the most difficult for you in terms of usage?	
Can you share your experience with this device?	
In what direction would the device change in order to make it easier for you to use it?	

Device 1

3. Chapter		Observation of Interaction with Devices
Tasks		Please perform the tasks I give you using your device
Open/Close		
Navigating between menus		
Performing the main function		
Device Maintenance	Battery Change	
	Cleaning a part	
	Changing a part	
After usage		Please answer the following questions regarding your device usage
Do you think you were able to accomplish the task given? Please explain.		
What challenges you have come up with during your usage experience? Please explain why.		☐ Weight of the Device ☐ Kinesthetic Feeling ☐ Shape ☐ Color ☐ Buttons ☐ Fonts used
What can be changed about the device and its		

environment to correct or ease these difficulties?	
What aspects of the device have provided you convenience during your experience?	
What were your initial thought before using the device? Was there anything you were abstain of? Please explain why.	
How did these thoughts you had affected after the usage? Please explain why.	

Device 2

3. Chapter		Observation of Interaction with Devices
Tasks		Please perform the tasks I give you using your device
Open/Close		
Navigating between menus		
Performing the main function		
Device Maintenance	Battery Change	
	Cleaning a part	
	Changing a part	
After usage		Please answer the following questions regarding your device usage
Do you think you were able to accomplish the task given? Please explain.		
What challenges you have come up with during your usage experience? Please explain why.		☐ Weight of the Device ☐ Kinesthetic Feeling ☐ Shape ☐ Color ☐ Buttons ☐ Fonts used
What can be changed about the device and its		

environment to correct or ease these difficulties?	
What aspects of the device have provided you convenience during your experience?	
What were your initial thought before using the device? Was there anything you were abstain of? Please explain why.	
How did these thoughts you had affected after the usage? Please explain why.	

4. Chapter	Comparison between the Devices
Which of these devices do you think differ in terms of usage? Please explain why. How can it be improved upon?	☐ Place of use ☐ Way of use ☐ Shape ☐ Appearance ☐ Texture
Which of these devices do think differ in terms of user interface? Please explain why.	

F. Consent Form

ARAŞTIRMAYA GÖNÜLLÜ KATILIM FORMU

Bu çalışma ODTÜ Endüstriyel Tasarım Anabilim Dalı yüksek lisans öğrencilerinden Zeynep Cansu İnal tarafından yürütülmektedir. Bu form sizi araştırma koşulları hakkında bilgilendirmek için hazırlanmıştır.

Çalışmanın Amacı Nedir?

65 yaş üstü katılımcıların farklı zorluk seviyelerindeki medikal cihazların kullanım deneyimi incelenerek cihazların tasarım sürecinde dikkat edilmesi gereken unsurların elde edilmesi amaçlanmaktadır.

Bize Nasıl Yardımcı Olmanızı İsteyeceğiz?

Araştırma isteğinize bağlı olarak yüz yüze ya da çevrimiçi platformlar aracılığıyla gerçekleştirilecektir. 65 yaş üzeri katılımcılar davet edilecek olup, yaklaşık 30 dakikalık bir süre boyunca ilgili medikal cihazlarda verilen görevleri tamamlamanız beklenmektedir. Çalışma öncesinde kullanıcı profilinizi tamamlamak amacıyla birkaç soru sorulacak olup çalışma sonrasında da çalışmaya dair belirli sorular yöneltilecektir.

Katılımınızla ilgili bilmeniz gerekenler:

Bu çalışmaya katılmak tamamen gönüllülük esasına dayalıdır. Herhangi bir yaptırıma veya cezaya maruz kalmadan çalışmaya katılmayı reddedebilir veya çalışmayı bırakabilirsiniz. Araştırma esnasında cevap vermek istemediğiniz sorular olursa dilediğiniz şekilde soruyu geçebilirsiniz.

Araştırmaya katılanlardan toplanan veriler tamamen gizli tutulacak, veriler ve kimlik bilgileri herhangi bir şekilde eşleştirilmeyecektir. Katılımcıların isimleri bağımsız bir listede toplanacaktır. Ayrıca toplanan verilere sadece araştırmacılar ulaşabilecektir. Bu araştırmanın sonuçları bilimsel ve profesyonel yayınlarda veya eğitim amaçlı kullanılabilir, fakat katılımcıların kimliği ve kişisel bilgileri gizli tutulacaktır.

Riskler:

Çalışma esnasında, medikal cihaz kullanımı herhangi bir risk oluşturmamaktadır.

Araştırmayla ilgili daha fazla bilgi almak isterseniz:

Çalışmayla ilgili soru ve yorumlarınızı araştırmacıya zeynep.unal@metu.edu.tr adresinden iletebilirsiniz.

Yukarıdaki bilgileri okudum ve bu çalışmaya tamamen gönüllü olarak katılıyorum.
(Formu doldurup imzaladıktan sonra uygulayıcıya geri veriniz).

İsim Soyad

Tarih

İmza

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G. Example of Data Analysis Table (for participant)

[illegible]

H. Example of Data Analysis Table (for devices)

[illegible]

	Ayınca Kapama	Tonkayın	Enişlebişlekle depolamasına	Feedbox	Bakım (PE, fibre...)	
P1		kabloya ulaşma tam lakamadığı için hawa gelmeydi.	Prize ve sırt bir yuvarı olduğu yene geldi.	Hawa gelmeyince bir penişli olduğunu anladı	Fibreyi hatamın içine dışarıya almaktı zorlandı	
P4		Sın kulanın 40 parçanın hangisi çıktı hangisi altına konuyordu dedi.	Çihani yününü değiştirmekten, arkasına eğilerek kabloya taktı.	Ne kadar süre çalışıyordun?	Elime almamam mı gerekliydi, bir cümlede mı almam lazım?	
		Sın yününü gösteriyordu, fır kadar koyuyordu bilmiyeli.	Bunlar biraz daha sırtı olduğu için, kaldırı burada olmamalıydı.		Ama burada indirip yok, elle almam doğru olur mu bilmiyorum.	
		Dökümü diye konuyordum.				
P5			Çihan kendine çevirmek kabloya taktı	Öst parçanın altına oturduğundan emir almamalı		
			Prize yakın bir manşet geçti.			
P6		Enişlebişlekle selebileti kabloya aşırdıklarını zorlandı.	Prize ve sırt bir yuvarı parçama muallaka kabloya için arada kullanıldı.		Fibreyi takip çıkarmada zorlandı, kayış geldi	Ne duvarları bir yere koyamk lazım, gözetimden, ama bir düzün gerekliydi.
			Çihan kendine dönürmekten , çihani arkasına geçip kabloya taktı			
P7			Kaldırı çikeni kendine çevirmek taktı.			
P9		Parçadaki kemik akıldığı sebebyle plastik kaldırım üzerine sahnelik oturulmuş. Oturduğundan emir olamıyor benden teydi istadı.	Çihan kulanımı için fır yakın bir yer seçti, sırt bir yuvarı sırtına getirdi.	Sın kapamın yününü kırıştırdı.		Bütün parçaların çihani için perşeydi bir yerde sahneliyordu, kulanı, ağ amartı ortaya çıkarttığı diye geldi.
		Aynı yerden akıldığı parçaları tekrar koyuyordu zorlandı.	Önce fır prize taktı, sonra çihani arkasına kendine dönürmekten kaldırım altına çihani taktı.			

[illegible]

I. Titles and Subtitles of the Data Gathered

