Applying Product Design Methods to Medical Device Design With a Case Study on Home Care Devices

By

Aslı ÇETİN

A Dissertation Submitted to the Graduate School in Partial Fulfillment of the Requirements for the Degree of

MASTER OF INDUSTRIAL DESIGN

Department: Industrial Design
Major: Industrial Design

İzmir Institute of Technology
İzmir, Turkey

July, 2004

We approve the thesis of **Aslı ÇETİN**

Date of Signature

..... **26.07.2004**

Assist. Prof. Yavuz SEÇKİN

Supervisor

Department of Industrial Design

..... **26.07.2004**

Assist.Prof. Dr. A. Can ÖZCAN

Co-Supervisor

Department of Industrial Design

..... **26.07.2004**

Prof. Dr. Akın SÜEL

Department of City and Regional Planning

..... **26.07.2004**

Assoc. Prof. Dr. H. MURAT GÜNAYDIN

Department of Architecture

..... **26.07.2004**

Assist. Prof. Yavuz SEÇKİN

Head of Department

ACKNOWLEDGEMENTS

I would like to thank to my supervisor Assist. Prof. Yavuz SEÇKİN for his invaluable advises and helps during my industrial design education. I would also like to thank to my co-supervisor Assist. Prof. Dr. A. Can Özcan for his endless patience and educational support during my academic studies.

I would like to send my loves and thank a lot to my best friends, my lovely father Vedat Çetin, who is my lifelong educator, my lovely mother Ayşen Çetin, who is my one and the only confidant and my lovely brother Ali Haydar Çetin, who is the light of my being, for their invaluable supports in my whole life.

I thank to my friends Nergiz Yigit and Elif Kocabıyık for their emotional support in all levels of my life of last three years and Çağlar Yıldırım for his love and patience during my thesis study.

And I would like to thank all people who support me in one way or another during this thesis study.

ABSTRACT

Medical device design is one of the most important and most promising fields of industrial design. Medical devices, which were once designed by doctors, technicians and other people, who usually use such devices, have become insufficient in meeting the needs of today's. In this respect, design of such devices and methods, which are used in the design process, comes away as main topics, which have to be carefully undertaken.

Product design methods have the capacity of solving the problems of medical device design field, as they have in many other fields. In this study, the ways of applying these methods into the medical device design process, especially in home care medical device design, are going to be examined.

ÖZ

Tıbbi gereç tasarımı, günümüzde, gittikçe önem kazanan ve en çok umut vaadeden tasarım alanlarından biridir. Geçmişte doktorlar, teknisyenler veya tıbbi gereçleri kullanan diğer kişiler tarafından tasarlanan ürünler, günümüz ihtiyaçlarını karşılamada yetersiz kalmaktadır. Bu açıdan bakıldığında, bu ürünlerin tasarımı ve bu süreçte kullanılan yöntemler, dikkatle ele alınması gereken konular olarak karşımıza çıkmaktadır.

Ürün tasarım yöntemleri, diğer birçok alanda olduğu gibi, tıbbi gereç tasarımı alanında da, uygulanması halinde, verimli sonuçlar doğurabilecek niteliktedir. Bu çalışmada, söz konusu yöntemlerin hangi açılardandan ele alınabileceği ve hangi ürün tasarım yöntemlerinin tıbbi gereç tasarımı, ve özelinde, ev tipi tedavi gereçleri alanında uygulanabileceği incelenmektedir.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1

INTRODUCTION

When you make a thing, a thing
that is new, it is so complicated
making it
that is bound to be ugly.
But those that make it after you,
they don't have to worry
about making it.
And they can make it pretty,
and so everybody can like it
when the others
make it after you.

PICASSO

1.1 Scope

In this study, product design methods those can be applied in the design process of medical devices are going to be examined. In this context, product design methods and medical device design process are going to be examined from the points of user centered design and human factors. Home healthcare products will be the central interest in the research process. At the end of the research, the design process and the methods of IDEO, a leading design firm, is going to be inspected with the examples of home care devices.

1.2 Limitations

This study is not attempting to identify the specific design processes for specific medical conditions or to border the medical design process with the methods identified within the research. The research is restricted to identifying and collecting together the design methods which can be also used in the medical device design. The aim is limited

with understanding the logic of medical design and suggesting alternative use of methods in designing medical devices by addressing living models.

1.3 Intended Audience

The intended audience for this study includes product designers, educators, healthcare managers, design and biomedical engineering students and other people who interest in product design and design methods.

1.4 Research Questions

This research addresses to following research questions;

- What are the main characteristics of the medical product design process?
- What points should be considered in effective design of medical devices?
- Why is medical device design different from the other consumer products design?
- What are the roles of human factors and user centered design within the medical equipment design?
- What methods are usually used within the design process?
- What are the roles of design methods in the medical design process?
- How a designer can choose the right methods?
- How can design methods be applied to home care device design?

An additional affix will contain numbered references addressing books, articles, web references and conference texts which help to identify those research questions.

1.5 Research Methodology

In this study, documentary investigation, bibliographic analyses, descriptive research and a small case study will be used for research. A primary research which addresses the future trends will also be contained within the study.

1.6 Summary of Sections

In the first chapter of this study, the reader will find a description of aim of the study.

The second chapter will present an investigation of medical device and medical device process, and an overview of design methods from traditional to new. In this respect, the main steps of a medical device design process and the origins of the need for new design methods will be examined.

The third chapter will examine the design methods those can be used within the medical device design process from the point of home care. Medical device trends and characteristics of health care will be reviewed in the name of design methods. At the end of this chapter suitable methods those can be used in the design process of medical devices will be provided.

In the fourth chapter an illustrative case study will be presented to make unfamiliar concepts clear, and give a common language about the studied subject. One of the most important leaders of the consumer and medical product design firms, IDEO, will be examined in this respect.

The fifth and the final chapter will examine how each research question was answered. It will also be argued that what might be done different if the research is to be repeated.

CHAPTER 2

MEDICAL DEVICE DESIGN PROCESS

In this chapter, a general overview of design methods and basic principles of medical device design are going to be studied. The ways of applying product design methods to medical device design process require knowledge about both medical device design and product design methods. Therefore, both two subjects are going to be studied in a detailed way.

To apply design methods to the medical device design, it is inevitable to analyze the design process of a medical device design and expose similarities and the differences of the processes. The analysis of the design process is going to be studied within the context of rational design methods, which encourage a systematic approach to design. These methods are selected because of the scientific and knowledge-based structure of the medical device design. The creative design methods are also going to be mentioned because of the structure of the rational design methods which have complementary aspects of a systematic design approach with creative design methods.

2.1 Definition of Medical Device

A brief description of the medical device can be useful to understand the design process of a medical device.

According to the European Medical Device Directive (93/42/EEC), a medical device is; ...any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for it's proper application intended by the manufacturer to be used for human beings for the purpose of;

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conception,

and which does not achieve its principle 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.

"In 1976, with input from the Cooper Committee, the Food and Drug Administration created the Medical Device Amendments to the FFD&C Act, which were subsequently signed into law. The purpose of the amendments was to ensure that medical devices were safe, effective and properly labeled for their intended use. To accomplish this mandate, the amendments provided the FDA with the authority to regulate devices during most phases of their development, testing, production, distribution and use. This marked the first time the FDA clearly distinguished between devices and drugs"(Fries, 2001, p. 4). Two new additions to the definition of the medical devices are made with the medical device amendments, which are:

-devices intended for use in the diagnosis of conditions other than disease, such as pregnancy
-in vitro diagnostic products, including those previously regulated as drugs

Since a medical device has direct impacts on the health of patients in varying levels, the regulation of these devices become inevitable. They have to be regulated, checked, tested and analyzed before they are allowed on the medical market. The main aim of regulating medical devices is to protect consumer's health and safety by attempting to ensure that marketed products are effective and safe. Food and Drug Administration of the United States, therefore, has formed a three leveled classification on the medical devices for regulatory purposes.

Classification is the process whereby a medical device is placed into one of three categories, dependant on the device's potential to cause harm to the patient, user or other people. Levels of regulations increase from Class I devices to Class III devices and Class III devices need extensive testing and trial to establish their performance. The lowest risk devices fall into Class I, where devices which exchange energy with the patient in a therapeutic manner or which are used to diagnose or monitor medical conditions, are in Class IIa. If this is done in manner which could be hazardous for the patient, then the device falls into Class IIb. Class IIb is also reserved for implantable devices or where absorption takes place. If a device connects directly with the

circulatory or nervous system or contains a medicinal product, and presents a significant risk factor, then it falls into Class III.

"A significant risk device is legally defined as an implant and presents a potential for serious risk to the health and safety or welfare of a subject;

- is purported or represented to be for use in supporting or sustaining human life and presents a potential for serious risk to the health and safety or welfare of a subject
- is for use of substantial importance in diagnosis, curing, mitigating or treating disease and presents a potential for a potential for serious risk to the health and safety or welfare of a subject
- presents a potential for serious risks"(Gelijns, 1989, p. 28).

"Approximately 30% of all types of medical devices are in Class I. Class I devices include such instruments as tongue depressors, which do not support or sustain human life and do not present a potentially unreasonable risk of illness or injury. About 60% of devices are in Class II. They may involve some degree of risk and are subject to federally defined performance standards (such as X-Ray devices) Finally, all devices that are life supporting or sustaining, that are of substantial importance in preventing impairment of health, or that have a potential for causing risk of injury or illness are in Class III. Approximately 10% of medical devices are in Class III, such as the artificial hearth, DNA probes or laser angioplasty devices"(Gelijns, 1989, p. 27).

This classification is also very important in the strategic planning of the design process. In this manner, main characteristics of the medical device design are going to be explained before starting the design process.

2.2 General Characteristics of Medical Device Design

Good design has become the main characteristic of the consumer product industry. End-users and consumers have become much more aware of good design than ever before. By the help of the developments in the consumer product technology, new management strategies, new materials, clever engineering and good design of consumer products have reached to a position of high-end and high quality. These new products not only have an impressive aesthetic appeal but also they have more user-friendly

interfaces and more affordable structures than the previous consumer products. This transformation of design conscious, of course, affected the medical device design field, and both manufacturers and customers started to realize the importance of product design within the medical device design. Industrial design gave device users the chance of reducing the possible errors and minimizing time lost with better designed medical devices. The participation of design teams in medical device development processes is, actually, a reflection of this expanded conscious.

As the demands of the users of the medical devices became more and more clear, medical device companies tended to find new opportunities such as giving more importance to the design of their products. This was essential for them, where, rapidly changing market gave chance only to manufacturers and companies, which differ from the others in a radical way. Medical device design has come, therefore, at the corner of changing management strategies and the design intelligence. "Design is no longer considered a styling option or frill for medical products. It is understood to be an authentic expression of the technology and use of most medical instrumentation. The advantages for medical device manufacturers in creating an early design vision include quicker development time, better manufacturability, holistically designed products that meet a full range of needs, and products that are better coordinated with the company's brand message"(Allen, 2001).

Interdisciplinary structure of industrial design tolerates the impact of multi-industrial experience of the market, and makes it possible for the medical device design as well. Solutions from the other industries have been commonly adapted to the medical device design by industrial designers. This type of adaptation of the technological development has improved medical devices and instruments rapidly. Multidisciplinary structure "let the industrial designer see how the same reality could be viewed differently, without being able to say that one view was more valid than another, that there are legitimately different ways of seeing the same thing. This highlighted the idea that there is a cultural bias, even in areas that you might think are based on scientific precision, like medical technology, there are things that are emotionally driven, but must be taken into consideration in the process of creating a viable new instrument"(Zaccai, 2001). The involvement of the industrial designer into the design process of a medical device, therefore, is a very important subject to be examined. Industrial design within the medical device design can avoid the user problems and gives manufacturer the chance of experimenting different design solutions.

Medical device design has a crossbred structure between biomedicine, engineering and product design, where the main aim is to find the best technical solutions and design approaches for safety and better medical devices. It has a very important and sensitive mission, as the object is human life. The key of a medical device design activity is to make a device usable by a person with health problems or by a person who solves such health problems. In both cases, the main common point is the human life. Therefore a device designer has more responsibility and he/she has to be more sensitive while designing such a product. A device designer, obliquely, has a mission of saving human life and raising the quality of life of the people. Safety is a priority where users could be very sensitive because of their conditions. The capacity of user reactions has to be analyzed carefully and possible failures have to be regarded during the design process. Thus a designer has some extra 'should do' things during the design process. While designing a medical device or equipment, a designer has to regard the regulations, ethics, new technologies and materials, medical and scientific innovations and so on. Since medical device design has such a wide area of inspection, it is not usually possible for a single designer to solve the whole problems of a medical device design process. This is why; medical device design is usually done with a design team which includes designers, sociologists, anthropologists, physicians and sometimes, according to the design field, doctors, nurses and patients. Most of the medical device manufacturers choose the way of working with professional design firms periodically as they have their own research and development teams including product designers.

It is an important point in industrial design to work by the knowledge of what people really do and want, instead of the written or documented data by the experts. One of the primary tasks of a medical device designer is, incase, to assure the safety of device and the interaction with the user. Medical device user cannot be generalized, and therefore, in every step of the design process, user oriented approach have to be followed. The most productive way of doing this is to be together with the users as much as possible. It is essential for a device designer to know the steps of the device usage. The best way to obtain this is to be a part of this action.

A detailed analyze of the design process of medical device design is going to be studied in the following section. For this reason, it will be sufficient to give some basic considerations for a medical device design process, as a conclusion of this section.

A medical device designer/design team has to consider the following subjects during the design process:

- Users:
  - User's physical and medical conditions
    - The general conditions of the users (elderly, mental condition, medical condition)
    - Abilities and disabilities of the users
    - Demands and the real needs of the users
    - Stress factors during the usage of the device (for the doctors, nurses, technicians, etc.)
    - Ergonomics
    - Social conditions of the users
- Environment:
  - Device usage conditions
    - The use environment of the device (hospital, home, within the human body, etc.)
    - Required space for the use of the device
    - Interaction of the device with other technical parts
    - Technical support
- Regulations:
    - National and universal regulations on the medical devices
    - Restricting laws that shape the devices
- Ethical considerations:
    - Universal design principles

Analyzing design methods through the medical device design requires knowledge about the design methods and historical evolution of these methods from the point of product design and, as a sub-field, medical device design. It will be useful to define the general meaning of 'design' and the 'design activity' before starting to examine design methods. However, the meaning and the history of design is such a wide area that, it is impossible to indicate all definitions. Therefore, just the 'should known' parts are going to be scrutinized.

2.3 Analyzing the Design Process of Medical Devices

'Design', in its general meaning, used to be understood as a styling option by the medical device manufacturers. However it is quite different today, as it becomes one of the most important factors in increasing the sales of medical devices. Medical device manufacturers are aware of the great competitive impact of design in the medical device market. Medical device industry, nowadays, focuses on developing products with quicker returns, and in such a competitive area design plays a very important role on the product's success. Design process of a medical device therefore should be identified carefully, and a designer who designs a medical device has to be aware of the needs of such a process.

"A design *process* is the series of activities by which the information about the designed object is changed from one information state to another. That is, a design process solves, or resolves, a design problem"(Dixon, 1995).

Product design process usually has a two-graded structure. The first grade is the 'design process based on the designer's knowledge', and the second is the 'process based on the organizational knowledge.' The new methods of product design which were formed under this conscious have one common point, 'externalizing the design process, which have the aim of making design more manageable. As Jones suggested in his book 'Design Methods', the simple way of externalizing design is reviewing the new methods from three points of view such as; creativity, rationality and control over the design process. Jones, had suited 'creativity' with the 'designers as black boxes' approach in which the design process was defined as 'what goes on the designer's head'. Methods used during the design process can not be clearly defined because of the unreachable structure of the process. This approach can be identified as 'intuitional process of designing.'

Rationality, on the other hand, has a more definable structure and has a link with the 'designers as glass boxes' approach. Glass boxes approach indicates that, "a human designer has full knowledge of what he is doing and why he is doing"(Jones, 1992, p. 50). For some design problems, glass box methods are useful than the others.

'Designers as self-organizing systems' are the recompense of the 'control over the design process.' This approach tends to overlap the previous two methods and gets a new view point to the design process. "The purpose of this model of self-plus-situation is to enable each member of the design team to see for himself the degree to which the

search actions decided upon do, or do not, produce an acceptable balance between the new design, the situations influenced by the design, and the cost of designing"(Jones, 1992, p. 55).

Design process, in general, is the combination of some action spaces. These action spaces, the 'requirements space', 'trace space' and the 'design product space', have a linear relation among each other. In practice, the process is usually difficult and full of conflict and risk. Converting a concept into a complex, technologic product, therefore, involves many steps of refinement.

The design process includes design steps which help the designer while designing a new product. The three stage Analysis-Synthesis-Evaluation model has been satisfactory in fitting many design activities, which the theorists agree on. Design process requires a great deal of analysis, investigation of basic physical processes, experimental verification, and difficult decisions. This is a recursive process and each step is directly related with the one coming before it.

A general frame of this process is shown in Figure 2.1 below:

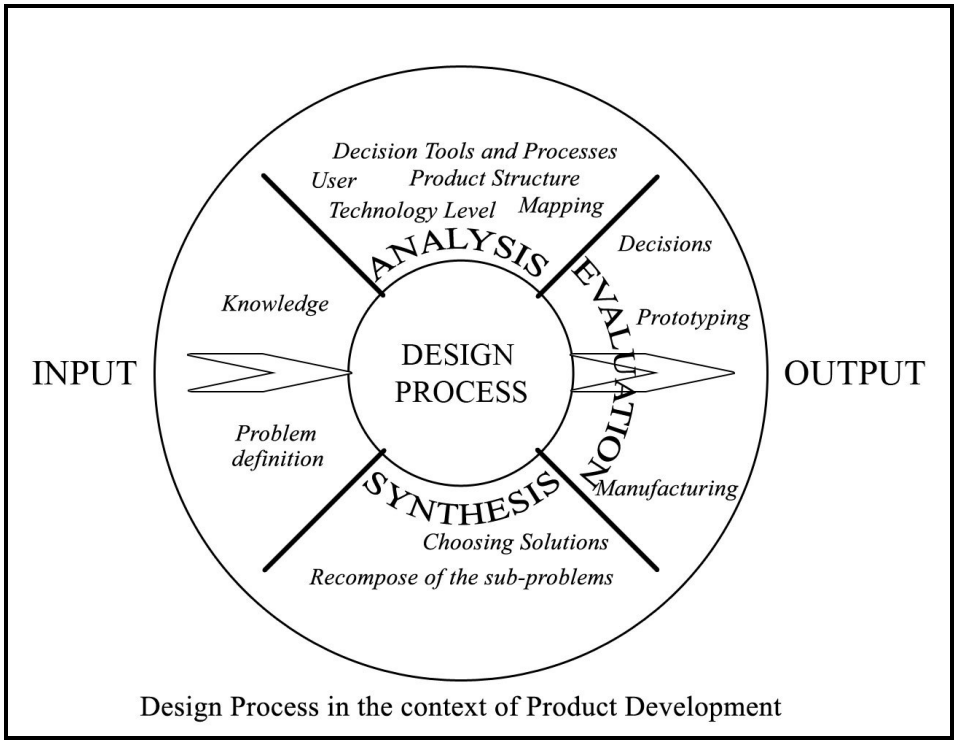


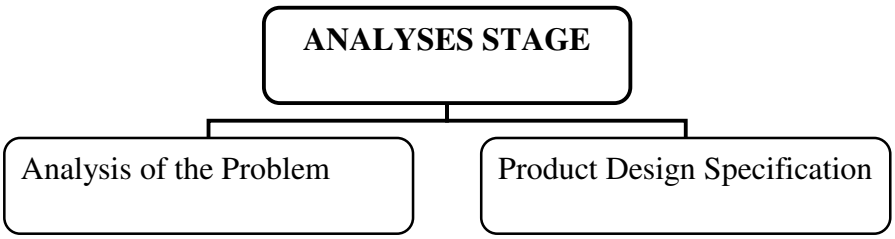
Figure 2.1: Product Development Process

In the analyses stage, the problem has broken into smaller pieces to make it easier to solve. In the synthesis stage, pieces have combined each other with a new point

of view. And in the evaluation stage, these combined pieces have tested before putting them into practice. In this context, design is an evolutionary process that starts with a set of input specifications, generates a basic idea in the early stages of the process, and refines it towards the product specification.

Each stage requires a different method and therefore it is quite important to understand and define the steps of the process.

Each stage has sub-steps which defines the procedure of the process.



2.3.1 Analysis Stage

2.3.1.1 Analysis of the Problem

Analysis stage begins with the analysis of the problem. This stage has the most importance within the design process. To determine the value and the scope of application of process-oriented design methods we have to know more about the structure of design problems.

Design is primarily a problem solving activity, because of the special nature of the problems it solves. “In the paradigm of design as a rational activity that follows Simon’s views, it is proposed that design is a process of searching for a solution in a certain problem space, that is, a metaphorical space in which the problem solving activities take place”(Dorst, 1997). According to Simon, design is a rational searching process: “the design problem defines the 'problem space' that has to be surveyed in search of a design solution. Problem solving theory is concerned with the ways in which people or artificial systems arrive at solutions to problems they encounter”(Simon, 1992).

Problem solving activity shapes the overall process and wrongly identified problem causes the failure of the end product. According to Cross, analyzing a problem have three elements;

- "A statement of the design problem proper
- Limitations placed upon the solution, e.g. codes of practice, statutory requirements, customer's standards, date of completion, etc.
- The criterion of excellence to be worked to

These three elements correspond to the goals, constraints and criteria of the design brief"(Cross, 2000, p. 31).

Problem structuring occurs mainly in the beginning of the design process but also reoccurs periodically as the design activity progresses. Design has a unique type of problem solving. It includes the maximum expression of human intelligence, as it requires goals, initial states and transformation of functions. However, problem solving is not a uniform activity. Problems are not equivalent, either in content, form, or process.

Since the design process begins when there is a need, the structure of the needs and identifying the real needs gain precedence. Meeting a need usually exists in three cases:

- the designer may have to invent a product
- the designer may change an existing design
- the designer may have improve an existing design

In both cases, the problem should be identified rather well.

Problems can be taken up in two categories as splittable and unsplittable problems. "If a problem can be split, more intelligence can be applied to the solution of each sub-problem, and the design time can be drastically cut"(Jones, 1992, p. 50). Processes which have a 'one to one relationship' between the functions and components usually have splittable structure. Products such as buildings, cars and like, on the other hand, do not have a splittable structure where the 'functions are not allocated to distinct parts.'

Designers usually choose the systematic procedure of dividing the design problem into several sub problems at different levels of abstraction. The sub problems at higher levels are frameworks, while those at lower levels are known pieces. Designers often try to represent these problems differently and use different strategies to solve ill-structured problems.

"The 'reasoning mode' of the problem covers three aspects of design—function, behavior, and structure. 'Function' refers to the designer's expectation of the product performance. From the perspective of working-forward strategy, this expectation is just a kind of abstract concept and can be regarded as the starting point of the design. 'Behavior' refers to the way the designer achieves the goal. Finally, 'structure' refers to the solution of the design. The solution consists of several known pieces; it can be seen as the end of design"(Gero&Neill, 1997).

Table 1 Problem domain categories

Level of abstraction		Definition
0	System	The designer is considering the problem as a whole.
1	System and Subsystems	The designer is considering the problem in terms of interactions between the subsystems.
2	Subsystems	The designer is considering details of the subsystems.
3	Design details	The designer is considering a subsystem from the point of view of the detailed workings of that subsystem.
Reasoning mode		**Definition**
F	Function	The designer is working with the functional aspects of the problem domain.
B	Behavior	The designer is working with the behavioral aspects of the problem domain.
S	Structure	The designer is working with the structural aspects of the problem domain.

Figure 2.2: Problem Domain Categories (Design Studies, p. 31)

There are mainly two different types of problem solving from the point of designer's experience. Experts often choose working-forward strategies, while less experienced designers choose working-backward strategies. Dreyfus distinguishes five levels between the novice and the expert designers according to the ways they use while solving a design problem. According to him; "a 'novice' will consider the objective features of a situation, as they are given by the experts, and will follow strict rules to deal with the problem. For an 'advanced beginner' the situational aspects are important, there is sensitivity to exceptions to the 'hard' rules of the novice. Maxims are used for guidance through the problem situation. A 'competent' problem solver works in a

radically different way. He selects the elements in a situation that are relevant, and chooses a plan to achieve the goals. At this level of involvement the problem solving process takes on a trial-and-error character, and there is a clear need for learning and reflection, that was absent in the novice and the beginner. A problem solver that then moves on to be 'proficient' immediately sees the most important issues and appropriate plan, and then reasons out what to do. The real 'expert' responds to specific situation intuitively, and performs the appropriate action, straightaway. There is no problem solving and reasoning that can be distinguished at this level of working"(Dreyfus, 1992).

A less experienced designer usually jumps to another problem where he failed to deal with the problem in hand. Then he starts to redefine the initial state of the new problem, and tries to approach the goal state. This process continues with the search of the required knowledge in the initial state in order to achieve the goal via working-backward strategies. This helps the designer to combine his own 'design criteria' and 'design knowledge' to look for the goal state by working-forward strategies. This process repeats until the problem was solved. 'New problems' usually accompany new design solutions. Problem solving process is shown in Figure 2.3.

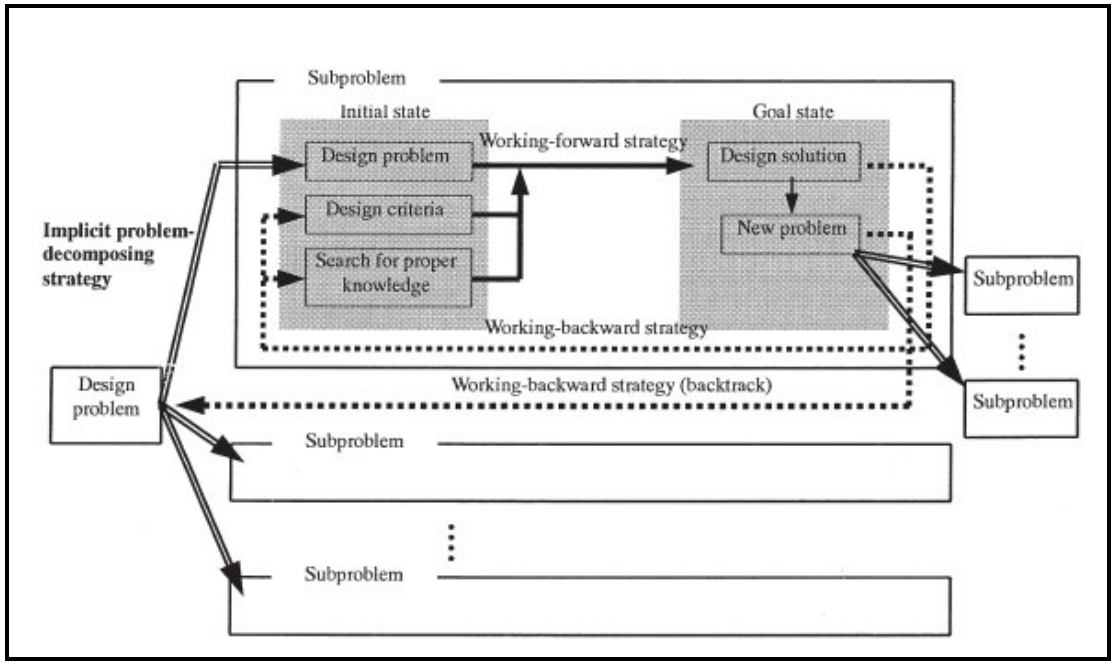


Figure 2.3: Problem Solving Process of Less Experienced Designers (Design Studies, p. 38)

Expert designers, however, usually approach directly the goal state of the problem first, and then adopt working-backward strategies to proofread the prior state of the problem in order to search the required knowledge. This specific design knowledge in turn leads to working-forward strategies which generate design solutions (Figure 2.4).

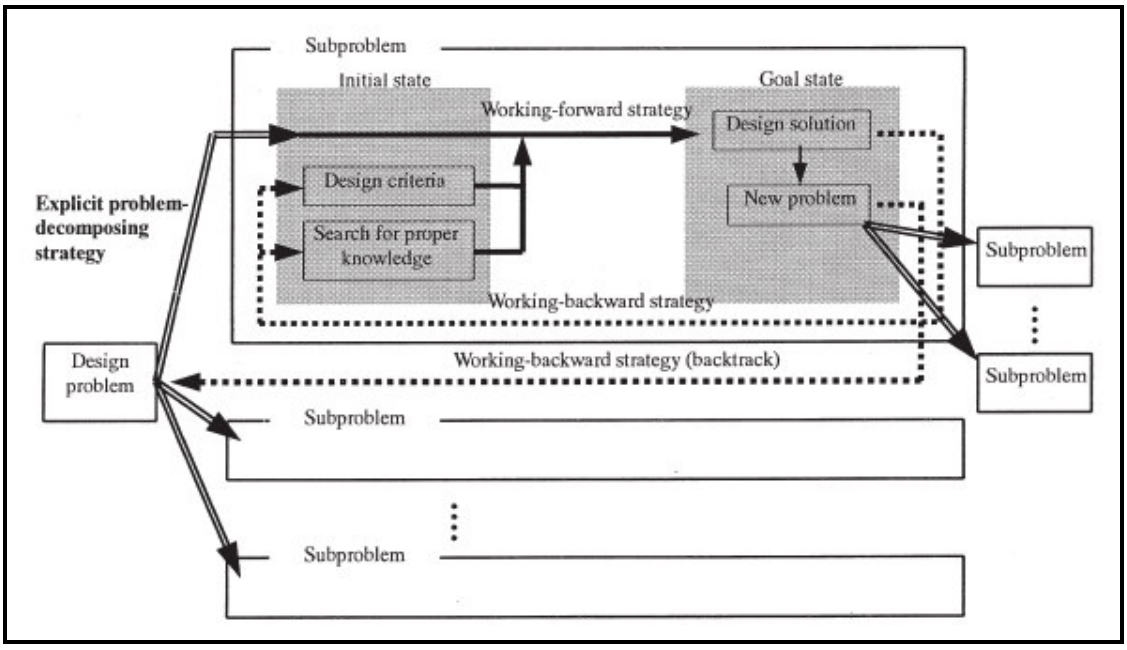


Figure 2.4: Problem Solving Process of Professional Designers (Design Studies, p. 42)

Those strategies defined above tends to only show the general ways of problem solving which used usually by the designers, however, the solution of a specific problem may require different types of approaches.

In medical device design the right definition of the problem have a special importance since the manufacturing process costs are higher than the other consumer products. Therefore, the risks of such a situation have to be minimized by strong investigations of working field.

One of the most striking examples of such a 'problem definition failure' is the "plasmapheresis" example which was designed by a pathologist and a surgery professor during the Second World War. The problem defined was the great need of plasma, and the lack of methods used to meet this need. These two scientists, Whitehead and Aaronson, started to work on an idea of a device which will automate the process of removing plasma from a blood donation in a practical and relatively inexpensive way. The most important point in the design of that kind of device however was portability. They worked on the design and prototyping of the product approximately six months

and they presented their work to the Red Cross, the Army and to the Navy. Unfortunately, they were told by these associations that 'the one thing the military had in abundance was blood plasma. In fact, both the Navy and the Army made a point of telling them that the first thing to be jettisoned in time of battle was blood plasma. This meant that, there is no need of such a device and therefore there is not a market to sell this product. The cost of this process is limited just by the efforts of the scientists spent during the designing, since the mistake was understood in a relatively earlier step. However, in the today's market, such errors return with serious time and money losses where the 'competition' is on the top of the relations. Products that are designed for mass manufacture have high costs of manufacturing that the design team can not afford to make mistakes. This means that "the design must be absolutely right before it goes into production"(Cross, 2000, p. 46). Successful product design does not happen by chance, therefore it is essential to part the development resources carefully and to constitute an appropriate infrastructure for a successful design process.

Needs those forms the structure of the design problem usually have hard requirements and intentions. A designer will have to reserve time in the early part of design process to reveal these 'hard facts' by information gathering and analysis. This information can be seen as a necessary input at the start of the design process, and this type of interaction can very well be described and modeled within the rational problem solving paradigm.

2.3.1.2 Product Design Specification (Clarification of objectives and investigation)

The second step of the product design process is the specification of the design. A product design specification is a structured description of the purpose, functions, characteristics and other kinds of information that describe the design problem. "The product specification is the first step in the process of transforming product ideas into approved product development efforts. It details the results of the customer survey and subsequent interface between the Marketing, Design Engineering, Reliability Assurance and Regulatory Affairs personnel. It specifies what the product will do, how it will do it and how reliable it will be. To be effective, it must be as precise as possible"(Fries, 2001, p. 232).

After stating the design problem clearly, the inputs that make the solution of design problem possible should be analyzed. It is very important to understand the driving forces behind the design, to reach at an effective design solution.

The development of the design specification consists of several steps:

- “The type of the product
- The market it addresses
- The function of the product
- The product parameters necessary to function effectively
- Accuracy requirements
- Tolerances necessary for function
- The anticipated environment for the device
- Cautions for the anticipated misuse
- Safety issues
- Human factors issues
- The anticipated life of the product
- The reliability goal
- Requirements from applicable domestic or international standards”(Fries, 2001, p. 233).

The main action that should be materialized during the process is “to ask a series of ‘why?’ questions about the problem, such as ‘why is the device necessary?’ ‘why can not it be eliminated?’ etc. each answer is followed up , like a persistent child, with another ‘why?’ until a dead end is reached or an unexpected answer prompts an idea for a solution”(Cross, 2000, p. 54). Other types of questions that are useful in expanding the search area are the ‘how?’ and ‘what?’ questions.

As an example of such questions those should be asked during the process, a part of the insulin pump design process can be viewed. “As a hypothetical example, suppose that an infusion pump designer decided to provide the user with the capability to "stack" flow rates, i.e., to program a sequence of rates that will apply to successive patient administrations. A number of questions arise: Should flow rate retrieval and administration functions be automatic or manual? What happens if one of the queued flow rates is accidentally deleted, defaulting to the next flow rate? How does the user

identify and track the flow rates? How does the user access and change a specific flow rate? If such questions are addressed early in the product's development, the answers will help shape the functional design, which in turn will help determine the user-interface alternatives"(Sawyer, 1996, p. 23).

The most important thing within this step is to identify the true needs, objectives and requirements about the product that is going to be designed. A design specification is the determination of the goal of a product development process. "We call any specific statement about a goal, an objective. Thus the design specification is a list of objectives which a product to be designed, has to meet"(Roozenburg & Eekels, 1995, p. 136).

"Objectives and functions are statements of what a design must achieve or do, but they are not normally set in terms of precise limits, which are what a performance specification does"(Cross, 2000, p. 91). Clarifying objectives is, therefore, a very important phase in the design process as it contains all the information necessary for a design team to successfully produce a solution to the design problem.

Requirements constitute a complete statement of what the system will do without referring to how it will do it. In this stage, designer works with the customer and the intended user of the product to analyze the marketplace to obtain a list of requirements which are necessary to produce a successful product. Requirements information ideally focuses on three main titles:

- Client requirements
- User requirements
- Design requirements

Customer, environmental and regulatory requirements have to be taken into account in the early steps of the research and product development phase. A medical device has to be designed sensitively to the environmental consequences from manufacturing, distributing, using, and disposing. This design approach not only helps to improve environmental profiles but also it avoids the potential of returning products. Therefore, the actual or intended customer should be consulted as fully as possible. A device designer has to analyze the user needs and combine the right technology with the way the patient wants to live with the designed product. Good design practice ensures this 'fitness for purpose' within commercial reality.

Design requirements include several sub-titles which determine the physical and operational characteristics of a design product, such as 'performance requirements, safety, reliability, life in service', etc. "The totality of requirements gives an attributive definition of 'solution', which is a just acceptable design proposal. A design proposal which does not meet one or more requirements is not a solution in the real sense of the word"(Roozenburg & Eekels, 1995, p. 138).

The result of the determination of the requirements is a better design process, which ends with a better final product. Classifying the requirements as mentioned above gives the designer the chance to solve the problem more effectively. Alexander proposes a hierarchical classification of product requirements. He emphasizes that such a classification can make the designer 'able to face the problem all at once'. An example of this kind of classification can be seen in Figure 2.5.

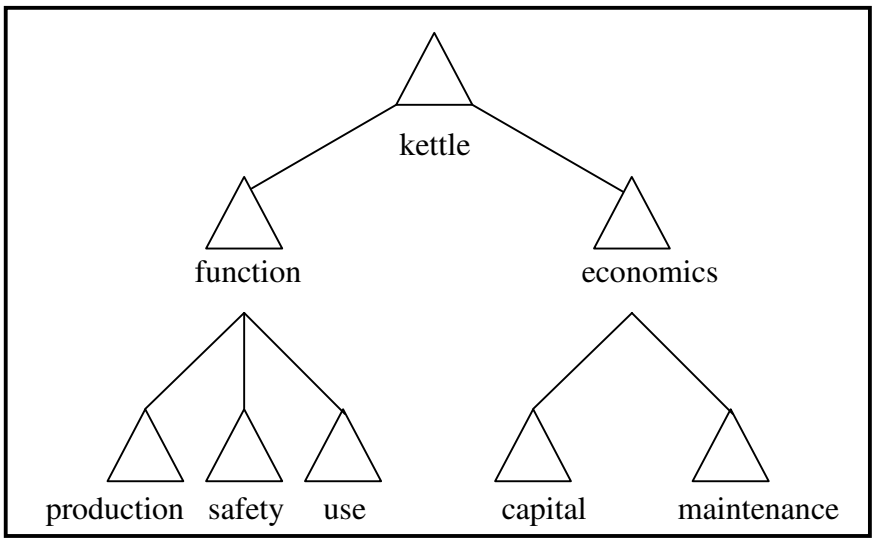


Figure 2.5: Specific Requirements (Alexander, 1999, p. 62)

From the point of the medical device design, analysis of the requirements and clarification of the objectives carries a big importance since the process involves high risks under high manufacturing costs. "As medical products encompass more features and technology, they will grow in complexity and sophistication. The dilemma is whether to tolerate longer development schedules in order to achieve the features and technology, or to pursue shorter development schedules. There really is no choice given the competitive situation of the marketplace"(Fries, 2001, p. 228). Connected to this reality, it is possible to say that, medical devices have a more complex product development cycle than the other consumer products. Usual cycle of a product

development process, design-build-test-rebuild, has 'trial-and-error-based' iterations which costs much. Incase, it is essential for a medical product design and development process to reduce the development effort with documenting the product requirements in a simpler way. This helps designer in lowering the overall product development complexity.

The objectives of a medical device design changes according to the specific use, and the specific group of users. These objectives have wider scopes when compared with other consumer products. Since medical devices are within a certain branch of industry, objectives of these kinds of products are called 'standards'. Use of standards can save time, reduce uncertainty in performance, and improve product quality and reliability. It can also lead to economies of scale. "To some extent, a designer is free to choose objectives; however, are imposed by an external authority. For that reason standards always have the status of requirements"(Roozenburg & Eekels, 1995, p. 140).

In most industrialized countries, the development of new medical devices is governed by regulatory schemes, either in the form of standards or extended pharmaceutical laws, which focus mainly on safety. Each country has its own regulations, where, the main principles are the same. One of the most important and the oldest of those regulatory associations are the Food and Drug Administration which was founded in the United States. "The critical nature of medical devices has caused them to come under stringent regulation in many parts of the world. Clearance to market devices in the United States is granted only after the Food and Drug Administration has determined through its classification and review procedure that there is reasonable assurance of the safety and effectiveness of the device. Such regulatory requirements are necessary and appropriate. They impart a degree of discipline and thoroughness to the process. They also provide a third-party appraisal of the suitability of a new technology in comparison with other available alternatives. A rigorous but responsive and responsible regulatory process helps to ensure that new medical technologies represent the state of art, have the real potential to do well as demonstrated in scientifically grounded studies, and reach patients promptly"(Hunziker & Jones, 1994, p. 57).

To ensure that good quality assurance practices are used for the design of medical devices and that they are consistent with quality system requirements worldwide, the Food and Drug Administration revised the Current Good Manufacturing Practice (CGMP) requirements. Those regulations and standards establish a framework

that manufacturers must use when developing and implementing design controls. Regulations and standards on medical devices are going to be mentioned in a detailed way in the following sections.

The determination of the requirements constitutes a design input which gives shape to the pursuing steps. The importance of the design input and verification of design outputs can be seen in this chart clearly.

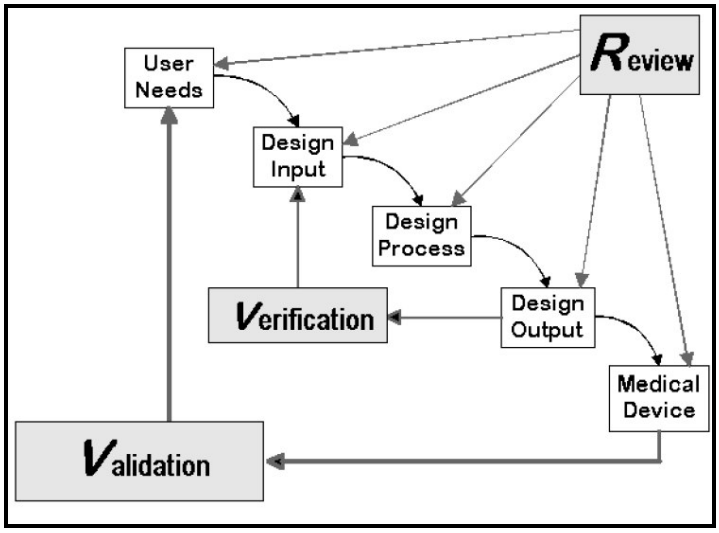


Figure 2.6: Requirements Analysis Process (Application of Design Controls to Waterfall Design Process-Do it by design)

'Design input' means in here, the physical and performance requirements of a device that are used as a basis for device design. When the design input has been reviewed and the design input requirements are determined to be acceptable, an iterative process of translating those requirements into a device design begins. The first step is conversion of the requirements into system .When verification that the high-level specifications conform to the design input requirements, they become the design input for the next step in the design process, and so on. This basic technique is used repeatedly throughout the design process. Each design input is converted into a new design output; each output is verified as conforming to its input; and it then becomes the design input for another step in the design process. In this manner, the design input requirements are translated into a device design conforming to those requirements. Design activities should be specified at the level of detail necessary for carrying out the design process. The extent of design and development planning is dependent on the complexity of the product to be developed.

Because of the innovational structure of the market, it is very important to be a leader in the medical device design. Incase, a medical device designer has to have the ability to follow the market needs and search the new materials. The designer should constantly refer back to his/her knowledge and documented datum to ensure designs are appropriate. Medical devices must be designed to fit the real needs of the users, where the environment is the most important driver of the innovation. Environment here has a two meaning structure, where, the first is, the use environment such as home, hospital, etc., and the second is, the biological environment such as human body. “It is important to note the hostile nature of the environment in which medical devices must function. Over its evolutionary cycle, the body has created a formidable set of defenses against foreign materials. It recognizes them as being potentially dangerous and vigorously sets out to consume, destroy, or isolate intruders. Only a limited number of materials such as silicone rubber, certain polyurethanes, a small number of other polymers, and an equally small number of inert metals and exotic alloys have been found to be clinically acceptable for implantation”(Hunziker & Jones, 1994, p. 55).

As the end-user of medical devices is different from the users of the other consumer products, industrial designer needs some extra information and some techniques to help them better understand the needs of clients and patients. This information usually has a random structure and can be obtained from whatever source. “Patents and the literature, an extremely fruitful source of information generated by the inventors, researchers, and other practitioners, can help designers avoid wasting time and money on approaches that will not work”(Improving Engineering Design, p. 20).

A device designer should have information about the physiology, clinical patterns and the healthcare market. A designer, who has such knowledge, can bring new approaches on design for manufacturing and highly cost-constrained design efforts. Medical products need to convey sophistication in relatively low production volumes relative to goods such as consumer electronic products.

There are several sources to understand the real needs of the device users and patients for an industrial designer as stated above. One of these sources is to work with the patients and simulating the usage process of the device during the design process. By including patients to the process, it will become possible to do usability tests and brainstorming with the real customer. Simulating diseases can help the device designer to see the way patients feel while using the device. Working with different user groups allows designer to find better product solutions for different types of specific therapies.

The design process depends on the feedback that is achieved from user groups and it becomes a continuous design chain indeed. “User requirements are based primarily on earlier interviews, observations, manufacturer’s experience, analyses, and literature reviews. Some requirements are specific, such as ‘installation should take no more than 30 minutes.’ At the conclusion of the test, the actual performance times can be compared to these criteria. In other instances, initial requirements will be broader, such as ‘novice users should reach high levels of efficiency after a few hours of training’”(Sawyer, Do it by design, p. 29).

Depending on the scope of the project, market research is also desired. Market researches include things like, competitive analysis, market availability; costs etc. In general, requirements do not describe the form, shape, material, or any other physical characteristics of the product. They rather focus on the functions of the product by which, the designer assumes a state of mind that is more open to new and innovative ideas.

In the design process of complex devices, there can be a major problem such as the terminology, where usually medical terms are used to express the product conceptual description. Medical terminology is appropriate in requirements when the developers and reviewers are familiar with the language, but it is often preferable to translate the concepts into design terms at the requirements stage to minimize miscommunication. Another problem is incorrect assumptions. Product developers make incorrect assumptions about user needs, and marketing personnel make incorrect assumptions about the needs of the product designers. Incorrect assumptions can have serious consequences that may not be detected until late in the development process.

Briefly, the main principle of this phase can be described as ‘to specify the design input requirements within the context of intended functions of the design product while carefully avoiding specific design solutions’.

For the conclusion of the analysis of product specification, an example of the design specification of a medical device can be useful to understand the overall process. The example is based on a project. At the beginning of the process, the problem had been defined; “4-D tomo-therapy treatment outcomes for lung cancer depend on the stability and repeatability of a patient’s breathing pattern. A portable patient training system is desired to allow more practice for the patients. The portable device will measure a patients breathing pattern, then display the guiding cycles and provide feedback on the patient’s current breathing curve on the display of a Pocket PC.”

According to this problem statement, requirements had been defined which had most importance during the solution of the problem. Workshop team had divided requirements into two main categories such as; ‘client requirements’ and ’design requirements’. Client requirements had been determined as:

- Device should be portable and be able to be used at the patient’s home
- Display should show patient’s breathing pattern superimposed on the guiding cycles
- Device should be easy to use and comfortable for the patient
- The client envisions three major components to the device:

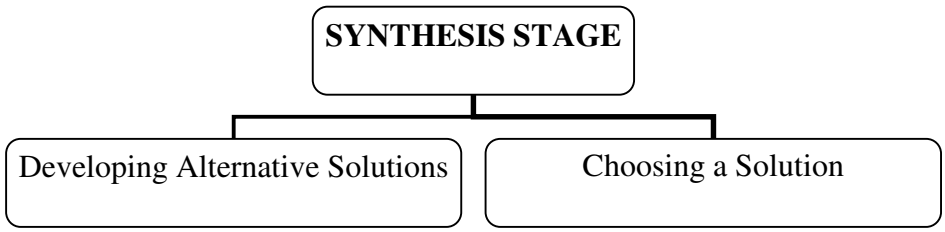
    1. Breathing measurement device
    2. Signal processor
    3. Personal Digital Assistant (PDA) + software

Design requirements had been determined in a more detailed way:

- “Performance requirements: Must be portable and intuitive to use by the patient.
- Safety: Must not harm patient in any way
- Accuracy and Reliability: Must be able to accurately calibrate the patient’s natural breathing cycle.
- Life in Service: Must be in service for as long as patient is able to utilize the device.
- Shelf Life: The shelf life will be five years stored at room temperature in a dry location.
- Operating Environment: This device will be used in a home environment. It will be subjected to constant use by multiple patients
- Ergonomics: Device should be comfortable and not affect the patient’s natural breathing pattern.
- Size: The device must fit for a range of bodily sizes.
- Weight: The entire device should not weigh more then 2 kg.

- Materials: There are no restrictions on materials.
- Aesthetics, Appearance, and Finish: Device should not appear dangerous or fragile to the patient"(BME 301-Portable Patient Training Device for Lung Cancer Treatment, 2004).

As seen in the given example of the design specification of a product, effective analysis of design input requirements encompasses input from both the product developer as well as those representing the needs of the user, such as marketing. The scope is dependent upon the complexity of a device and the risk associated with its use.



2.3.2 Synthesis Stage

2.3.2.1 Developing Alternative Solutions

Synthesis stage includes the combination and re-ordering of goals and objectives, which defined in the previous stage. It is a creative process and presents in every design action. "Making variations on established themes is an important feature of design activity. It is also the way in which much creative thinking actually develops. In particular, creativity can be seen as the re-ordering or re-combination of existing elements. This creative re-ordering is possible because even a relatively small number of basic elements or components can usually be combined in a large number of different ways"(Cross, 2000, p. 123).

The aim of this phase can be determined as combining non-related elements into meaningful relations in order to define the borders of the solution system. In this phase, ideas are examined and a concept of the overall design is developed. Preliminary sketches are used to document the design, so that problems can be "designed out" easier. Construction of relationships within such a framework is necessary because of the need

of setting rules for elaboration and generalization. This helps to find the right ways for the effective solution of the problem defined. This step can be summarized as the abstraction of the knowledge gained within the previous step. This stage is the progress stage from knowing to making abstractions. Synthesis includes four main tasks that should be fulfilled, which are:

- Exploration
- Induction
- Decomposition
- Analogical reasoning

In this stage, "the problem is split up into sub-problems each of which is judged to be capable of solution in series, or in parallel, and in relative isolation. The instruments at this vital stage are the specialized words and symbols that are invented to define sections of the problem. These comprise the 'problem language' upon which subsequent work will be based"(Jones, 1992, p. 67).

The synthesis phase starts with the question of 'how can each goal defined are accomplished?' This question triggers the exploration of the condition. The designer has to make basic decisions which will soon arrive at a possible solution. The main theme is to generate alternatives as much as possible even the wild ones. Synthesis of the analyzed datum is the most amusing but at the same time the most critical phase of the design process. It is very important to draw or write every possible solution since the following phases requires discussions with the other people. And also such documentation helps the designer in remembering and describing the process.

The generation of solutions is very important especially from the point of economic considerations, since the success or failure of a product's design is directly related with the existence of the company. However, generation of solutions has still been neglected by some of the sections of the industry. The sense of emergence, exteriorization and usage of ideas and concepts are not considered important for a profit orientated, therefore, pragmatic in thinking and making companies. Especially in medical device design process, solution generation constitutes an overwhelming structure since it directly affects the product's success within the market.

A designer has to be careful while generating such important solutions and avoid poor design outcomes by selecting the best available design option from a range

of alternatives at all stages of the design process. The solutions to almost any problem can take a wide variety of directions. Treatment of diabetes, for example, can be accomplished by pills, insulin pens, inhalers, and so on. Choosing an insulin pen, as a solution, only begins the process of insulin pen design.

To reach at an optimal design solution is usually very hard, since the space of possible solution concepts is extremely wide. Identifying the right solutions to problems and/or sub-problems, therefore, is a critical process which forms the success of the end-product. It is also very important to recognize the requirements those were determined in the analysis stage. The elimination of such subjective solutions requires a professional knowledge and should be done carefully. At that point, again, the expert and the novice designer differentiation come into being. "Experts may readily be able to re-invoke relevant solution ideas from their vast stores of experience-based knowledge, and may stick with these ideas because they *know* that they are good ones. Novices, on the other hand, may fixate upon the first solution idea that they come up simply because it is the *only* solution that they can generate given their limited knowledge-base, and they *know* that they are unlikely to be able to generate any viable alternatives"(5th Design Thinking Research Symposium).

2.3.2.2 Choosing a Solution

Choosing a solution is one of the most important phases of the product design process since it is the phase of making the final decision about the product. As emphasized in the previous steps, wrong decisions can cause irreversible or very expensive to reverse results which is an unwilling situation, especially within the medical market. It is very difficult, of course, to select the best solution among a number of design solutions since the value of something, which guides designer in the decision point, is directly related to the personal point of view. The fact is that in most ill-defined complex situations, there is no single correct answer. Many paths will lead to the same goal or to parallel and satisfactory goals, which generally involve tradeoffs in time, risk, or resources. Therefore, actually, it is very hard to talk about a 'best decision' in the strict meaning of the world. However it is essential to make a decision to continue the development of the design process and the mission of the designer is to make the best decision according to the aims and goals defined in the analysis and the synthesis

stages. Although the chosen solution should, ideally, be the one that best satisfies the specifications, other constraints such as time, cost, or skills may limit the decision.

There are several factors which plays role in the success of a decision making phase. The most important one is, of course, the knowledge and the experience of the design team about the related field. This knowledge and experience can be obtained from different fields of design discipline. According to Booker from Product Genesis, the reason of why they have a broader approach to development is that they have the ability to be objective and serve them a generalist for their clients. When they were designing a steerable catheter for a medical device client, for example, they drew from their past experience in designing a cable-driven system for NASA.

Highly skilled and experienced designers naturally are expected to take the optimum design solution among the others. Cross-disciplinary design teams, which are very important within the process of medical device design, have also more chance in determining the best solutions with their innovative structures.

The information collected is the most evident guiding datum during the decision making. Actually, decision making takes place in every step of the design process including the information collection, and the other phases of the design process, since the design process is "a process of converting information that characterizes the needs and requirements for product into knowledge about a product"(Bras & Mistree, 1991, p. 453). From problem specification to the testing and evaluating step of a designed product, there exists various decisions that have to be taken. However the most important decisions are made during the concept selection stage.

There are critical considerations those have to be taken into account during this important phase. A design team or an individual designer, at first, has to be aware of his/her skills while making a decision. Some types of product classes necessitate highly skilled product design teams which can be able to undertake the responsibilities of relatively expensive design processes in the case of error. Also the technology and the materials those are available at the moment of decision making have to be identified clearly before making public the selected solution.

The environment of the object, the desired effects and the laws of interaction with the intended user has to be determined and means should be exposed in an honest approach, where, the constraints such as time, cost, or skills are the main designators while determining the limits of the production process. As Popov suggested in his writing on the social aspects of designing, designers need to understand well all of the

elements that they work with, the effects they produce and the overall successfulness of the emerging artificial system. Design actions and design agents differ in terms of the amount of explicit information that is available, conscious apprehension of design situations and awareness about the major problems.

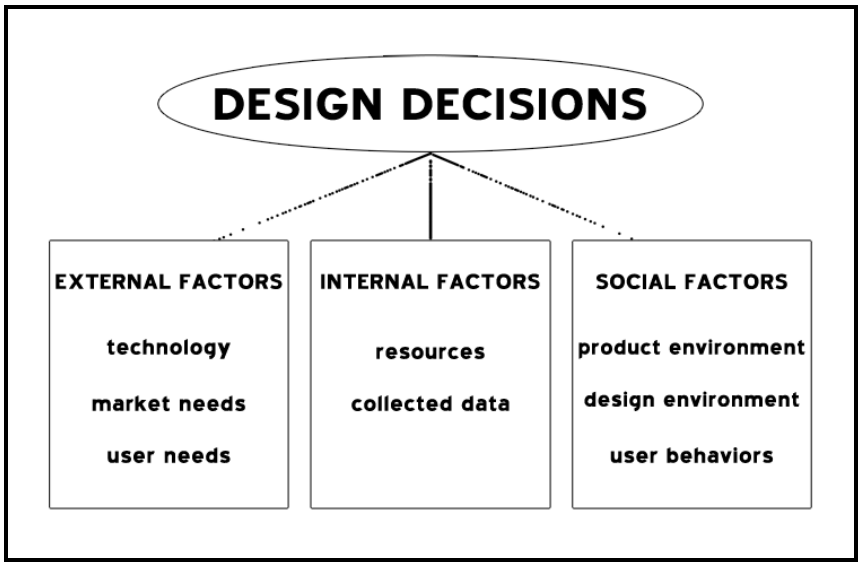


Figure 2.7: Design Decisions

According to Ulrich and Krishnan, the concept selection decisions are related to the decisions those were taken within the three main designators of a product design process, which are, product strategy and planning, product development organization and project management. The first one, product strategy and planning, is relevant to the market strategies on technology, intended section, etc., which are external factors as subjected above. "Product strategy and planning involve decisions about firm's target market, product mix, project prioritization, resource allocation, and technology selection. Mansfield and Wagner (1975) show that these factors have a significant influence on the probability of economic success"(Ulrich & Krishnan, 2001, pg. 10). The second one, product development organization, is social factors that include social system and environment. "By product development organization, we mean the social system and environment in which a firm's design and development work is carried out. Related decisions include team stuffing, incentives and reward systems, metrics for monitoring performance, and investments in productivity-enhancing tools and 'processes for product development"(Ulrich & Krishnan, 2001, p. 11). The third and the

last one is the project management, which is related to the internal factors such as time, resources of the firm and collected data during the analysis phase.

Time needed to build the selected solution is a very important subject while deciding on a solution. Since the growing competition is the designator of the market, selected solution has to be the fastest producible and competitive one in most of the product categories. “Product development performance is generally measured by the lead time to develop the product, the cost of the development effort, the manufacturing cost of the product, and the product’s quality or attractiveness in the market”(Ulrich & Krishnan, 2001, p. 12). The use technologies in medical device design, that proof their success and prove high production volumes in other product categories, may be one of the ways of decreasing the time of process, since, they have succeeded procedures.

The level of decomposition of sub-solutions is another designator during decision making. It shapes and gives clues about the system approach of the design team. System approach is directly related with the selection of methods those are used during the process and therefore have to be shaped in a very careful way. The evolutional chart of the design process (Figure 2.8) exhibits a transformable structure where a vicious cycle of decision making forms the main structure.

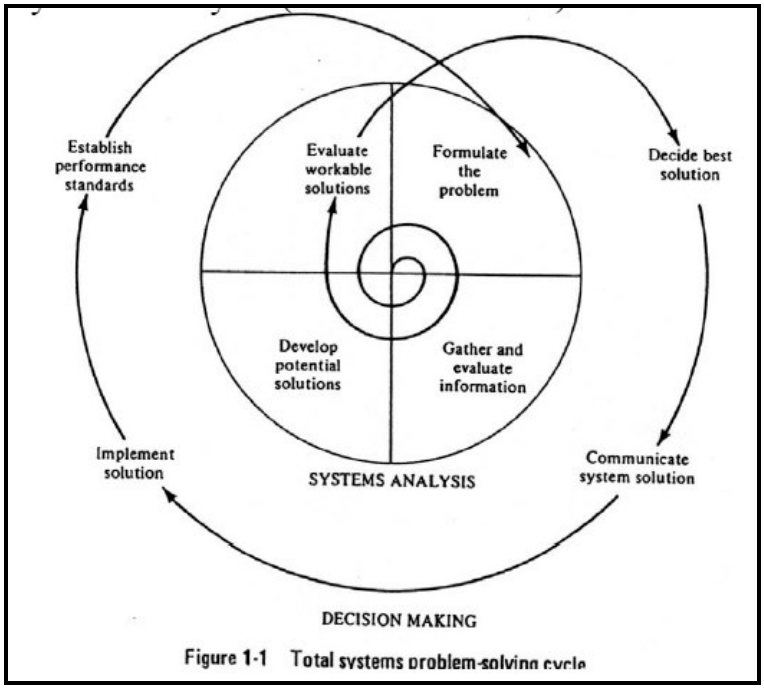
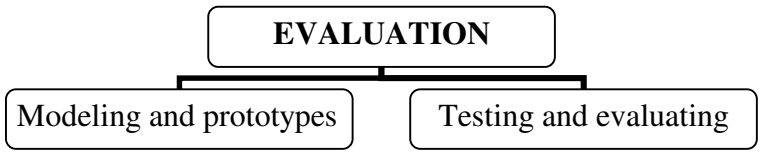


Figure 2.8: Decision Making

Once, the solution which gives hope for the market has selected the presentation of them to the client or the possible users of the product become essential. With the presentation of the advantages and disadvantages of the various ideas, the client is able to make general choices favoring one design over another or possibly selecting elements from several to be incorporated into a new design. As this process of refining the design takes shape, the designer also addresses a particular design's consequences in relation to product approvals, permitting or costs. Once the client has approved of a schematic design it becomes possible to move on the next phase.



2.3.3 Evaluation Stage

2.3.3.1 Modeling and prototypes

The evaluation step can briefly be described as the exact analysis phase of the design. It includes drawings, modeling, projections and predictions. The concept is evaluated and re-evaluated according to the identified functional requirements. Especially where new technology is created, time for learning will pay big dividends. Design refinement in this way yields the best possible products. Briefly, this step is intended to quantify the performance of the design.

The very first step of this phase is to draw the chosen design including all the details that are important in the construction phase. The application of sketching and drawing skills on the selected solution allows designer represent his/her ideas and begin the evolutionary process of design. In this phase, detailed structural or mechanical systems may be even needed to see if a solution can be made to work.

A detailed concept drawing is essential to identify the functions of each part within the selected concept. Detailed drawing can be done in two ways; the first is documenting ideas by hand drawings and the second is by using computer aided drafting and design systems. This detailed drawing should involve:

- Dimensions
- Material
- Ways of production
- Required finishes

The existence of CAD based design systems are saviors in many sections of the market. In such systems, it is possible to see the finished product before it is produced, and therefore, it have increasingly been preferred, by most of the design teams and manufacturers. 3D design software helps designer in having a much better idea about the performance of the device he designed. It not only reduces time but also helps the designer to see the end product in a reliable way. Appearance models do not function but are intended to show what a product will look like when it is produced, where, the functional models may not look like the end product, but they are operational. These are usually used to work out the mechanical or electronic systems.

The step which comes after modeling of selected solution is prototyping. This step is simply taking the design from the virtual and imaginary field to the physical world. It is far easier to understand an idea when seen in three-dimensional form. A prototype is the first working version of the designer's solution. It is generally full-size and often handmade.

“Prototyping is an important tool for reducing time-to-market and providing models used to evaluate quality and producibility. At present, prototypes that are faithful representations of the final product are frequently required for use in experiments to optimize the product and work out assembly procedures”(Improving Engineering Design, p. 20).

This step includes weighing and judging instead of classification. Usually an analytical model is used to calculate the performance of the selected solution in a detailed way. The evaluation phase involves extensive simulated service testing of an experimental model or perhaps a full-sized prototype.

In medical device industry, the products are quite complex and require several iterations of design. Medical device industry has a technology-driven structure and intended users are usually the patients. Therefore, modeling and prototyping is especially essential in medical device design. Sketches, detailed drawings and

prototypes are one of the most effective communication tools in medical device design. Verbal sketching and communication usually can not be able to explain the product especially to people outside the design discipline. It is only when there is at least an understandable model or sketch of the concept that the other people, clients, users, etc., will have a realistic chance to understand the full intent of the suggested solution.

"A prototype's fidelity, or resemblance to a working device, is determined by its physical and/or conceptual attributes. If installation, control and display layout, or manual operation (e.g., of surgical tools) are of special interest, mock-ups should be used for physical simulations, or "games playing". Users can perform the procedural steps to confirm or repudiate the design or layout details. If underlying machine logic and information presentation are of concern, story boards, screen prints, interactive computer models, and working models can be used to evaluate user efficiency with a given interface design. An early test might consist of users completing tasks by performing data entry operations on a sequence of screen prints. The test participants would indicate their selected keys, while verbally describing each action. Each user input is followed by the presentation of a new print showing the appropriate feedback, prompts, or status change"(Sawyer, Do It by Design, p. 28).

"During prototype development, more detailed hazard and risk analysis can be performed. At this stage of design, process and mechanical drawings are available, and the basic process operations have been defined. The device and its operation can be reviewed by a number of analysis techniques, including top-down and bottom-up approaches"(Ozog, 1985).

By the help of prototypes, it becomes possible to reduce design cycle times tremendously. This is great event where getting the task done quickly is an important requirement. It also supplies to understand if the device meets the requirements such as safety, ergonomics, and etc. Use of prototypes can provide insight into potential errors under real-use conditions where it is difficult to do "in use" testing on medical devices. These technologies can be very effective while identifying the real user problems with the device by simulating those patients in a digital platform and consequently integrating digital users into the design process.

"The last strategic use of ergonomics occurs after the design phase and includes the development stage through the creation of the functional prototype. During this time, an array of testing techniques is used to validate the design by making sure that the product is in fact what people are looking for, at the price they are willing to pay.

Specific tools and techniques include one-on-one questioning; on-site/in-home suitability tests; covert observations of product usage; and detailed studies in which human performance, perception, emotion, and behavioral experiences are measured. The results from these types of assessments are used to refine and enhance the design"(Rutter, 1999, p. 37).

2.3.3.2 Testing and Evaluating

The aim of the testing and evaluating stage is to determine the fitness between the solution of the problem and its functional environment described in the process of problem formulation. The evolution activities involve knowledge and expertise about the functional environment and the elements that constitute it just as the previous steps. "In medical device evaluations, a distinction needs to be made between diagnostics and treatment devices. With the former, it is usually not direct patient benefit, but benefits in terms of clinical utility (i.e. its contribution to further diagnosis or therapy) that are to be evaluated. Generally, evaluations provide information on the technical and diagnostic of a diagnostic device, and possibly on its risks and complications. The main measures of diagnostic performance are sensitivity and specificity"(Gelijns, 1989, p. 29).

In testing step it is essential to be aware of what effects will the product create and what unintended consequences are most likely to happen. This step is an ongoing process and intended to be sure of if the project does the job for which it is designed. The specifications and requirements have to be checked carefully to reach the aim. There are several questions to be asked during the testing stage those help the designer in checking the system uprightness. Some of them are;

- Does the system of the product work?
- Does the product meet the requirements?
- Does the design function well?
- Does the product look good?
- Does it safe to use?
- Does the materials used are suitable for production?
- Does the product need modifications?

- Does it possible to improve the product?

There should be a test plan which includes the list of ‘should do’ and ‘must be’ approvals. Development of the test plan usually begins during the design specifications phase. “The plan includes performance, environmental, reliability, and safety testing. Encountering conflicting requirements, unforeseen design constraints, changes in implementation, etc. can require that the plan be changed. Therefore, the test plan is revised and updated as the design proceeds. The completed plan includes detailed test procedures that take into account worse-case operating conditions. It includes acceptance criteria that are tied to the design specifications. Where criteria or procedures are based on standards, those standards are identified. Tools such as trace matrices are used to ensure that all device specifications have been accounted for and that testing is traceable to the design specifications”(Design Control Guidance for Medical Device Manufacturers, 1996).

Testing is critical where it is very important to ensure that there are no loose ends to the project. Errors those are noticed during the prototype testing would reduce the possible problems of production. Principally, testing is to make final corrections on the design before full-scale production. Review of the product before production usually focuses on achieving the performance, feasibility and cost. It is also essential in medical devices to take the customer into consideration.

Because the life cycle of a device is short and next generation versions of a particular device may emerge relatively quickly, speed is the dominant identifier in the market. In respect, it is essential in bringing the medical device ideas as rapidly as possible into the design process. Therefore, being right is very important for quicker involvement into the competitive process. Without a detailed testing it is impossible to predict how each component in a designed device or instrument is going to behave. Because medical device design verifications and testing protocols can take months or years for approval, the efficiency of the design process is essential to minimize the product cycle time. In this respect, the right design of medical devices can also play a crucial role in the time to market and the product's commercial success.

A change in the design after production could have undesired financial impacts on the company which is developing the product. Therefore, high-quality user testing and user feed back at various points in the development cycle is very important. Testing before production can turn up some important results, since it provide peerless feedback

on the performance of the device in the real world and lead to possible improvements or modifications.

There are various measures used during the testing process. “Errors may be recorded by direct observation, videotaping, or electronic data logging. Speed of operation is based on completion times of tasks, and other objective measures may be used, such as the number of times the user must refer to the device manual. Verbal responses also are important and can be obtained by interviews or by having users state the rationale for their actions as they progress through task sequences. Also, subjective impressions of usability and potential safety problems are important.” (Sawyer, pg: 29)

The test environment is especially important for medical products since, the use environment of a device directly affects the productivity of the designed product. For example; medical devices intended for home use should be tested in that environment. This can be especially useful in assessing devices that expose problems related with portability, space, availability of substructure, noise, and complexity. There has been a linear relation between the consciousness of users and their expectations from the environmental value of products. Since expectations of the environmental value of products increases, suppliers and manufacturers will need to look for efficient ways to determine the environmental needs and values of their customers and incorporate these features into the products they offer. Including customer needs at the research and development level is crucial to the success of the product because it is most efficient to take into account production changes at this stage.

“When doing analyses and tests on devices being considered for purchase or already in use, there are a few guidelines to keep in mind. Be careful not to bias the users. Staff should be told that it is the device, not the users, being tested. If this is not made clear, users may feel that their performance will be discussed with their superiors, and thus they will not be forthcoming about errors and deficiencies related to interface design. Also, should a device be evaluated during actual use on patients, data should be collected over a reasonable length of time, not just a day or two. In real world settings, actual problems often emerge slowly and require repeated observations for identification. Findings may prove of great value to both healthcare facilities and manufacturers”(Sawyer, 1996, p. 38).

Since the aim is to produce the best possible design, tests have to be conducted from a user perspective to determine if user expectations are met. One key point would be involving the device users early in the design process rather than waiting until the

product has been built and manufactured. Human factors testing would be very effective especially on determining the safe of medical devices in which user's cognitive limitations shapes the borders. By the help of feedback comes from such tests more medical devices can be designed and redesigned that enhance patient safety.

A very striking example, as a conclusion, that shows the importance of user testing in the early steps of the testing process comes from IDEO. When they were working on a medical product which had two electrodes meant to be positioned on the chest, the design team recognized an important detail. Through user testing they realized that, people, who use the device, were confused by the similarity of the electrodes and are concerned about making a mistake. Since then they went back and label the electrodes with clear illustrations and made them different so that people did not spend time worrying about it." As Simons of IDEO stated this was an example of how intuition can fail you and why user observations are a critical part of the design process. Briefly, testing, as in this example, can help designers to recognize the problems about the device that they think they will not have to face.

In this chapter, the design process of medical devices are tried to be explained. As a conclusion, the main terms and considerations of each phase, those are studied in a detailed way above, are given in the below chat.

"Touchstones for Design:

- **Customer:** Who is the customer? What does he or she really need?
- **Ease of use:** Human factors design needs to be addressed early in the design process.
- **Documentation:** Essential; match to user's needs
- **Environmental impact:** Determine if the manufacture or use of any product may adversely affect the environment.
- **Testability:** How will the product be tested?
- **Prototypes:** Consider how the final product may differ from the prototype if prototype and production processes are not identical"(Committee on Engineering Design Theory and Methodology, 1991, p. 31).

2.4 Historical Overview of Design Methods

Design can be explained as a part of the everyday activity as its widest meaning. People do designs purposely or unintentionally in their daily lives. They designed and continuing to design tools that have purposes to meet varying needs which will make living better for them. According to the structure of the needs, the structure and the definition of design and its process differs among each other, whereas, the main common aim is solving a problem. Some of the definitions of design made by the design theorists are;

- Relating product with situation to give satisfaction (Gregory, 1966)
- The initiate changes in man-made things (Jones, 1970)
- The conscious effort to impose meaningful order (Papanek,1971)
- A way of looking at the world and imposing structure upon it. (Archer, 1981)
- A process in which all sorts of things are done (drawing, building models, experimenting etc.), but above all, a process of goal-directed reasoning. (Roozenburg & Eekels, 1991)

As an everyday activity, design is a 'by one-self' action and begins with the first abstractions of the human being; however, the literature on this activity had only begun to be formed in the late 1950's. The formation of new design methods can be anchored back to the invention of new technologies and new scientific approaches. New technologies caused novel problems which emerged new scientific methods. Before that time, there was not a methodological approach which has a logical point of view, since the design process had a completely different structure. In the 1960's "scientisesing design" approach marked the agenda of the design methodologists. This period was the golden era of the design science revolution, which was pioneered by the "radical technologist" Buckminister Fuller.

When it comes to the 1970's, a new approach based on rejection began related to the design methods. The early pioneers of the design methodology such as John Chris Jones and Christopher Alexander made notable rejections of design methods. Jones pointed out to the 'machine language' and 'the continual attempt to fix the whole life

into a logical framework' when announcing his rejection against design methodology. This rejection, probably, was a result of the new movements of liberalism and continued just until the second generation of design methods which were pioneered by Rittel, in 1973. Rittel's proposal of 'generation of methods' had opened a new gate for the development of new design methods. According to the Rittel's theory, "the first generation (of the 1960's) was based on the application of systematic, rational, 'scientific methods'. The second generation (of the early 1970's) moved away from attempts to optimize and from the omnipotence of the designer, towards recognition of satisfactory or appropriate solution types had introduce the notion of 'satisficing' and an 'argumentative', participatory process in which designers are partners with the problem 'owners'. However, this approach tends to be more relevant to architecture and planning than industrial design and engineering"(Cross, N., 1993, p.17).

The endeavors of applying scientific methods to the design problems, however, continued in the second generation of design methods. Constituting new design solutions based on "rationality and objectivity" became the major argument subject of the design theorists. Three different comments, "scientific design, design science and the science of design", formed the bottom-line of the design methods arguments.

2.4.1 Scientific design, design science and the science of design

Solving problems of modern industrial design with newer models and methods was the origin of the "scientific design" approach. According to this approach, solving those new and more complex problems can be possible by using rational scientific methods. 'Scientific design is probably not a controversial concept, but merely a reflection of the reality of modern design practice.' as Cross suggested in the 5th Asian Design Conference.

In the 1965 Design Method Conference, a new approach appeared which the follower of the "scientific design" was. This new comment was "design science" and it was suggesting a completely logical, organized and systematic view of design and accepting design as a scientific activity. Most of the design theorists did not consent this effort of molding design with scientific templates and the non-scientific structure of the design process emphasized.

When it comes to 1970's, "science of design" approach became evident within the design researches. This approach was the most agreed one among the other two and

brought a new view point to the position of the design discipline. As one of the most important advocators of this approach, Nigel Cross, defined, “the science of design refers to that body of work which attempts to improve our understanding of design through scientific methods of investigation. And let us be clear that a “science of design” is not the same as a ‘design science’”(Cross, N., 1993, p. 21).

Over viewing the brief history of science-design relationship will be useful to understand the medical device design-consumer product design relationship which is going to be mentioned in the following chapters, since medicine has a direct connection with science and therefore logical, systematic and organized, but design does not as defined above.

As a conclusion of this brief exposition of history of design methods, it can be possible to say that, methods of designing, are not still very clear and it is not possible to talk about a general method which fits to all design problems, and this is because the nature of designing does not have a stable structure in itself. The development of design methods, nevertheless, is continuing and using methods within the design process is still one of the best ways that can be followed.

2.5 Traditional Design Methods and Early Medical Devices

When we go one step further on analyzing design methods, we come across with two periods that mainly formed the “before” and “after” of the design methods. These two periods are distinct among each other according to the methods used within the design process. The first period is the craft evolution period, which the traditional methods, or other saying craft methods, were used. And the second is the industrialization period, started with the industrial revolution, which the new methods were emerged according to the needs of the industry.

It will be useful to touch on the concept of “method” before analyzing the traditional design methods.

In its dictionary meaning, a method is:

- a way, technique, or process of or for doing something;
- a procedure or process for attaining an object
- a body of skills or techniques

- the habitual practice of orderliness and regularity

"The linguistic origin of "method" comes from the ancient Greek and it is the combination of 'meta' and 'hodes' which means 'the way that should be followed'"(Bayazıt Nigan, 1994, p. 10). In general, a method can be described as 'the way followed to solve a problem.' In this description, 'the way' refers to any procedures, tools or techniques. Therefore, a design method can be described as 'the sum of tools', or as Papanek suggested, "the interaction of tools, processes and materials"(Papanek,1974, p. 20), that are used to solve a design problem. "Design methods represent a number of distinct kinds of activities that the designer might use and combine into an overall design process"(Cross Nigel, 1942, p. 46), therefore a design method might be a combination of different types of methods.

A fact has to be 'general' to be accepted as a method. This means that, a designer can be able to use a method in more than one problem. This acceptance does not mean that a method is a 'must have done' action. As Roozenburg and Eekels mentioned, "a method is not an order or recipe. An order would be: 'paint this door green.' A recipe is of a more general nature: green paint can be made by mixing blue and yellow paint in the proportion of 1:1. A method is even more general, and refers to a whole class of actions, for example: mixing of paints in general"(Roozenburg & Eekels, 1991, p. 39).

As clarified in the previous section, craft methods, or traditional methods does not have a systematic basis. Therefore it is not possible to talk about such a 'method' described above. In the craft era, 'necessity' was the main designator of the innovation process and it "gave the law at every detail, and in scores of ways insisted on conformity"(Jones, 1970, p. 18). The formation of the methods that were used in craft oriented design process was lying on the accumulation of the experiences on a specific product. Those methods which had a chance to stand alive just by the craftsman-pupil reliant, usually, did not have a formal procedure that can be used by any others. The conception and the production of a product were not separated since there were no processes of drawing or modeling. The reasons of the design and the production process which were therefore depending on the practice of the craftsman, and usually, could not be explained in a detailed way also by the craftsman himself. Of course, this state did not constitute a problem since products were produced for a single customer and there were no need to worrying about the serial production.

Necessity was the igniter also in the design history of medical devices; however the evolution path of medical devices was a bit different from the other product categories seen in the craft era. The designer of a medical device was usually a physician and the knowledge of the design process was based on innovation instead of craftsman-pupil relationship. Design idea of a medical device was requiring a medical knowledge and high skill, since the end product was related to the human body. Actually, earlier designed medical devices can be anchored back to the ancient Egypt and the Roman Empire. Devices of this period were formed, exactly like the other products of the era, by the method of experimenting and blundering. Those devices, especially surgical ones, are still used in the modern medicine.

From the 17th century devices began to be invented which supplied major contributions to the modern medicine. This period can be described as the period of the experimental methods in the medicine. Although the origins were based on the beliefs of the period, those devices can be taken into account as the fathers of the modern medical devices. One of the best examples of such devices is the bloodletting devices, such as lancets, which were used in the 17th to 19th century. Physicians, in those years, believed that the diseases were caused by an imbalance of the four humors: blood, phlegm, black bile and the yellow bile. Patients thought to suffer from excess blood were cut by the lancets and allowed to bleed into a bowl.

Figure 2.9: Bloodletting lancet-1830-National museum of health and medicine

Another very important contribution to the modern medicine was the invention of the thermometer by Galileo. “In 1603, Galileo invented a device to measure the temperature and Sanatoria Santonio made improvements to the device, allowing him to measure the temperature of the human body”(Fries, 1977, p. 6).

Nevertheless, the most important progresses in the medicine were materialized in the 19th century. When it comes to the 1816, the big bang of the medicine was realized by a French physician, Rene Theophile Hyacinthe Laennec. His invention, stethoscope, was accepted as the most important discovery in the history of physical

diagnosis. This new device helped doctors in determining the definite location of internal addictions and contributed an eventual change in their perception of body and how it functioned.

Figure 2.10: the binaural stethoscope-1816

The technological milestone of the medical diagnosis was the ends of 1890's. Wilhelm Roentgen discovered X-Ray in 1895. "Roentgen's discovery helped usher in the equipment age of the medicine. Wilhelm Einthoven's invention of the electrocardiograph in 1903 started the wave of physiological measuring instrumentation that is used in every hospital and doctor's office today"(Fries, 1977, p. 6).

Figure 2.11: A patient, under examination of the phrenoscope

Figure 2.12: French X-ray instrument that gives a view of the human diaphragm

"An example of an early innovation that continues to find new applications in medicine is the laser. Invented in 1958, the laser was first applied in healthcare as a non-contact scalpel. New applications of laser include reshaping corneas, photodynamic therapy for cancer, and transmyocardial revascularization for severe angina. Despite its apparent early success, researchers are still not sure if it really works and, if it does, how"(Hanna, Manning, Bouxsein, Pope, 2001, p. 3).

Over the past quarter century there has been acceleration in the development of new medical devices, in part because of rapidly expanding scientific and design knowledge. The most important contributor to the medical device innovation was the Second World War, during which, the needs were shapers of the innovative process. During the Second World War, emergence of new technologies and need for new and usually portable devices triggered the design of medical devices. "The vast array of medical innovations since World War II has led to a tremendous growth in the complexity of health care. However, the health care sector has not evolved to accommodate this complexity. In other sectors which complexity has significantly increased, sophisticated production systems have been implemented, an information technology infrastructure installed, and teamwork developed"(Aspden, 2002, p. 13).

"In the 1950's, medical devices such as large-diameter vascular grafts for the first time permitted surgeons to replace body parts that had become defective. The year 1958 saw the implantation of the first electronic device, the cardiac pacemaker. This revolutionary technology stimulated the heart experiencing bradycardia, a too-slow rate, to a rate approximating resting normal"(Hunziker & Jones, 1994, p. 54).

Another important element that affects the development of the medical devices is NASA, which has widest research and development studies around the world. The main aim during those researches is the development of medical devices to support of astronaut health and biomedical research. "This collaborative R&D has been based on the need to utilize a broad range of expertise and experience to meet special requirements, minimize development costs, and exercise the NASA mandate to "provide the widest practicable…dissemination of information concerning its activities and the results thereof"(Hanna, Manning, Bouxsein, Pope, 2001, p.32).

2.6 Need for new methods in medical device design

20th century was one of the most important milestones of the design and manufacturing of the new medical devices like many other kinds of products. Difficulties and the deprivations of the Second World War created new problems and new problems emerged new methods for the solutions. Increasing complexity of modern design caused traditional methods to become insufficient to solve the problems of the new era. Casualties were increasing day by day and there must be founded quick and efficient solutions. There was a need of easy to use and quickly producible devices. The new technologies and new materials discovered in this century were also the other important motivating factor in searching new methods for the changing conditions of the new production system.

Since medical device design has a technology and performance driven structure, emergence of the new methods within the design and manufacturing cycle became especially important. As the technology grew up so rapidly, variety of the devices and the number of the manufacturers increased and this formed a competitive environment. 'Tentative solutions' of the traditional design became too risky for the mass production conditions.

Another very important subject related to those conditions was the design process of the devices. Design of the devices gained a great importance since the same kinds of devices crowded into the market. Design became one of the most important elements in the sales and the profits of the market. Medical devices which once designed by the medical professionals, physicians, veterans, doctors and biomedical engineers who use them, started to be designed by the professional product designers. Manufacturers saw the necessity of including design teams into the process and they recognized the importance of working in coordinate with the supporting services such as industrial design, prototyping, mechanical engineering, and design for manufacture, design planning, and branding to avoid the inappropriate product solutions, increase the ease of use and improve the functionality.

The changing approaches to the medical device design showed that the methods, scientists or medical professionals used to be used, have some deficiencies. Some very important subjects such as human factors, usability, user interfaces and user oriented design principles which were not taken into care became very important. Medical

technology which once provides better treatment conditions for the patients caused synchronous increase of the technical complexity and more accidental injuries because of the imperfection of the user centered design principles. The importance of human factor approaches came in to being in the medical equipment design because of these human-machine interaction deficiencies.

The emergence of the new methods indicated its existence in the beginning of the century; however, the works on this subject had not begun as early. Also today, it is not possible to say that the medical device design has its own clear methods for designing a product, whereas, involvement of the product design methods within the design process will be a key to solve this problem. As Simon suggested; "The intellectual activity that produces material artifacts is no different fundamentally from the one that prescribes remedies for a sick patient or the one that devises a new sales plan for a company or a social welfare policy for a state"(Simon, 1992, p. 130). From the point of this view, it is possible to say that, methods used in a creative process, can be adapted and applied to another process with its main principles. An innovative approach which is based on simulating the design process using a cross-disciplinary approach and mimics the behavior of the design team can be a useful way to apply product design methods into the medical device process. The aim of doing such an adaptation is to implement the knowledge-based model of product design in medical device design to reach from a robust synthesis to a successful design outcome.

There are two very important factors which change the medical conditions and make the medical design methods necessary to analyze; first one is the "user" of the medical device is changing. Devices which once used only by the doctors, nurses and the medical technicians are started to be used by the patient himself. The second factor is the devices which were used just in the hospitals are stared to be used within the other environments such as homes of the patients.

In the following chapter, these changing conditions of medical market and medical device design are going to be scrutinized. Since it is a wide area, medical trends are going to be chosen as restrictive components and among these trends, home-care is going to be selected because of its structure which focuses on the devices which are usually used by the patients themselves.

CHAPTER 3

SEARCHING FOR THE SUITABLE METHODS FOR MEDICAL DEVICE DESIGN

Methods those used to solve the main problems of an industrial field usually have the potential to solve radically the problems of medical device design. In this section the ways of adapting and applying product design methods within the medical device design are going to be searched.

3.1 Identifying the Field of Study

In this section, the field of study which is chosen for applying design methods is going to be analyzed. The study is going to focus on trends, which shape the medicine and the medical market. Home care and the main inputs of home care device design are going to form the main stream of the section.

3.1.1 Emerging Trends in Healthcare

Medical devices, as stated before, are technology and performance driven products. Today, technology is the fastest developing event, where, most of the products are related to it. It is inevitable for the medical product field, therefore, to be affected from this rapid development of the technology. The new technologies which shape the device trends also constitute a corner in the design of medical devices.

The competitive edge of the medical market which is based upon the catching the technology is one of the most important shaper of the medical device design trends. The researches are showing that the trends through this field are going to lie in improving products that are interaction with users in all ways. Those new medical device design trends, incase, tend to be focus on the end user as the increasing amount of devices caused patients become conscious. As the technology drives the competitive device area, differences in the technological structure becomes the key factor to success. After the new technology matures, the key factor returns to the design of the products

using this same new technology and at this point, accounting user becomes main differentiator.

The mainline of the medical device design trends lay on the user-oriented design approaches, however, a more extensive research and study is required from the professional point of view. It is therefore, Food and Drug Administration, surveyed a group of experts to identify major trends anticipated in medical device technologies. There were several participants which were professionals on different fields related to medicine in a way. "Participants put forward ideas on medical developments those are likely to be important for the development of new products. Participants assigned numerical scores to 21 medical technology areas reflecting their expectations regarding (A) probability of new product development, (B) likely patient population size, (C) potential benefits, (D) potential risks, and (E) overall importance of the technology area for medical device evolution over the decade. In completing the questionnaire each participant identified significant examples of specific device groups for each generic technology. Expert participants scored the generic technologies and specific device examples with respect to several factors including (1) probability that substantial new developments would lead to new clinical products, (2) probable size of the affected patient population, (3) magnitude of expected benefits and risks, and (4) overall importance for causing significant changes in health care practice"(William, Donald & Harvey ,1998).

The main variant that affected the decisions about the trends was the evolving large-scale issues they expected to influence the evolution of medical devices. Nearly all of the participants underlined the relation between manufacturers, healthcare providers, institutional payers, patients and consumers that shape the medical trends and emphasized that the composure between these is the main designator.

In the end of the discussions and voting, thirteen issues emerged:

- Changing U.S. health care system, cost containment pressures, and 'outcomes' research
- Computerization
- Device customization
- Molecular medicine
- Home/self care

- Prevention
- Reducing invasiveness
- Miniaturization
- Tissue engineering
- Pharmaceutical developments
- Neuroscience advances
- Cancer therapy advances
- Social factors (e.g., activist patients and consumers, aging patient population, etc.)

The most anticipated trends between those were the ones based upon the intelligent device technology such as microprocessors, smart robotics, etc. participants also emphasized that the miniaturization of medical devices will be one of the most important trends towards the following years. After a discussion session, six major trend categories were determined those are potential to affect the future medicine:

1. Computer-related technology
2. Molecular medicine
3. Home-self-care
4. Minimally invasive procedures
5. Combination device/drug products
6. Organ replacements and assists

"The first two of these trend categories comprise developments grounded in scientific advances; the second two in growing delivery modalities; and the last two in specific product-types"(William, Donald & Harvey ,1998).

Computer related technologies were marked to be the fundamental input of the intelligent device technology. Participants stressed on the growing up computer aided diagnosis, computer-aided diagnosis, intelligent devices, biosensors and robotics (which panelists associated with intelligent devices), and networks of devices. Molecular medicine was pointed out where the development of this field is very rapid and impressive. Genetic diagnosis, genetic therapy, and tissue-engineered devices are

selected among those types of devices. Home and self-care was the third trend that was selected by the practitioners and home/self therapy, telemedicine and home/self monitoring were the topics that were emphasized. Medical imaging, microminiaturized devices, robotic surgical devices and laser technologies were pointed out within the minimally invasive procedures trends. The fifth trend was focused on implanted drug delivery systems and drug impregnated devices within the combination device/drug products trend. And the sixth and the last trend, organ substitutes and assist, was including specific product examples such as heart valves, heart pumps, blood vessels, kidney and regenerated nerve cells.

Those trends, that are expected to change the overall regulatory of the medical system, have some major common characteristics:

- "Medical hardware seems certain to become smarter. Devices and systems are likely to reflect a more sophisticated capability for intelligent behavior, and more mature information data bases to guide product performance.
- Smarter and simpler products will facilitate a growing trend to decentralization of care.
- Product development will increasingly blur the boundaries between biological systems on the one hand, and physical and engineering designs on the other. Integrated and hybrid approaches will play an expanding role.
- Technological developments will help to catalyze a trend toward greater precision in clinical interventions, both spatially and temporally. Reductions in invasiveness will probably mirror advances in miniaturization and improvements in early diagnosis"(William, Donald & Harvey ,1998).

The trends identified above are very important since they point to a near-future in which the majority of aged population and chronic diseases is going to shape the needs. It is obvious that high costs of treatment and the amount of people heaped in the hospital queues change the way of medical devices to home. The self-care devices which can be used by the patients themselves are going to snatch the medical market. The systems regarding user-driven models for healthcare, including smart devices,

wearable devices and wireless internet linked systems, are going to be the major designators of the future medical device field.

3.1.2 Home Healthcare

World War II was the cornerstone of technological and medical development, as emphasized during the previous chapter. The new conditions those were caused from the results of war had affected everything, and so the healthcare habits. Before the development of the specialization in professions, generally, health care was applied at home by nonprofessionals. Diseases were threatened by neighbors or people who gained the trust of community and so physicians played a small role in the care of the patients in those years.

By the end of the World War II, with emergence of new technologies, medical technology became so sophisticated that, medical care in the homes could not be possible any more. Hospitals and clinics took the place of homes, due to the complicated medical device technology. After the modernization of the hospitals and the increase in the number of professionals, specialized operations such as surgical operations become possible and the speedy development of the medical technology took people away from the past habits about treatment. Such a transformation in the healthcare facilities forced more and more people to go to the hospitals for medical care.

After 1970's, a new period have started for health care. "Changes in health care economics, as well as demographic changes, have stimulated a significant evolution of the "hospital" model, with more and more patients being cared for at home or at other non-clinical places for their convalescence, after the patient's acute medical status has been stabilized. And inevitably, their care has been performed or maintained more and more by patients' parents, spouses, or other non-clinical personnel. As patients have been moved to the home and other non-medical facilities for their recuperation or long term care, the medical devices needed for their care (e.g., respiratory and intravenous therapy devices) have followed them"(Arcarese, 2002).

"This return to decentralized care is being catalyzed by the emergence of the Internet as an unprecedented conduit of health information to patients, and by the diffusion of inexpensive computer technology as an aid to medical decision-making by individual consumers"(Herman, Marlowe & Rudolph, 1998).

There are of course several reasons in the transformation of medical care towards home care. For a home care device designer, it is inevitable to analyze physiological conditions of patients and the reasons of preferring home-care. Therefore the reasons of homecare preference are going to be studied during the following section.

3.1.2.1 Why Home-Healthcare?

Understanding why people choose home care treatment is essential in the beginning of the design process, where, the key issues of home care device design are to be understood. “Knowledge of the contexts in which patients are failing to take their medicines as prescribed is essential if future work is to be efficiently and effectively targeted to improve patient safety in the home. Only then can design solutions be developed against the background of well-understood contexts in which they will function. It will also make it easier to evaluate the effectiveness of new designs as to whether they really are improving patient safety and supporting caregivers in carrying out their work”(Design for Patient Safety, 2003, p. 6).

The reason in why people choose to be treated in their homes includes a series of reasons. One of the most important ones is the changing conditions of the healthcare facilities according to the growing population. As the population grows, the insufficiency of patient-doctor relationship against the increased number of patients becomes a problem. As demands of patients increase, the medical system becomes dramatically incapable. Those demands are driven by some basic subjects:

- “An aging population presents tremendous challenges to the healthcare industry.
- Individuals are not only interested in their state of health when disease symptoms are manifested; they also desire warnings for developing conditions.
- In-person patient-physician visits are inefficient both in time and resources.
- Currently, home care is usually provided by individuals who are close to the patient, e.g. a friend or relative. Because these individuals are often

untrained and experience burnout, it is very difficult to maintain consistent, high quality services.

- In some situations, in-person medical service is unavailable simply because of geographical limitations or lack of transportation infrastructure"(Yao, Schmitz&Warren, 2003, p. 1).

The changes, those caused from the technological development, let the healthcare manufacturers constitute knowledge about home care devices. "Advances in medical technology have enabled people to consider homecare for chronic illnesses and disabilities that would have kept them in a hospital or a nursing home in the past"(Klatzky, Kober, Mavor, 1996, p. 1). Growing pressure for the use of home devices has hanged the ongoing device design and manufacturing processes. Devices which have been used in hospitals and specialized treatment spaces are started to guide to home environment. The role of the extraordinary expenses of hospital care and arise of the patient population, of course, are the main designator during this period.

The main igniter of decentralization from hospitals to home is the growing participation of patients and medical device users to the treatment process. As lifestyles changes, the habits of people about treatment follow a freer path. Patients of today's want a more specialized space for their treatment and they want to make more responsibility for their lives. Patients are now aware of the risks of long hospital stays caused by increased risk of infections. It is also very hard to pay the hospital expenses, since the hospital based treatment is very expensive for those people who have chronic diseases. They want the comfort of their homes and they need to be with their relatives during the treatment period. In short they do not want to make concessions from the habits of their daily lives. Therefore, home healthcare not only improves the quality of life, it also avoids patients from the expensive hospital procedures.

There are some very important situations those have to be considered while analyzing the user and the use environment of home devices. As the trend towards the medical device field moves from hospitals to homes, the users of such devices moves from doctors or professionals to the ordinary people who have less technical knowledge. This new perception of user not only show itself on the technical knowledge end, but also on the physiological end because of the difference of the new end-user is very different from the doctors or physicians as they are not healthy people. They need more attention and therefore, they need a special approach.

The users of home care devices, of course, are showing a big variety from babies to elderly. However, most of the people who benefits from the home care services are the elderly people, since the chronic diseases are more widespread among those population. Therefore, the habits of elderly people are going to form the focus point of this section. Elderly people, as the users of medical devices, have quite different characteristics from the other people. It is usually very hard to identify the true needs of such a wide segmented user group. It is therefore essential for a device designer to have detailed knowledge about the field he/she works on. Analysis of true user needs requires true knowledge about the users.

Patients, who prefer home care treatment, consider the privacy, autonomy, and sense of control that home care gives them. The most important reason in this selection is the sense of freedom comes from being in a familiar, comfortable environment, in which they can interact with family and friends. Home care, for those types of patients, is an escape gate to be saved from the psychological stress that is caused from being in a foreign surrounding. In short, the key point is 'the sense of identity' that home care gives them.

There the designer comes to face to face with the concept of 'place' as the main designator. For home care device design, place and space are the fundamental inputs. The difference between the space and place have to be understood well, where, the space is the abstract concept, whereas place is space transformed and given cultural meaning by human activity. As people live more comfortably in some places, and because, home is the most important place which has such an intensive cultural meaning, medical treatment at home becomes preferably popular. Hospitals are usually accepted as the space of the doctors who have the power as a notion; therefore, patients who are unfamiliar to the hospitals usually prefer to be treated at their own homes where has semiotic meanings such as safe, warmth and the place of the whole family. "Home often represents the fundamental safe place of comfort and familiarity in difficult times. The idea of going home represents hopeful ideas about the possibilities of wellness and recovery and leaving behind the institutional discomforts and lack of privacy of hospital space. Home is also where most people state they prefer to be when they die, so even people in relatively serious need of sub-acute or daily life care may want to simply go home (Cartier, 2003, p. 2295)."

To collect all those reasons together, the highlights from the report of HCT Workshop, which is organized to identify the significant issues of 'why home care', will be useful:

> "Cost Savings, Efficiency: Pressures for efficiency in healthcare delivery are major motivators for accelerating development of home- and self-care products and processes.
> Market Potential: The potentially gargantuan market for home- and self-care products is likely to engage the interest of an increasing number of commercial participants
> Prevention: Home- and self-care products and techniques can be especially well-suited to an emerging clinical paradigm shift to reliance on prevention for better health and lower costs.
> Responsibility Patterns: Home- and self-care approaches can align naturally with an ongoing global trend toward individual- and community centered health care.
> Demographic Patterns: Home- and self-care approaches can be expected to align well with the increasing health interests and independent attitudes of the 'boomer' generation, and with the quality-of-life needs of the growing elderly population.
> Replacement vs. Complementary Care: Ethical issues may arise regarding changes in the current standards of care depending on whether home- and self-care becomes (1) a complementary adjunct to or (2) a replacement for care which is more appropriate for face-to-face access to a healthcare professional.
> Technology Trends: Home- and self-care patterns are inextricably intertwined with the development of enabling technologies such as smart devices, noninvasive sensors, and telecommunications systems.
> Internet: One of the principal developments affecting home- and self-care is the information superhighway, which enables patient and consumer access to extraordinary amounts of information, but also poses difficult issues of information reliability"(HCT Workshop, 1996).

Because of the reasons emphasized above, decentralization of treatment from hospitals becomes a popular trend towards the following years. By the help of home care approach, patients will gain more control over the health of themselves. The most

important thing to do in this situation is to identify the most meaningful things, for which the result will make a difference within the home care treatment.

3.1.2.2 Home/Self Care Device Definition

Since the Office of Science and Technology which is founded in the structure of Center for Devices and Radiological Health have projected the home and self care devices as the one of the most speedily growing area within the medical trend concepts, the design of such devices gained a dramatic importance in respect of the previous years. Such a growing area required a detailed home/self care device definition. Thereupon, CDRH dealt with the definitions again and published a general home care device definition.

CDRH defines a home use device as: 'Medical devices used in the home environment by persons who are ill or disabled and need, or whose providers of care need, education and/or other related health care services to use and maintain the devices safely and effectively.' This definition however has some basic deficiencies about the use environment and the users of the home care devices. In this respect, Food and Drug Administration decided upon some attachments to this definition, according to the changing conditions of medical care. The decisions those were taken during the home use medical device meetings have expanded the definition of home use devices, however there are still some question marks about this subject since home care device technology is directly related with the lifestyle habits.

The changes on the home care device definition includes some basic principles those which were not stated in the first one. There, some decisions about the deficiencies of the previous definition were taken and the ways to get better were searched. "First, it may be incompatible with telemedicine and telemetry. Second, it doesn't take into account those people who are recovering (i.e., not presently "ill" per se) and who may need to be monitored during their recuperation. One person thought that adding the term "at risk" might also help characterize that not all home care users are presently ill. Third, the word "home" is too limiting and "home use" is an inaccurate characterization, because there are other non-clinical venues besides the home where medical devices are used (e.g., car or other transport). Some monitoring or therapeutic devices are used on the person wherever he/she might go, inside or outside. To deal with this, it was suggested that the definition be changed to speak about the use of

devices outside of controlled environments (or outside of "traditional health care settings"), where the concept of controlled environments is understood to mean those venues under relevant regulatory and professional control"(Arcarese, 2002).

The reason of the importance that has given to the definition of home care devices shows itself in the end products. When the migration of devices from hospital to home first started, manufacturers tended to premise and sell the products that are designed for the hospital environment for home use. This situation, of course, caused serious problems, since the devices that are used within the hospital conditions did not suit to home environment. There, the need for the new definitions and standards for the design and manufacturing of home use devices had appeared.

The most important thing to be identified within the home use devices have appears as the prescriptions for home use that take into account the hazards and unique situations in the home. Since home is a less specialized area for the use of the medical equipments, the improvements that are necessary for an effective use environment has to be identified in a clear way. Design of such devices, therefore, has to be made by knowing all these situations in mind.

Nowadays, after the necessary regulations have done, medical device manufacturers are aware that the devices those are designed for the hospital environment does not meet their requirements for home use. Since the migration of such devices have became out of control, manufacturers tend to the devices especially designed for home use and they are more aware of that such a design based approach can make them different among the others. Although presumably the production and manufacturing of devices designed for home increases their markets, it also has significant advantages on the safe and effective use of their products.

3.1.2.3 Human Factors

The patients, as users, have the ability to affect the design of devices. The involvement of the users in the early steps of the design process can exterminate wrongly identified problem solutions and shorten the time needed for the design. From the point of the manufacturers, identification of the real needs of the users, and therefore, identification of the user segment carries a big importance. Medical device manufacturers which once used to focus on manufacturability and quality of the engineering success, nowadays, have been recognizing the importance of paying

attention to the usability. ‘User centered design’, therefore, comes into being within the medical device design principles, since the usability of a device is directly related with the users.

In case, designers often act as conciliator of different user voices, such as doctors, technicians, service personnel, and patients. Therefore, it is very important for a device designer to recognize the characteristics of a device user. By looking at the problems from the user’s point of view and by using technology as a tool, a product designer will be able to add substantial value to the design and create high end medical devices.

User centered design is closely tied with the concept of usability, as stated, and comes from the field of human factors. This design approach begins with the admission that the users are the main point of the design activities. It gives importance to understand user characteristics and needs, and focuses on developing products that meets user’s requirements.

As the technological development results with more complex medical devices, human factors in medical device design and device-user interfaces becomes increasingly important. “Human factors is a discipline that seeks to improve human performance in the use of equipment by means of hardware and software design that is compatible with the abilities of the user population. The terms "human engineering,” “usability engineering” and “ergonomics” are often used interchangeably for the process utilized to achieve highly usable equipment. Human factors focuses on those variables that affect the performance of individuals using equipment. The subject of this primer is the impact of design upon safe and effective use of medical devices. Errors in the use of such devices often are caused, at least in part, by the design of the user interface, i.e., those features with which healthcare practitioners and lay users interact. Mistakes made during device operation not only can hamper effective patient treatment, monitoring, or diagnosis but in some cases can lead to injury or death”(Sawyer, 1996).

Since, there is a linear connection between the complexity of a device and its usability, the need for a field which seeks to overcome complexity by getting in touch with users abilities. This is especially important in home care devices, where, as stated before, users of such devices are usually no trained. Human factors is very important in this respect, where, the study field of it is the interactions between people and technology.

“In medicine, rising concerns over the safety of anesthesia gas machines triggered interest in the application of human factors (to the considerable benefit of

patients), in the late '70s. In the late 90's, medical error emerged as a serious issue in the delivery of healthcare, spawning new interest in human factors as a means of reducing error. And like their counterparts in non-medical industries, medical software and device manufacturers have turned to human factors as a tool for shortening time-to-market, managing development costs, reducing product support costs, reducing the risk of product recalls, and improving customer satisfaction with their products"(Human Factors and Medicine, 2004).

Increasing number of chronic diseases and lay people increases the level of medical device usage. Because of the varying characteristics of this population, medical device designer usually comes face to face with special challenges. Lack of medical training and differences between the patients some devices are those designed without considering human factors lives so short in the market. This causes serious time and money losses. Since this situation is recognized by the manufacturers, they have started to include human factors within the design process. "Strategic marketers are including human factors early in the product design process. Both medical device marketers and designers want to develop highly reliable successful and therefore, profitable products. To achieve this goal, they are best served when they have a more complete and accurate understanding of how the device is used combined with the limitations and failure modes of users. What are the device failure hazards and use-related hazards and how do they interact? All are functions of Human Factors"(Drake, 2002, p. 9).

However there is still lack of human factors within the medical device design. "At present, human factors science is not well integrated in the design of home medical equipment. Many manufacturers can produce a home medical device that looks good, and many can make one with a good user interface, but medical products still have a long way to go in terms of usability. Some products tend to be driven by technology rather than by user needs. Others are designed more for clinicians than for home users"(Klatzky, Kober& Mavor, 1996, p. 19). The reason of this lately involvement is, of course, the difficulty of setting up human factors research, where, the designers face "daunting demographic changes, including more lay users of our devices, new roles for patients as users, aging users, users not proficient in English, and the use of devices beyond the four walls of the provider institution. Communication is faster, devices are tied together in complex configurations, demands on users are increasing and, as we all know, devices are now being used as crucial factors in the war against chronic conditions, pushing the stakes for success even higher"(Ron Goodenow, 2003, p. 1).

The use of human factors within the medical device design includes usability testing, training of users or sales personnel, writing operating manuals and writing labels and package inserts. These studies go with technological development and design and human factors works together during the design process. “The field of human factors provides a systematic approach to accommodating the capabilities and limitations of people in equipment design and training. Researchers in the field conduct studies that describe people’s sensorimotor, cognitive, psychophysical, and anthropometric characteristics. The data from these studies are used by practitioners in conjunction with the results of targeted user studies to design work environments, to make equipment compatible with the intended user, and to develop effective training. Human factors issues arise in every domain in which people interact with the products of a technological society”(Klatzky, Kober& Mavor, 1996, p. vii). Medical device design and human factors, therefore, are customarily interdisciplinary. Such interdisciplinary teams usually include industrial designers, engineers, psychologists and anthropologists. The main aim of such a team is to realize greater recognition and understanding of man's characteristics, needs, abilities, and limitations when the medical devices are being designed. "The field of human factors uses scientific knowledge about human behavior in specifying the design and use of a human-machine system. The aim is to improve system efficiency by minimizing human error”(Adams, J. A., 1989, p. 3).

"The central focus of human factors relates to the consideration of human beings carrying out such functions as (1) the design and creation of man-made objects, products, equipment, facilities, and environments that people us; (2) the development of procedures for performing work and other human activities; (3) the provision of services to people; and (4) the evaluation of the things people use in terms of their suitability for people”(McCormick & Sanders, 1982, p. 4).

Including human factors in early steps of the design process reduces product development costs, possibilities of product recalls but first of all it reduces the errors those are caused wrongly identified patient characteristics, where, it will increase product acceptance, prevent costly post-market ‘upgrades’ and offer a new competitive advantage.

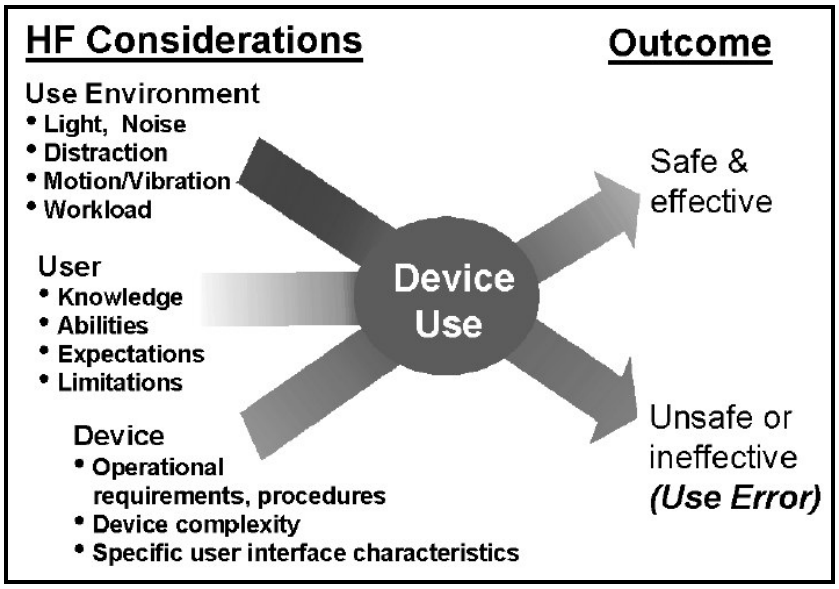


Figure 3.1: Human Factors Considerations (Medical Device Use-Safety, 2000)

"Human factors considers four factors that influence people's performance all driven by what the performer is trying to accomplish. Information is the first factor. What information does the performer need and where should that information exist (internal/long term memory, or external to the performer)? Environment is the second factor. How systems, devices and work processes are designed to help or hinder performance. Selection is the third factor. All things being equal, does the person have the requisite abilities to perform? And, motivation is the fourth factor. Are there clear goals and feedback mechanisms? Is the effort to use the system or device worth it — does it help the users achieve their goals reasonably quickly, easily and safely"(Drake, 2002, p. 8). "There is no doubt that customer satisfaction will improve. Health care professionals want to give patients the best possible treatment, and any product that minimizes error and accidental injury is a better product to use. Fewer errors will also reduce product and practice liability----another important consideration. For the manufacturer, sales of a device designed with user/machine interface in mind are likely to increase. And most importantly, human factors considerations result in safer devices and fewer injured patients"(Burlington, 1996).

In today, human factors within the medical device design have been demanded more than there were ten years ago. Since the safe and effective use of a medical device is very important in preventing errors, it seems that, design processes including human factors is going to become more widespread.

3.1.2.4 Safe and Effective Use

Good design has the power to reduce risks, make the products usable, and feel people better while using the product. The main aim of the designer while designing a home care device is obtaining the efficient use of the device he/she has designed. This is of course an influential and tiresome process, since the users are patients. The medical products are not happy products and therefore it is needed to give much more importance to make products that are user-friendly and give the patients information in terms that they can understand, where, the aim is to lessen their frustration level.

The first thing to do in this respect is to design home care devices those appears as normal as possible. Researches have shown that, patients prefer medical devices that are more distinctive and pleasurable than the ones they currently have. They want to perceive nearly the same feelings while they are buying a Beetle or a colorful line of Apple computer. Products those are designed with the conscious of going in a circle both usability, functionality and aesthetic quality are usually preferred by the users and therefore have more chance in the medical market. Elderly people and children, who mostly use the home care devices, tend to use devices those interact with them and they usually build a relationship with their products, where they search for the meaningful relationships with the devices they use.

Figure 3.2: Meaningful Product Categories (Battarbee & Mattelmäki, 2002)

"Elders rely on assistive technologies in many of their daily activities. When these devices look like they belong in a hospital, there is a significant impact on the user's self-esteem and emotional outlook. Designers need to consider not only product functionality, but usability and aesthetic considerations as well. For instance, one participant praised her coffeemaker, which was favored for its size, its ease of use, and how it blended in with her décor. When designers take contextual, social and emotional

factors into consideration, they will create products that are not only accessible to the aging, but also universally usable products that help people bridge the gap between themselves and their environments"(Forlizzi, Hirsch, Hyder, Goetz, 2001).

Figure 3.3: Scooters, unlike wheelchairs, avoid stigmatizing aesthetics: they are styled to be fun and sporty. (Forlizzi, Hirsch, Hyder, Goetz, 2001)

Aesthetically appealing products, usually give the patient the feeling of safety and belonging. Assistive home care devices therefore have to be designed not only with the technological knowledge, but also with the aesthetic conscious. The researches are showing that the treatment period of a patient is directly related with the physiological condition of his/her, where, if he/she rejects to use the necessary devices or do not follow the right procedures, the result may be death.

Next generation home care devices those are designed with this design approach are becoming widespread. The professional design teams and firms are detecting the ways of designing and producing home care devices that give the same taste with the other popular consumer devices.

Figure 3.4: The Medi-Jector Vision Needle-Free Home-Use Injection System-Refac Design

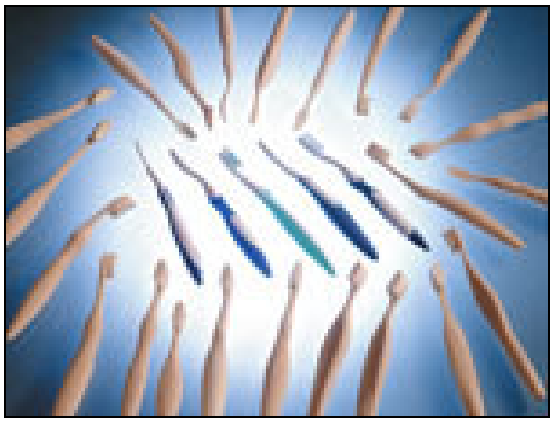


Figure 3.5: Oral-B Cross Action toothbrush Lunar Design

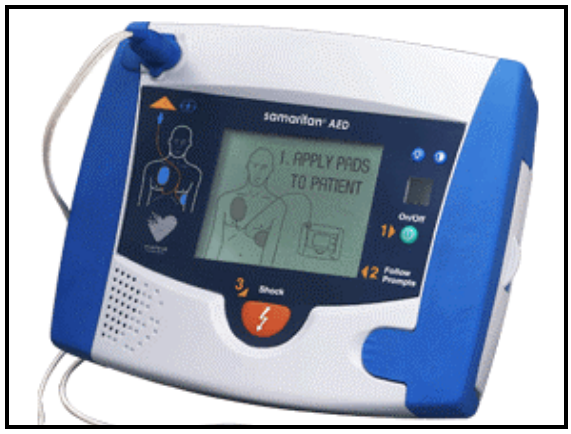


Figure 3.6: Samaritan AED, Heart Restarter-Philips, (http://www.restartaheart.com/training.html)

In short, home care devices have to enable social and sensory experiences to avoid pointing out the users. Good designed home care devices affect the patient's sense of identity and ideas of her abilities. Such assistive devices not only help to accept the illnesses but also they can increase functional capacities which are very important in the safe use of devices.

There are three types of problems come into being while examining the safety and effective use of medical devices;

- Use problems
- Device problems

- Clinical problems

Analyze of those problems, forms the starting point of a medical device design, and so home device design. During the analysis process, use factors and design factors should be thought together and synthesis through these two main subjects have to be done. A medical device designer has to make his/her most strategic decision while examining the basic use problems and according to them he/she has to decide upon the portions of medical products that should be carried to house. Striking point in this perception is to be aware of that the users of home devices can be a variety of people from lay patients to highly trained health professionals.

"There are a number of categories of issues that need to be examined with regard the suitability of certain devices for home-use, including:

1. Age and Disability of the User
2. Competency of the User
3. Environmental Suitability
4. Design Issues
5. Architectural Barriers
6. Miscellaneous Factors in the Home (e.g., children and pets that may interfere with the proper functioning of medical devices)"(Arcarese, 2002).

Industrial designers have much more limitations while designing home health-care products than the other devices designed to be used in the medical facilities. The physiological condition of the home device user differs a lot from the medical professionals. Patient who uses medical device, generally, doesn't want it to be emphasized that he/she is disabled or special. By the way, it requires much effort and intelligence to design home devices to such a different target consumer. The patient who is in such a physiology, especially elderly people, usually ignores to use the device or do not pay attention to the right usage procedures. Therefore, it is a critical subject to understand the main principles of designing devices both from the point of easy- use and acceptability.

As stated in the previous section, the future trend in the medical marketplace is the transformation of the device usage in the medical facilities into the usage in the patient's houses. In this transformation, the patient takes the mission of the medical

professional and the device usage changes hand in some ways. In such a situation, medical device design task needs a different approach from the traditional device design perceptiveness. According to this new trend, home health-care requirements gives shape to the changing nature of the new design task. Main difference of this new approach from the traditional one is, as pointed, the consumer who uses the medical devices is no more trained for using those devices. They also are not so healthy, so strong or as cool as the professionals. Thus, the problems that occur by the usage of medical devices that designed by traditional design approach will increase automatically. Designer is responsible in such a case for finding new solutions that meets the needs of this new design problem.

A medical device designed for home-use applications have to reflect the idea of 'can do' to the patient. End users, who comprehend that the medical devices are not different from the other objects they use in their daily lives, want devices that they can use easily as the other consumer products such as cell phones. For this reason, user experience appears as the key designator of the next generation products design and so in medical device design, which means that feasibility and technological newness that once formed the design process of medical devices have given off its place to ease of use.

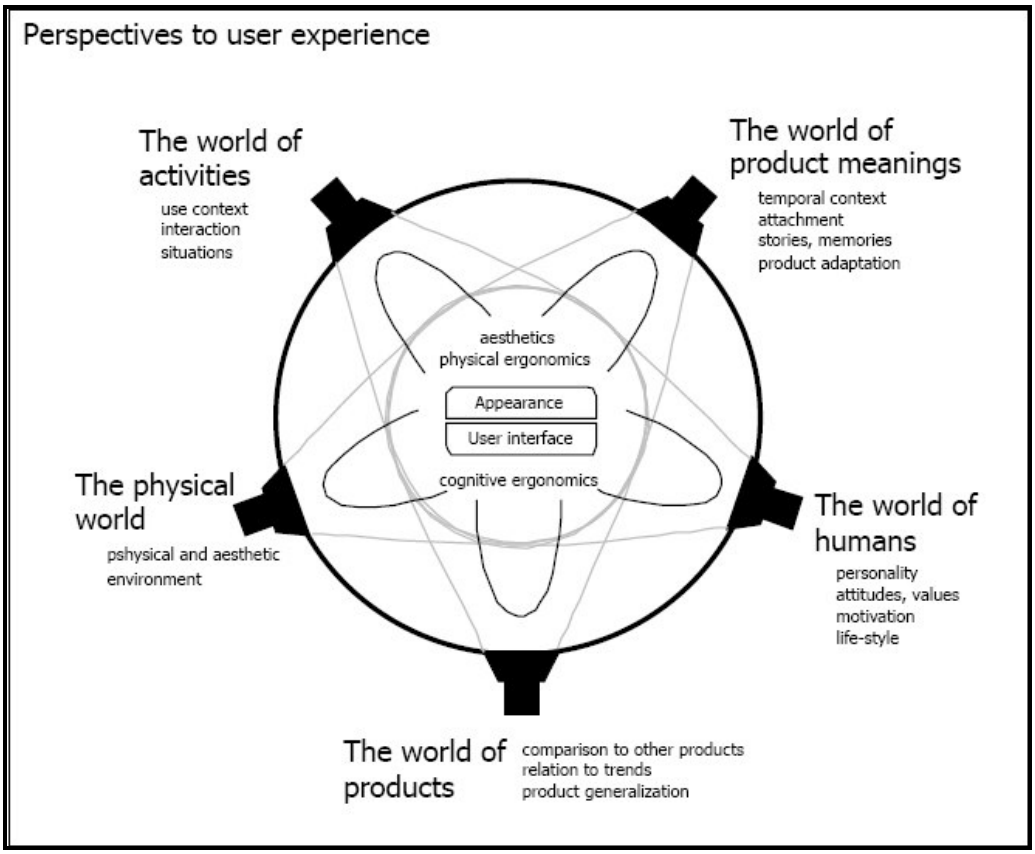


Figure 3.7: the perspectives to user experience (Jääskö & Mattelmäki, 2003)

Usability of a home care devices changes according to the physical and mental capabilities of the user. Designing a home care device therefore requires knowledge of some factors those affects the usability. These factors can be summarized as;

1. "Individual Factors:
    - Age
    - Anthropometrics
    - Gender
    - Educational background, personal history, experience, models of activity
    - Impairments
    - Personality factors, attitudes, models of thinking
    - Preferences and habits
2. Environment Related Factors
    - Social environment (Cultural and organizational settings, division of work, social relations, norms)

- Tools
- Physical environment
- Lighting
- Noise
- Temperature

3. Task Related Factors
4. Situational Factors"(Ekberg, 2000).

Ease and effective use of a home device includes several inputs, such as "medical training and experience, language barriers, literacy, memory, learning ability, dexterity, vision, and hearing, from the point of patients"(Lewis, 2001). As stated above, as the age of the patients increases, difficulties in the use of device increases. In contrast to typical clinical devices, a user of home care device could be anyone that needs to constantly monitor his or her health. Rather than simply lying in bed like an acute-care patient, they likely participate in normal daily activities, such as walking from one room to another or working outside. They might even leave home for the day. Therefore, the key is to design home care devices which can be used by as many patients as possible.

"As part of the national trend toward home care, a growing number and variety of medical devices have become available for use in the home. They range in sophistication from wheelchairs, walkers, and basic mobility aids; to patient monitors, glucose meters and ventilators; to high-technology infusion, dialysis, and respiration devices"(Klatzky, Kober& Mavor, 1996, p. 1). A general concept for the usage of such various home care devices should be formed to success in this field. There should be a common language of using such devices all around the world. The main way to do this is to consider the man-machine interface in all steps of the device design which points to the communication between the user and the device. Home care devices, which have developed by the recent technologies, needs more attention on the design of interface, where, those devices which once had just a switch interface, nowadays usually have a color display showing both text and graphics and accepting user input by a key panel.

An example can be useful at this point to describe the importance of this relation from the point of ease of use principles. Example is on an infusion pump and points to the wrongly identified human machine interaction. At first glance, this device looks

wonderfully simple, where; “it has an up/down switch, a select/active button, and a display. So what is the problem? These simple controls mask some complex technology inside. By using just these two controls, you can set seven different infusion modes, but there is only one display. So if someone wants to program a continuous dosage, instead of intermittent dosage, she has to press ‘select’ seven times, then the ‘activate’ button twice, then the select button once, then the activate button three times, then the select button once. Then she adjusts the interval with the up-down arrows. Confusing, to say the least”(Klatzky, Kober& Mavor, 1996, p.17). The basic concepts of error scenarios are very important in this sense.

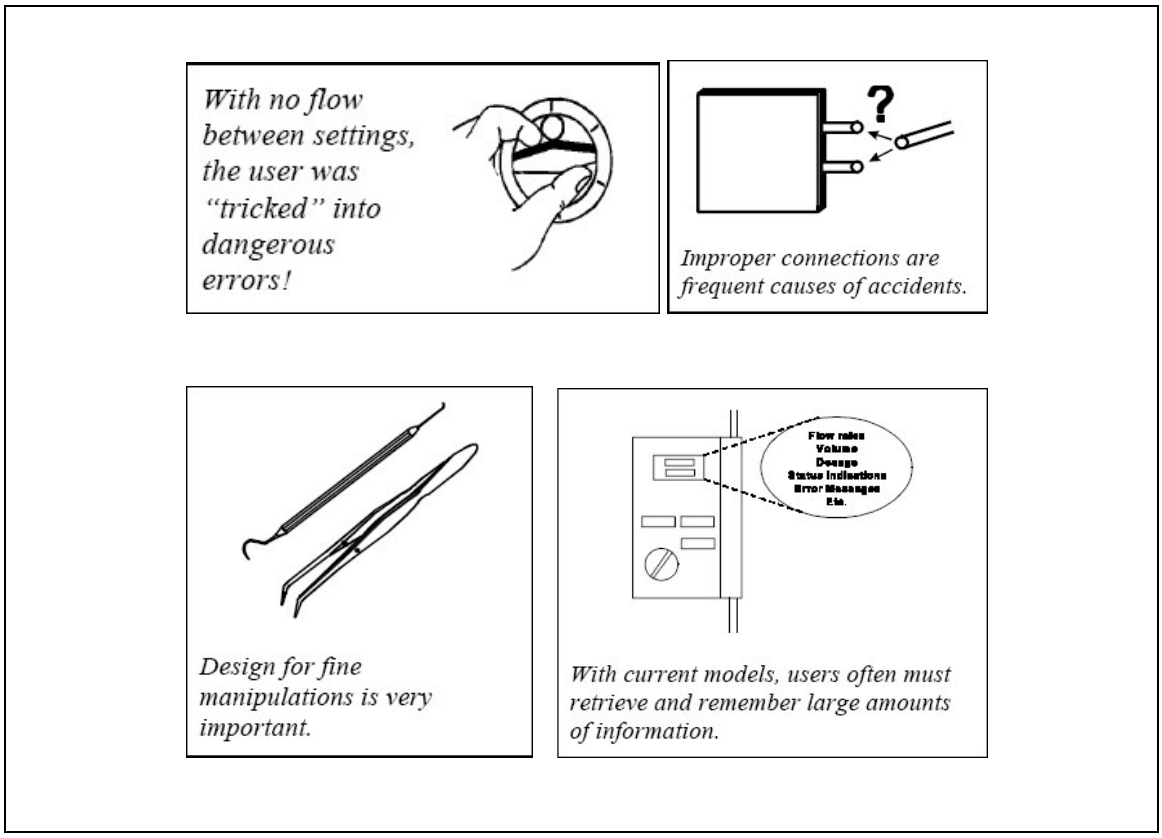


Figure 3.8: Error Scenarios (Do It by Design, pg.6, 12, 15, 9)

There are many devices that will substantially improve the connection between the patient and the system, and put more capability in the hands of the patients. However this relationship is directly related to the perception of the user and the knowledge of the designer on the end user. A way of developing man-machine interface in the home medical devices may be to take the advantage of other consumer product categories. In this case, the trend towards device miniaturizing may be a good example. As the technology grows and the trend towards miniaturizing devices is in force within

the medical market, displays of the devices appears as the one of the biggest use problems. This new trend is nominee to increase the number of the product such as hand scaled glucose readers, blood analyzers and laboratory instruments. Especially for elder people, it is very hard to use such devices, where, they may not be able to see well or they may have a disease which causes their hands to shiver. In such a case, one way may be to solve such a problem, by using the mobile phone technology, for example. As soon as the main principles of use are nearly the same, such an approach will help designer to solve some problems quicker and as stated in the example designer may be able to design more clear and swift displays.

As understood until here, the key in designing a home care device "is to make a product usable by a person with a dexterity problem or a visual or cognitive deficit, but not to telegraph the fact that the product has been designed for the disabled. The reason for device abandonment is . . . that devices symbolize a change in competencies that is associated with negative social judgments"(Wilcox, 2003).

Studies have shown that medical equipment exhibits some classic human-machine interaction deficiencies which increase the risk of human error. "'Error' is a generic term that encompasses all occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome and the failure can not be attributed to the intervention of chance. Error is either the failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan of action (error of planning) to achieve a goal. It is also important to distinguish two other kinds of errors: active errors, whose effects are felt almost immediately, which reason has further subdivided into slips, lapses, and mistakes and latent errors, whose adverse consequences may lie dormant within the system for a long time and become evident only when combined with other factors that breach the system's defenses"(Dain, 2002, p. 254). Risk of human errors occurs during the medical device usage, where, the psychological and physical factors, such as absent knowledge, stress, are involved to the device usage process. "Obtaining and using home medical equipment carries a great deal of emotional stress, and that affects how we learn about the equipment and how we use and maintain it"(Klatzky, Kober& Mavor, 1996, p. 6). Such a stress is a potential for the errors and therefore it has to be taken under control by the designs that will not embarrass the user during the usage process.

"Use-related hazards occur for some of the following reasons: devices are used in unanticipated ways; devices are used in ways that were anticipated, but were

inadequately controlled for; device use requires physical, perceptual or cognitive abilities that exceed those of the user; device use is inconsistent with user's expectations or intuition about the device operation; the use environment effects device operation and this effect is not understood by the user or the user's physical, perceptual, or cognitive capacities are exceeded when using the device in a particular environment"(Medical Device Use-Safety, 2000).

The best solution for preventing use errors may be to consider possible situations that are potentially able to cause use errors, from the beginning of the design process. The first thing to do is, of course, to understand the range of potential users and how they function in different environments. The requirements definition must be done in a clear way and they must be incorporated into product specifications. This may be possible by being included to the usage process of the device and examine each step of the usage process. "If you design medical products, you inevitably have to see those products in action, which means that you have to spend some time hanging around hospitals and/or other medical facilities"(Wilcox, 2003). This means that if you're working on diabetes products, you have to learn a lot about sugar levels, the various insulin related syndromes, and so on.

One another point that should be considered to design safer home care devices is to design medical devices with the conscious of standards, regulations, and market forces, which are supported by the medical community. It is inevitable to have the knowledge of regulations and standards while designing a medical device. Such regulations identify the borders of the usage of home devices, where, some of them may be used by patients, and some of them may not. It is therefore critical to determine by whom the device will be used during the design and manufacturing processes. "But many such medical devices were given CDRH approval for marketing under the expectation that they would be used by trained health care practitioners in controlled health care delivery facilities. Thus sophisticated medical devices are being used under conditions that neither their manufacturers nor the regulatory system had necessarily contemplated or intended consequences for the safe and effective operation of these medical devices, especially those with sophisticated requirements for proper operation, maintenance, calibration, electrical power, etc. Anecdotal reports of patient deaths or injuries as a result of problems with these factors are increasing"(Arcarese, 2002).

The final point about the designing safety and easy to use devices is to design products that get people to the right facility for the right kind of treatment. If the

designed product is in the right place and right setting, it will be able to control and decrease the use errors related to medical devices.

Since those criteria are not considered or the problems of users are identified wrongly, it is inevitable to become face to face with serious use-error problems which may cause the death of the patient. According to medical institute reports, over 98.000 people dies each year caused by the use-errors of medical devices. A medical device can be used safely and effectively only if the interaction between the operating environment, user capabilities, and stress levels are considered within the design process of the device. Easy-to-use controls, intuitive operation and low reliance on manuals, easy-to-read displays, effective alarms, and safe connections are some of the solutions that should be taken into consideration by the device designers to design safer devices.

The main dilemma of designing safer devices is appears while deciding on 'what is safety?' to answer of such a question a designer has to have the knowledge of risks and problems for the device he/she is going to design. There is, of course, nothing that is completely safety and purified from risks. Even under the best of circumstances, and with the best processes of design, manufacture, and implementation there will always be a risk factor. "Distractions, such as children or other family members, variations in lighting and noise levels, and the demands of using the device exceeding the user's capabilities, all can contribute. Patient receiving oxygen, for example, died when a pressure hose loosened from the unit. The alarm was not loud enough to be heard over the drone of the device. Dropping a device or using it in changing temperatures or high humidity (such as a bathroom or shower) also may affect its performance"(Lewis, 2001). However, the existence of risks can not, by itself, hinder the use of a device in the home.

So, what can be a home care device designer can do to prevent the device usage risks? "Patient safety cannot be improved by simply adjusting the design of medical devices, packaging and information because, at present, there is little in-depth understanding about how staff and patients use – and sometimes misuse – these items. This knowledge is required so that patient-safety 'hotspots' in the system (risky situations, risky moments, risky items and risky users) can be systematically identified and acted upon. This is the first, critical, stage of the design process: without this understanding, design briefs and procurement decisions will be flawed and solutions unlikely to be effective"(Design for Patient Safety, 2003, p. 29). The intersection field

of the environment, patient and the device, which is the product application environment, is, therefore, has the potential to solve the safety problems.

Home care devices that are designed to;

1. "Prevent user error from occurring – by encouraging simple-to-use and intuitive device operation
2. Alert users to possible dangers - by providing warning messages
3. Reduce the effect of use errors – such as through the use of fail-safe systems or backup safety systems, should an error occur"(Klatzky, Kober& Mavor, 1996, p. 43-44). are able to prevent such device errors.

By summarizing those subjects mentioned above, seven key concepts for a safer medical device design can be obtained:

• Considering man-machine interface drives on the rightly designed devices with more understandable and clear interfaces.
• Understanding the use environment and the habits of patient during the use of the device is very important and should be considered from the beginning of the design process.
• Designing devices those addresses as much patients as possible may direct the designer to simplify the use procedure.
• Taking the other consumer products as the models for error preventing may shorten the problem solving duration.
• Considering the regulations and the standards about the design and manufacturing of the devices is very important from the point of the device decisions.

And by the help of that knowledge, design issues appear as;

- make things visible
- simplify the operation
- avoid reliance on memory
- avoid reliance on vigilance

- use natural mappings
- use forcing functions
- make it easy to reverse an error"(Ensuring a Safe Device-User Interface, 2000, p. 12).

In short, the main thing to be understood while designing a home medical device is "how the user thinks about the equipment. Misunderstanding how a product works or being overtaxed by its complexity can be critically important causes of misuse or outright product failure"(Klatzky, Kober& Mavor, 1996, p. 19).

In spite of the challenges of designing such complex devices and putting everything together in an appropriate form is very hard, "the best designed products are those that make intuitive sense to the people who use them, without the need for complicated instructions or training"(Klatzky, Kober& Mavor, 1996, p. 16). The ideal is to design a device that a person can operate without referring to a manual.

3.1.2.5 Future of Home Care

Medical device trend searches have shown that the future of home medical devices could focus on three main titles:

- Tests
- Telemedicine
- Smart Devices

According to the participants joined to The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH)'s workshop to identify the future trends in the medical marketplace, the future trend for home-healthcare will be focus on the "tests involving urine and blood chemistry, as well as drug concentrations, particularly for elderly patients. Improved monitoring of glucose levels for diabetics was frequently mentioned. The most common form of home therapy cited was drug administration using simplified delivery techniques. Some participants noted the prospect of using home-based intelligent devices to modulate therapies and to "coach" patients. Several participants noted the possible use of relatively simple forms of

telemedicine for home care, especially within the confines of a local or regional medical system. Interestingly, participants anticipated greater significance for this "low-technology" telemedicine application than for some other "high-end" versions, perhaps because of potential interstate jurisdictional difficulties during the time period addressed by this study"(Herman, Marlowe & Rudolph, 1998).

In addition to the trends those are determined by FDA, another fields determined by the professionals those provide hope are the developments on the robotics, interactive technologies and smart devices. There is also the assumption that "smart house" technologies in the future will help provide capabilities for assisted living.

The development of the technology and the innovative structure of the medical device design field, of course, the main designators of such future concepts. If the changes in the life and technological conditions have to be taken into care, such as geographical decentralization, wireless systems technologies, etc., those concepts are not so far away from now on.

Figure 3.9: "Point-at-what-hurts" interaction aids diagnosis. The device lets you monitor your parents' health, too. (www.businessweek.com)

Developments in the sensor, computer, information and telecommunication technologies address to the smart devices for the future home care devices. "Increasingly-capable tele-health systems and the internet are not only moving the point of care closer to the patient, but the patient can now assume a more active role in his or her own care. These technologies, coupled with (1) the migration of the health care industry to electronic patient records and (2) the emergence of a growing number of enabling health care technologies (e.g., novel biosensors, wearable devices, and intelligent software agents), demonstrate unprecedented potential for delivering highly automated, intelligent health care in the home. Here, "intelligent health care technology" means smart devices and systems that are aware of their context and can therefore

assimilate information to support care decisions. A systems perspective is used to describe a framework under which devices can interact with one another in a plug-and-play manner"(Warren & Craft, 1999, p. 1).

Figure 3.10: fast home server will manage a wireless, high-bandwidth home network. (www.businessweek.com)

Smart devices those tend to catch the market are started to be used in some special cases already now. "The word "smart" implies the ability to process information within context. Intelligence can exist on a stand-alone device given that the knowledge set required to make decisions is maintained in the memory of the device. However, more flexible implementations of intelligent devices should accommodate a modular design that allows access to geographically distributed knowledge (information) and the software capable of processing those data"(Warren & Craft, 1999, p. 5). By the usage of such intelligent home care technologies it will be possible to leave some of the basic decisions to the smart devices, and thus medical professionals could be able to pay attention more patients. It will be also possible with such devices for the professionals to be aware of each patient's location and general health status. By the help of Bluetooth technologies, it will be more than a fantasy to exchanging information with other systems.

Figure 3.11: Smart Devices, (The Wall Street Journal, August 15, 2002)

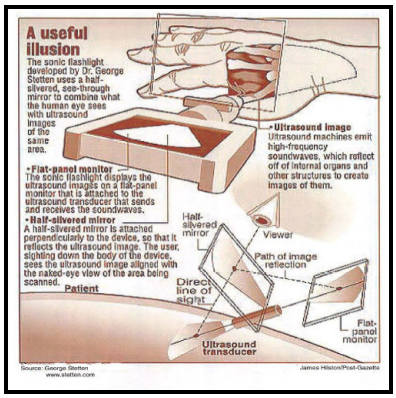


Figure 3.12: the Sonic Flashlight, (http://www.stetten.com)

"Realization of automated, intelligent health care delivery in the home requires smart devices that are aware of their context and are therefore able to assimilate information to support care decisions. Sensors distributed throughout the home will help to provide this context, since each sensor will acquire information regarding a patient's physiology as well as environmental factors that influence their state of health"(Warren & Craft, 1999, p. 3).

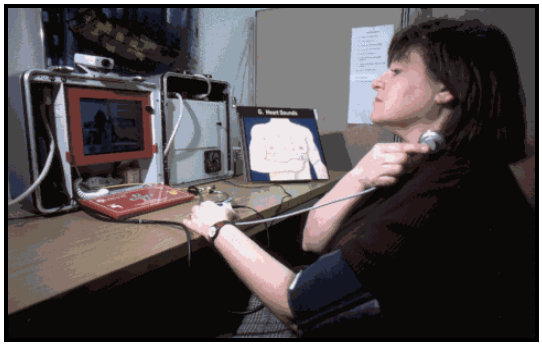


Figure 3.13: the patient end of a state-of-the-art, desktop telemedicine system (Warren & Craft, 1999, p. 4)

New technologies also have the potential to solve the problems of lay or lone patients, where, each home will be a 'smart space'. By the help of the assistive devices such as digital cameras, recognition mechanisms, and/or pressure-sensitive flooring that would identify occupants to identify the places of patients will become possible.

Also the PC and flat screen technologies can be used with the aim of telecommunication and the patient will no more need to go to his/her doctor for ordinary problems. Cesaroni, from Cesaroni Design Associates Inc. emphasizes about this subject that, the outpatient care is being driven by PCs, and flat-screen technology will permeate all medical products in the future because it's the most explicit way to deliver instructions, and it's becoming cheaper. With flat-screen displays, patients will reference the screen to get feedback on how to use the product, or what the results of a blood analysis are, where before they were not read the printed versions. It's like the old saying, 'a picture is worth a thousand words.'

The new technologies those drive the home care device trends are pointing to the direct relation with the devices and the patients. By the effect of such technologies, patients will be more within the devices. Since the devices are being miniaturized, it becomes possible to live with them without discriminating the place. Wearable and mobile devices, therefore, are becoming more and more popular between the patients.

Figure 3.14: the ClearPlan Easy Fertility Monitor, Medical Device Design Awards 2001

Figure 3.15: the Braun ThermoScan IRT 3520, Medical Device Design Awards 2001

Figure 3.16: Mbracelet-wearable computer prototype (Constas & Papadopoulos, 2001, pg.197)

Actually, the users of today's are directly related with the wireless systems technologies and therefore, it seems that crossing to the smart device technologies will not be so hard. Since there is few to learn for the patient, intelligent devices with web-based is going to be more popular not only with its advantages in urgent cases but also with its easy to use structure.

3.2 Searching for the Suitable Methods

After the identification of the field of study, the most complicated and the difficult part of the process begins. As stated in previous chapters, it is impossible to talk about a general methodology which fits to all kinds of design processes. Therefore, in this stage, designer has to make a very important decision, where, all design process is going to be set up on. This stage is the selection of suitable methods for the design process.

There are several methods which are being used by the designers and design teams during the design of a product. However, since all are different in some ways, the team or an individual designer has to be able to decide on the suitable methods which will be effective and will bring the design to a conclusion. In this respect, a decision making process (described in the Chapter II), as in all steps of design, is needed. In this case, a decision maker, who has knowledge about such methods, has to analyze the general characteristics of the design process and select the most suitable methods. "The specific description of this situation is the decision basis. The three elements of the decision basis can be thought of as the legs of a three-legged stool. The quality of a decision rests on having framed the decision correctly, that is, answering the right question, understanding the issues (knowledge), what can be done (options), and what

you want (desired outcomes)"(Allen, Caudill, Hunter, Howard, Magee, Ostrach, 2001, p. 10).

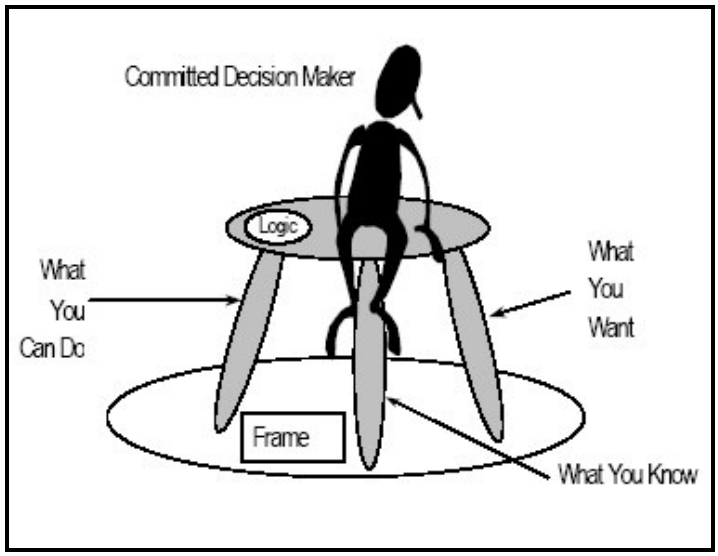


Figure 3.17: the quality of a decision (Allen, Caudill, Hunter, Howard, Magee, Ostrach, 2001, p.10)

As described in the figure above, it is very important to identify the data that the design team has and to determine the aim, where, the strategies and methods will be founded on them. "A general rule is to find and use those methods which best fit the problem as well as the abilities of the problem solver. It is a task similar to that of selecting the route, side roads and overnight stops for an auto trip. Just as any competent trip planner would examine the alternative routes on a map, and read through several brochures, books or articles before choosing a route for his trip, so should the problem solver review the methods available, and not be afraid to adapt any of them to his special needs"(Cross, 2000, p. 189).

The general approach to select the methods appears as identifying the strategies first. Strategy is simply the list of methods that a designer intends to use. "The term 'design strategy' is used here to mean a list of actions taken by a designer, or by a planning team, in order to transform an initial brief into a final design. ….. The actions of which a design strategy is composed can be decided at the outset or they can be changed according to the results of previous actions. Each 'design action' can consist of whatever the designers choose: some actions will be new methods, some will be traditional actions like sketching or scale drawing, while others may be novel procedures that the designers invent for themselves"(Jones, 1992, p. 75). In this sense, a

design team which constitutes a design strategy also constitutes the ways to reach the aim.

The first thing to do in this respect is to identify the product design process, since all strategies will be selected through it. The detailed explanation of the design process that is made during the Chapter II may be a useful starting point from this point of view.

Cross and Kruger emphasizes on four different models those encompasses the steps of a design process, where each model focuses on four different precedence of the design process.

- Problem driven design process
- Information driven design process
- Solution driven design process
- Knowledge driven design process

Most of the next generation design processes are tend to be solution driven, since, time is usually restricted and competitive market requires different solutions.

However, in spite of having restricted time and a competitive market force, medical device design process can not be identified by solution driven design model alone. It is rather the combination of solution driven design model and knowledge driven design model, where a beforehand medical knowledge is necessary in each step of a medical device design process.

According to Cross and Kruger, each model of process includes and excludes some steps as to its structure:

Problem driven design		
Solution ideas		Few
Requirements identified		Many
Activities		Emphasis on problem defining
Solution score:	Creativity	Low
	Overall	High
Information driven design		
Solution ideas		Few
Requirements identified		Many
Activities		Emphasis on data gathering
Solution score:	Creativity	Low
	Overall	High
Solution driven design		
Solution ideas		Many
Requirements identified		Few
Activities		Emphasis on solution generating
Solution score:	Creativity	High
	Overall	Low
Knowledge driven design		
Solution ideas		Few
Requirements identified		Few
Activities		Emphasis on modelling
Solution score:	Creativity	High
	Overall	Low

Figure 3.18: Expectations about design strategies (Cross & Kruger, 2000, p. 15)

As seen in the table, solution driven design process and strategies are more related with the solution generation phase, where, knowledge driven design process and strategies are on modeling phase. “In solution driven design, the assignment is quickly scanned for basic requirements. The design problem remains ill-defined. The designer skips the Assess task. The process consists of a short problem analysis stage, and long generate and evaluation stages, with short steps back to the analysis stage. In solution driven design the amount of time spent in the analysis stage is similar to information driven design, but instead of gathering information, knowledge is retrieved from memory”(Cross & Kruger, 2000, p. 13). Where, “in knowledge driven design the assignment is read carefully, and is compared to knowledge about similar problems. Those aspects that seem new are explored through gathering information. The designer takes the knowledge they already have as the basis for proceeding. The design problem is defined with clear links to existing knowledge about the problem. Knowledge about similar solutions is used for generating design solutions rather than developing entirely new solutions. In knowledge driven design the emphasis lies on retrieving knowledge from memory rather than gathering information. Knowledge driven design therefore depends heavily on prior knowledge, and this knowledge is used during the solution generating stage”(Cross & Kruger, 2000, p. 13).

Beside Cross and Kruger’s process based strategies selection model, Jones recommends a criterion based classification system of design strategies, in which the criteria are:

- The degree of pre-planning
- The pattern of search

This classification is also made due to the structure of the design process; however, the main difference of this approach is the strategies depend on the relations between the steps during the design process. Jones identifies five types of strategies according to that process-cycle based approach:

- Linear strategy
- Cyclic strategy
- Branching strategy

- Adaptive strategy
- Incremental strategy

where, “when design actions are wholly independent of each other a ‘branching strategy’ is possible. This can include parallel stages, which have the great advantage of increasing the number of persons working on the problem at one time, or alternative stages which allow some adaptation of strategy according to the outcome of previous stages. ‘Adaptive strategies are those in which only the first design action is decided at the start. The choice of each action thereafter is influenced by the outcome of the previous action. This is, in principle, the most intelligent strategy in that the search pattern is always being guided by the best available information. ….a reliable but modest version of adaptive search is the incremental strategy. This conservative strategy is the basis of traditional designing, particularly in craft-based industries”(Jones, 1992, p. 76).

Medical device design mostly suits in the branching strategy, where it is impossible to design a medical device, except the extraordinary conditions, just by an industrial designer. The main theme of this strategy is shown in the table below;

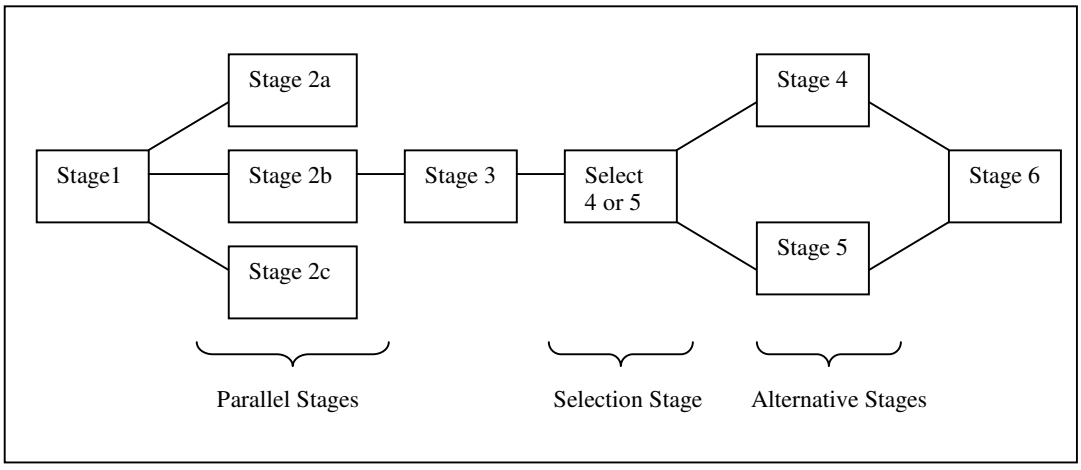


Figure 3.19: Branching Strategy (Jones, 1992, p. 77)

Briefly, medical device design has;

1. knowledge and solution driven design process
2. is closer to the branching strategy

where, in here, only the industrial designer’s front is going to be analyzed.

There is one more point, however, that should be considered while selecting the suitable methods for the home care devices. Since the most important thing during a medical device design process, and so, home care device design process, is considering the patients, means users, the usability factors and user-driven design appears as the third input for the method selection.

To draw a conclusion, it can be said that, the methods selected for the home care device design process should suitable with both knowledge, solution and user driven design processes, and have to allow to work with other branches those work within design team.

To select the suitable methods, one should know the general characteristics of methods. Product design methods usually show a four dimensional structure as; innovative, adaptive, convergent and divergent. Innovative methods "tend to detach the problem from the way it is customarily perceived and, working from there, are liable to produce less expected solutions, whereas, adaptive methods "reduces problems by improvement and greater efficiency, with maximum of continuity and stability"(Kirton, 1994).

"Definitions for highly innovative methods and highly adaptive methods are:

- Adaptive divergent methods are methods that generate solutions for problems that have been identified in a concept through successful incremental improvements. Value engineering and fishbone chart are, for instance, highly adaptive divergent methods. This type of method should be used to improve products and maintain a low level of uncertainty in the product development process.
- Innovative divergent methods are methods that facilitate the search for novel concepts. Examples of innovative divergent methods are the ladder of abstraction and wishful thinking. This kind of method should be used to generate radical change in projects having a generous time schedule.
- Adaptive convergent methods are evaluation techniques that require the use of precise, quantifiable data, such as, the parameter profile matrix. They should only be used when precise and consistent information of the evaluation object is available.

- Innovative convergent methods are methods that require qualitative information about the concepts that are evaluated, such as, highlighting technique. They should be used when the concepts for evaluation do not have a high level maturity"(Lopez, 2003, p. 16).

The most important point about the divergent methods is that they are usually used in the beginning of the design process and are used to obtain the right starting point. Convergent methods, however, are used in the end of the design process and they are useful in obtaining the right outcome.

There are hundreds of methods which are used within the design process. It is impossible to touch on all of them, where, some of them are formed within the 'black boxes' of designers. Therefore, the most frequently used ones are going to be mentioned according to their appropriateness to home care device design.

3.2.1 Classification of Design Methods

In this section design methods are going to be classified and briefly described according to their use areas. Classification of these methods is going to be made according to their divergent and convergent structures.

Fifty most frequently used methods are mentioned in Figure 3.20.

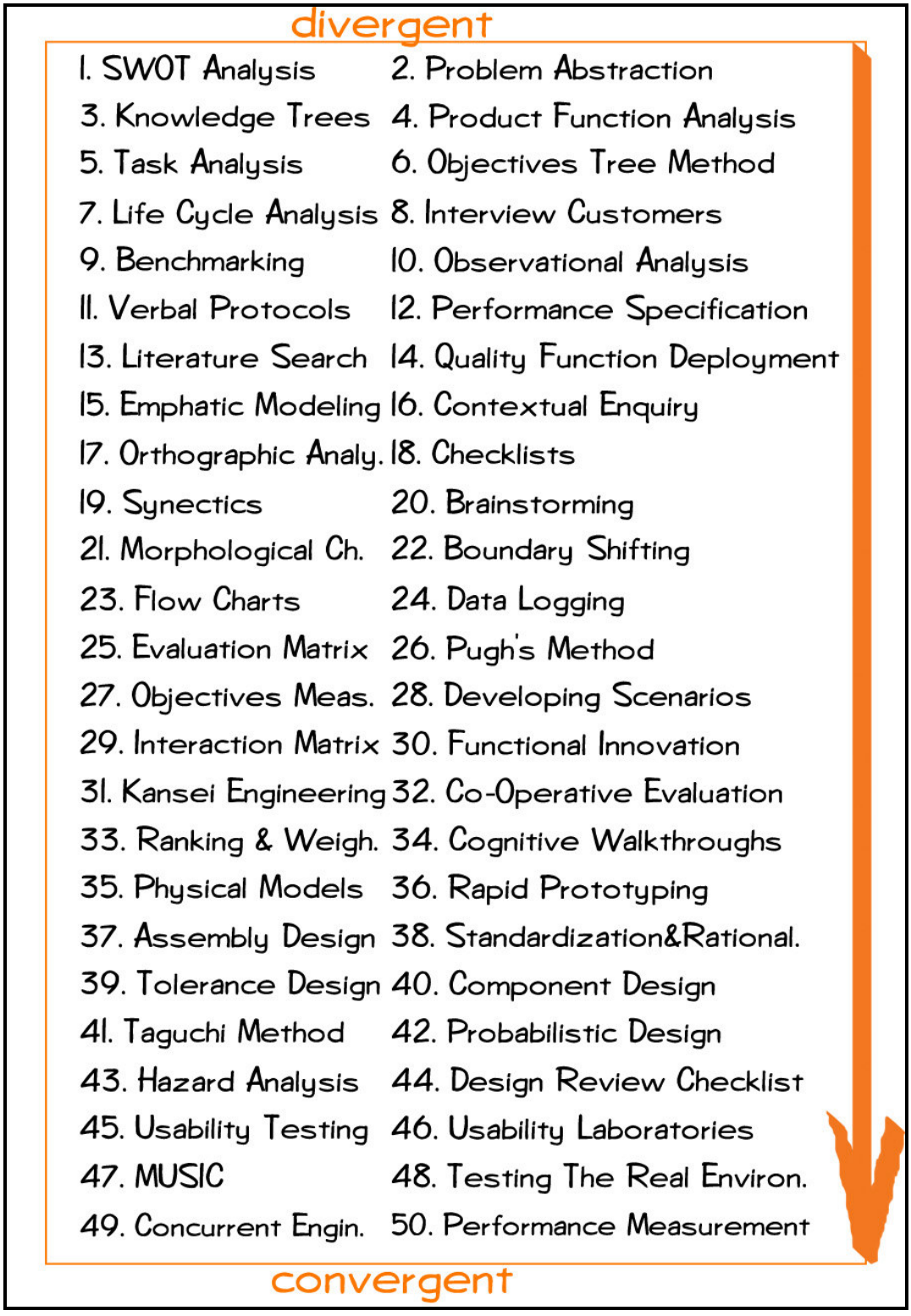


Figure 3.20: List of design methods collected from literature (All of these methods are collected from literature and are from different sources)

3.2.1.1 Methods of Design Planning and Understanding the Problem

In this section design methods those can be used during the analysis stage of a medical device design process are going to be mentioned by taking the 'usability methods' as reference. The classification of methods has done according to their proximity to the human factors principles.

List of methods:

1. SWOT Analysis
2. Problem Abstraction
3. Product Function Analysis
4. Objectives Tree Method
5. Knowledge Trees
6. Task Analysis
7. Life Cycle Analysis
8. Interview Users
9. Observational Analysis
10. Benchmarking
11. Performance Specification Method
12. Quality Function Deployment Method
13. Verbal Protocols
14. Literature Searching
15. Empathic Modeling
16. Contextual Enquiry

1. SWOT (**S**trengths, **W**eakness, **O**pportunities and **T**hreats) Analysis

Aim: is to identify the strengths and the weaknesses of the problem and to focus the design team's activities into areas where they are strong about the project, and where the greatest opportunities lie.

2. Problem Abstraction

Aim: is to detect the relevant or critical information and action for a particular problem. It is often used in problem solving stage in order to form a condition list for designers that lead from one complex state to another based on the criticality of the precondition.

3. Product Function Analysis

Aim: is to establish the functions required, and the system boundary, of a new design. Product function analysis allows the design team concentrating on what has to be achieved by a new design, and not on how it is to be achieved.

4. Objectives Tree Method

Aim: is to clarify design objectives and sub-objectives, and the relationships between them. The main subject of this method is to ensure if the "statements identifying the objectives are compatible with each other and with information that becomes available while designing.

5. Knowledge Trees

Aim: is to generate specifications and share the product knowledge for general understanding. This method may be highly effective when used by cross functional teams. It can be applied to virtually all aspects in the product design phase.

6. Task Analysis

Aim: is to get a sense of the knowledge structures or mental models which users use when they perform a task using a product. Task analysis allows designer to capture the structure of tasks underlying the activity

7. Life Cycle Analysis

Aim: is to map the projected life of a new product. Life cycle analysis maps the expected revenue (forecast) of each product within a portfolio and projects when sales are likely to decline. New products can then be planned to replace existing products. The main phases of a products life are Introduction, Growth, Maturity and Decline.

8. Interview Users

Aim: is to obtain useful information from the people who interact with the product in a way. Users may give important opinions and references about the design of the product. It is one of the most flexible ways of gathering data about the specific problems about the product. It supplies to understand the real problems of the people.

9. Observational Analysis

Aim: is to determine the real needs of the users and gathering information about the use process of a product. Users can behave different from expected actions while using a product. The best way of noticing such underestimated situations is observing users in their daily lives. It allows the designer to see some very important details during the use of the product which the design team may not realize by themselves.

10. Benchmarking

Aim: is to incorporate best practices to improve performance, search for innovative ideas and gain a competitive advantage. Benchmarking is used to establish the required goals. The method is designed to functionally benchmark the current product against the competition to understand the current level of functional competitiveness. This data can often be found in published reports by independent consulting agencies or developed independently by the company. The goal of benchmarking is to learn from others, adapt, implement and improve.

11. Performance Specification Method

Aim: is to help in defining the design problem, leaving the appropriate amount of freedom to the designer. A specification defines the required performance, and not the required product. The method therefore emphasizes the performance that a design solution has to achieve and not any particular physical components.

12. Quality Function Deployment Method

Aim: is to translate customer requirements into product specifications then into process controls. It is a method for capturing and delineating requirements based on identifying what is desired by the customer or stakeholder, along with how that desire may be satisfied. Quality Function Deployment method also defines what the end user is really looking for in the way of features and benefits

13. Verbal Protocols

Aim: is to capture the user's thoughts by recommending thinking aloud. It allows a researcher to find out how a person approaches to a problem or task and describes the problem solving techniques or interpretations he/she uses. It also provides qualitative information about how a person describes his/her actions in specific situations.

14. Literature Searching

Aim: is to obtain the required data for gathering output for the latter steps by searching the published resources. It makes possible to existing data about the subject. By the help of the literature searching a designer will be able to reach accurate information about the subject he/she studies on.

15. Empathic Modeling

Aim: is to simulate the positions of device usage by disabled and elderly people and to aware of the mechanism changes according to the obtained feedback. This method is useful in appreciating the difficulties of disabled people that the visually impaired experience in everyday scenarios. By the help of this method, designer may be able to notice some of the coping strategies and adaptation techniques that the visually impaired will use in specific situations.

16. Contextual Enquiry

Aim: is to examine and understand users and their environments, tasks, issues and preferences. It can be used to in producing user needs analyses and task analyses in the latter steps of the design process.

3.2.1.2 Methods of Idea Generation and Concept Selection

Idea generation and concept selection methods are usually used in the synthesis stage and are useful in transforming the information obtained in the analysis stage to useful technical datum.

List of methods:

17. Orthographic Analysis
18. Checklists
19. Synectics
20. Brainstorming
21. Morphological Chart
22. Boundary Shifting
23. Flow Charts
24. Data Logging and Data Reduction
25. Evaluation Matrix
26. Pugh's Method
27. Objectives Measures
28. Developing Scenarios
29. Interaction Matrix
30. Functional Innovation
31. Ranking and Weighting
32. Kansei Engineering
33. Co-Operative Evaluation
34. Cognitive Walkthroughs

17. Orthographic Analysis

Aim: is to arrange several attributes of a problem in a graphical representation of corresponding dimensions. A general purpose version of orthographic analysis takes a product and represents its Material, Manufacturing Processes and its Market along three orthographic axes.

18. Checklists

Aim: is to verify correctness of product documentation and identified requirements. It is also useful in indicating the absence or presence of a particular behavior or product. This method identifies the types of safety issues, problems, and deficiencies easily that have the potential to develop at each particular design.

19. Synectics

Aim: “is to direct the spontaneous activity of the brain and the nervous system towards the exploration and transformation of design problems”(Jones, 1992. p. 278). “Synectics is a group activity in which criticism is ruled out, and the group members attempt to built, combine and develop ideas towards a creative solution to set the problem”(Cross, 2000, p. 52).

20. Brainstorming

Aim: is to create an atmosphere of creative thinking in the earlier steps of the design process. The staring problem is usually presented with a question such as, ‘How the device can be improved?’ or ‘What can be done to x to make it more user-friendly?’. It is very important for a brainstorming session to leave the participants free while they constitute the solutions for the given problem. It is an affective way to write down all possible solutions, where those solutions will have be discussed among the other participants of the session. The method has been widely used in design, and has also been applied in the assistive technology field.

21. Morphological Chart

Aim: is to generate the complete range of alternative design solutions for a product, and hence to widen the search for potential new solutions. The morphological chart method “encourages the designer to identify novel combinations of elements and components. The chart sets out the complete range of elements, components or sub-solutions that can be combined together to make a solution”(Cross, 2000, p. 124).

22. Boundary Shifting

Aim: is to move the exploration outside the problem boundaries that are implicitly taken for granted. It supplies to identify the resources outside the assumed problem boundaries, and by this, transforming the problem.

23. Flow Charts

Aim: is to present a process. Flow charts tend to provide a common language and reference point when dialing with other participants of the design process. They enable designer to form the documentation of how various steps work together in the design process.

24. Data Logging and Data Reduction

Aim: is to address compatibility issues and facilitate the widespread application of actual user-performance data collection. This method allows designer to determine 'the patterns of behavior' which are very important in decision making.

25. Evaluation Matrix

Aim: is to divide the problems and processes into individual stages by the help of a numerical scoring tool to evaluate each part individually.

26. Pugh's method

Aim: is to rank concepts against a pre-existing concept and it is a form of decision matrix. It allows designer to generate the insights needed to choose the best solution quicker and without large amounts of detail design information. Pugh's method is an analysis method by comparing various alternatives in identifying the better attributes. The most important advantage of Pugh's method is that it is simple to use and can be applied quickly.

27. Objectives measures

Aim: is to "be closer to traditional empirical science, in that hard information is gathered which can be easily compared, and subjected to statistical analysis techniques. It allows predicting the likely success of a product, and for this reason subjective measures are also often used"(Ekberg, 2000).

28. Developing Scenarios

Aim: is to get a better feel of the user's needs. It enables designer to recognize new design requirements and get a physical representation of the environment in which a person lives. Scenarios are similar to, but more informal than, design-based test cases.

29. Interaction Matrix

Aim: is to define relationships between the elements. "Interaction matrix permits a systematic search for connections between elements within a problem"(Jones, 1992, p. 300).

30. Functional Innovation

Aim: is to mitigate innovation failure. It allows; designer "to find a radically new design capable of creating new patterns of behavior"(Jones, 1992, p. 331).

31. Ranking and Weighting

Aim: is to compare the possible alternatives which were determined by the design team. By the help of this method it becomes possible to choose the most promising solution among the others by the help of a 'common comparison measurement' tool. The main aim of it is to compare the utility values of alternative design proposals, on the basis of performance against differentially weighted objectives.

32. Kansei Engineering

Aim: is to link consumers' emotional responses to actual design elements. It allows mapping the design elements into individual words and phrases. By using this method, designers may be able to develop prototype products that evoke specific feelings in the users.

33. Co-operative Evaluation

Aim: is to identify what users are thinking when they perform a task. This method supplies better understanding of the solution way by a problem list and associated severity ratings.

34. Cognitive Walkthroughs

Aim: is to evaluate earlier prototype systems by observing the product in action. It enables designer to be aware of the device usage environment and facilitating communication when design teams.

3.1.2.3 Methods of Detailed Design

Detailed Design methods are usually used in the evaluation stage and are useful in examining if the designed product reaches the aim.

List of methods:

35. Physical Models
36. Rapid Prototyping
37. Standardization and Rationalization
38. Assembly Design
39. Tolerance Design
40. Component Design
41. Taguchi Method
42. Probabilistic Design
43. Design Review Checklist
44. Hazard Analysis
45. Usability Testing
46. Usability Laboratories
47. Testing The Real Environment
48. MUSIC (Measuring Usability In Context)
49. Performance Measurement
50. Concurrent Engineering

35. Physical Models

Aim: is to experience shape, shape details, shape compositions and functionality of the designed product. Physical models in the conceptual design stage are, due to the nature of conceptualization, different from rapid prototyping models, which are applied during the detailing stage of design. Some reasons for this are vagueness and incompleteness of product models, and different model usage and design. Model making is expensive and the useful effect is often not straight forward visible. So, the effect of such an investment is questionable.

36. Rapid Prototyping

Aim: is to construct physical models from Computer-Aided Design (CAD) data. It is one of the best ways of communicating ideas with co-workers or customers and can be used in design testing.

37. Standardization and Rationalization

Aim: is to "reduce information content of the manufacturing system as a whole by limiting the number of design choices to a few 'best' options. In the S&R approach, standardization is the reduction in the number of options (e.g. Parts, processes, and so forth) used in existing products. Rationalization is the identification of the fewest number of best options to be used in future products"(Stoll, 1999, p. 301).

38. Assembly Design

Aim: is to develop "a coordinated overall part decomposition and detail component geometry that reduces assembly cost by facilitating and easing product assembly. In addition to reducing manufacturing costs, it often generates significant productivity and quality improvements"(Stoll, 1999, p. 181).

39. Tolerance Design

Aim: is to supply thinking in terms of modern systems. The requirement for tolerance design is to adjust product/process tolerances and materials to achieve a desired performance, with cost-benefit trade-offs factored in. Tolerance design takes into consideration the fact that parameters of components the systems are made of as well as parameters of the environment in which the systems operate deviate from their nominal values but still stay within the admissible tolerances.

40. Component Design

Aim: is to "ensure that the designed components are functionally acceptable and also easy to fabricate using the selected material and manufacturing processes. Component design is implemented by creating detail component configurations that minimize information content of the tooling and the process"(Stoll, 1999, p. 220).

41. Taguchi Method

Aim: is to optimize the design with respect to performance and functionality. This method of design establishes a specific approach to design. The objective is to minimize the deviation from the desired target level, while minimizing manufacturing costs.

42. Probabilistic Design

Aim: is to provide an analytical framework which allows the designer to leverage available design margin to improve performance. “The probabilistic design approach seeks to incorporate real-world randomness and variation into the design decision making process by treating design parameters and characteristics statistically rather than deterministically”(Stoll, 1999, p. 335).

43. Design Review Checklist

Aim: is to assist a project developer and designer from the early stages of a project concept to final site development plans. Design reviews consider questions such as; ‘Do designs satisfy all specified requirements for the product?’, ‘Are product design and processing capabilities compatible?’, ‘Are safety considerations met?’, ‘Have appropriate materials and facilities been selected?’, and so on.

44. Hazard Analysis

Aim: is to isolate hazardous device failures. Hazard analysis allows designer to obtain possible device failures and hazards those are caused from electrical and mechanical problems or device usage. “Hazard analysis meetings provided an excellent collection point for possible hazards uncovered from complaint files during earlier studies, as well as from tests, user studies, and task analyses. One should note that hazard analyses may pinpoint low-frequency errors not discovered in prototype tests involving users”(Ekberg, 2000).

45. Usability Testing

Aim: is to ensure that if users can safely and effectively operate, install, and maintain devices. Usability testing encompasses a range of methods for identifying how users actually interact with a prototype or a complete product. The goal of usability testing is to find out what is and is not working well on the product.

46. Usability Laboratories

Aim: is to “provide a place where new equipment or prototypes of equipment can be tested in laboratory settings (usually by specialized staff). Commonly such laboratories will be organized to include a subject area and an experimental area, with trained observers being able to watch and record users trying to operate the equipment under

test. Commonly, users are given specific tasks to perform which are designed to be representative of the tasks that users are likely to need to perform with the equipment, and aspects of their performance on those tasks are then measured"(Ekberg, 2000).

47. Testing the Real Environment

Aim: is to test the designed product under real usage conditions. Testing a device in a realistic condition allows the design team seeing the possible failures and can be done in four ways; 'Simulating Actual Conditions in the Laboratory', 'Simulations in Healthcare Facilities', 'Simulations in Homes', 'Clinical Trials'.

48. MUSIC (Measuring Usability in Context)

Aim: is to measure the quality of use. "These tools incorporate a set of clearly defined methods and metrics for investigating different aspects of usability. The tools also support the diagnosis of problems underlying the metrics obtained during an evaluation"(Ekberg, 2000).

49. Performance Measurement

Aim: is to know how much of the budget has been expended at any one time and how far the project has progressed. Progress can be measured in two ways: by the basic work packages (tasks) that are finished, and by the state of the system performance (i.e. how close the system is to meeting the requirements of the system specification). The latter monitoring activity is called technical performance measurement.

50. Concurrent Engineering

Aim: "is to cause the developers, from the outset, to consider all elements of the product life cycle from conception through disposal, including quality, cost, schedule, and user requirement. Concurrent engineering is defined as "a systematic approach to the integrated, simultaneous design of products and their related processes, including manufacture and support. The concurrent engineering environment has the following characteristics:

- Reduced cycle time
- Overlapping of functional activities
- Collaboration in functional decisions"(Ekberg, 2000).

This classification of design methods due to their use areas will help the designer/design team in selecting the right methods for the right conditions and stages.

Another approach which may guide the designer in the process of method selection is the Jones's 'input-output chart'. Again in this approach, the classification of methods is the starting point. A chart, based on obtaining the design inputs and design outputs is the origin point of the selection.

The Figure 3.21 which is designed by taking the Jones's chart as the reference includes the methods described above.

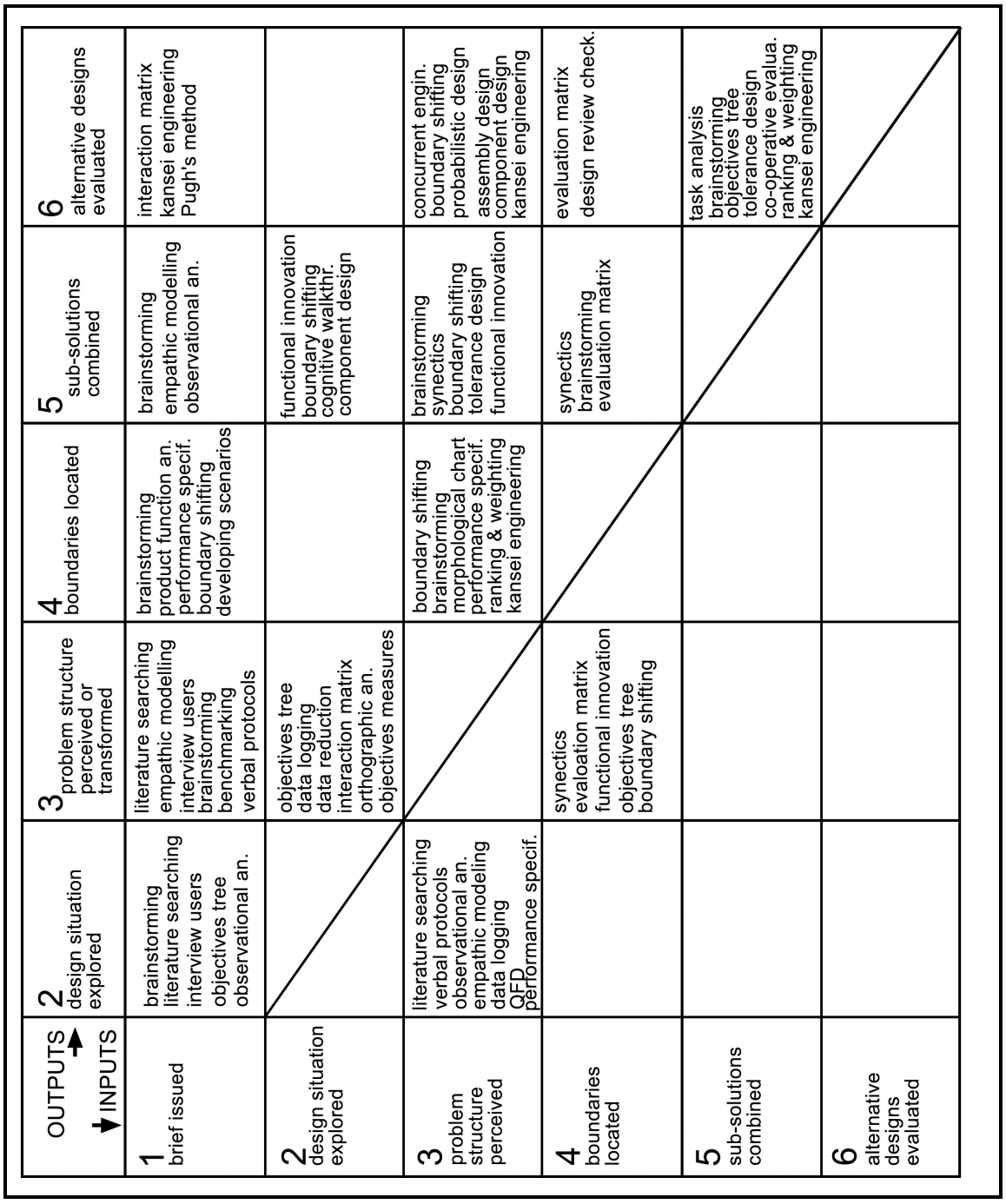


Figure 3.21: Method Selection Chart

“Inputs, shown on the left, are the kinds of information that must be available before a method can be used. Outputs, appearing across the top, are the kinds of information that the methods produce. The two scales, input and output are exactly the same and are placed in order of decreasing generality and increasing certainty. Methods that are useful in the early stages, when nearly everything is uncertain, appear at the top left of the table whereas methods that fit the final stages of design thinking appear at the bottom right”(Jones, 1992, p. 79).

Of course there are many more methods that can be used during the medical device design process. The methods defined above, as stated before, are just the most used ones among the design teams. However, unilateral use of these methods alone will not prove an effective design process, where, each project deserves a unique perspective on how user needs are interpreted, how concepts are created, and how presentations are structured. The most important thing in this respect is to be open to different methods and approaches. The subject for a designer is to challenge himself/herself outside his/her comfort zone and explore new methods for solving new problems.

CHAPTER IV

CASE STUDY ON IDEO

4.1 Introduction to Case Study

"We are searching for some kind of harmony between two intangibles: a form which we have not yet designed and a context which we cannot properly describe.

Christopher Alexander

In medical device industry of today's, good design has become the main road to be driven by the medical device manufacturers. Devices which are designed with the sense of human factors and usability have started to snatch the big slice of the pie. Manufacturers and users have recognized that medical devices which are designed in this sense not only increase the performance of the users but also they increase the rates of sales by their user friendly forms. Therefore, medical devices which were once designed by the medical practitioners and engineers are started to be designed by the professional design teams. Medical device manufacturers become more aware of the invaluable support of the design teams, at the point of improved functionality, effective product solutions and competing advantage within the market.

Another point to be emphasized in this case is the design competitions which gives the design teams and design manufacturers the chance of having awards from the design committees which have formed of design consultants. Such awards increase the sales of that product and are very important in the manufacturing field. Medical Design Excellence Awards and Industrial Design Excellence Awards are the most important examples of these award programs.

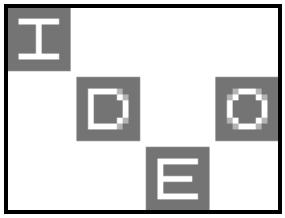
From the point of the design teams, the process goes quite different. Product design teams nowadays are much more aware of the importance of the 'design experience' and 'innovation' within their works. Each design firm, of course, its own strengths and weaknesses. To increase the level of strengths, successful design teams are tending to use the design methods within their design processes. Design teams which are venturing going one step further outside of their comfort zone are snatching

the chance of good design. Today's successful design teams are the ones, therefore, which are open to new design methods and which have the potential of produce the best design solutions.

"Good design is good business."
Thomas Watson, Jr., IBM

In this thesis, until here, the overall structure of design methods and the possible solutions to solve design problems of medical device design by using these methods were tried to define. From here, an illustrative case study is going to be presented to make the unfamiliar concepts clear and give a common language about the studied subject. The main procedure of the case study is going to be founded on the organizational performance of design methods, where, design is primarily a field of application. In this respect, IDEO, a leading design firm, is going to be inspected from the point of the usage of design methods within their design processes. IDEO was selected because of its novel and different role in offering a multi-disciplinary creative process in the design process, and having a unique process approach in the actual design process. Those criteria are defined according to the market researches and the design awards they have taken with their products.

4.2 IDEO



As stated above, innovation is the key factor within the successful product design. Innovative and creative organizations drive the future product design and create new advantages. IDEO Inc. is one of the most important of such organizations where their designs are revolutionizing the market.

"IDEO began in 1991 as a merger between David Kelley Design, which created Apple Computer Inc.'s first mouse in 1982, and ID Two, which designed the first laptop computer in the same year"(Nussbaum, 2004).

Figure 4.1: Mouse for Apple Computer for Lisa and Macintosh, (http://designcollector.ru)

Figure 4.2: Palm V for Palm Computing, (www.cad.at/.../ photoworks/photoworks.html)

Since than IDEO has become a worldwide firm with its fourteen studios varying in size from fifteen to thirty-five people. Furthermore, the firm is one of the most important examples of organizations which use product design methods in its design processes. IDEO has formed a pack of design methods which have been applied a wide variety of applications. A wide range of products from Apple Mouse to Palm V designed with this conscious had been gained IDEO a deserved fame.

The design intelligence of IDEO has become a lantern for many designers. The design experience that IDEO has created through the good design makes the team long for in design market. David Kelly, the founder of the IDEO and the writer of 'The Art of Innovation, Lessons in Creativity from IDEO, America's Leading Design Firm', relates this success with not only having the talented designers but also with their overall approach to design founded on group work and cross functional development.

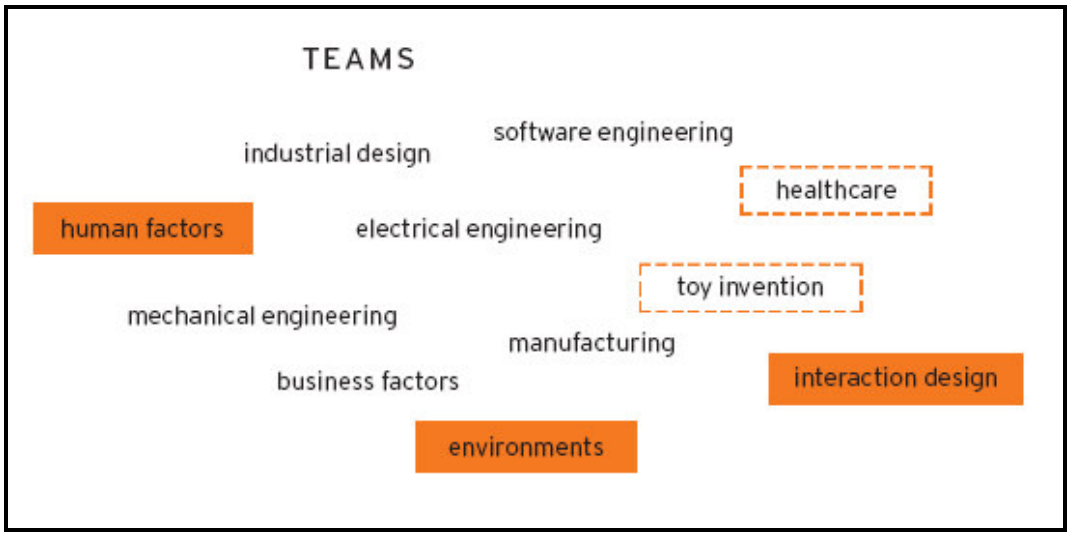


Figure 4.3: IDEO teams

They rather focus on understanding the needs of the users in all ways and turn these needs into functional, aesthetic and producible products. In this sense IDEO represents a triangular innovational process, where the 'design' is at the center.

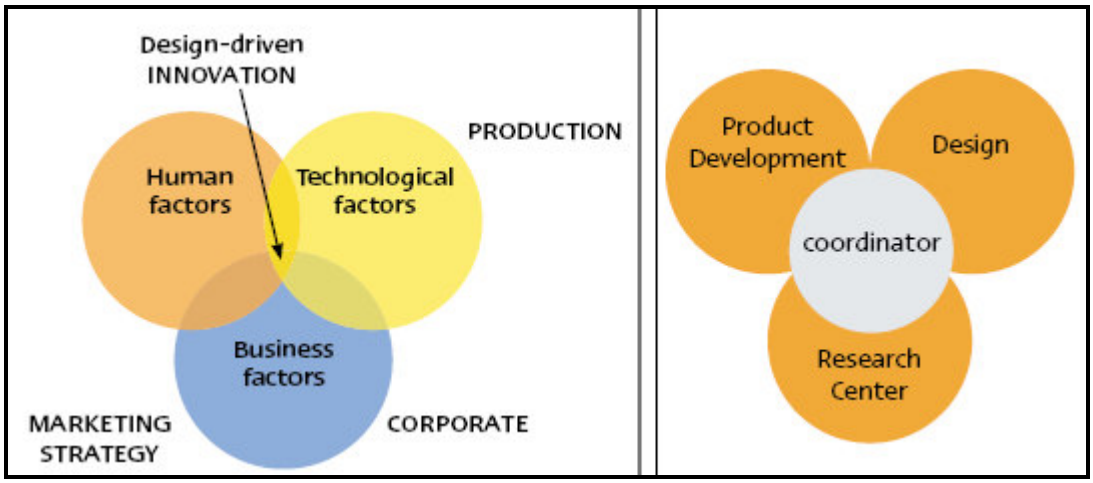


Figure 4.4: IDEO concept & The Innovation Engine

Divergent side of IDEO is, however, lies in supporting this design experience with a common language of methodology.

"The magic is not in the steps of the 'what'; it's over in the 'how.' If 'what' is the methodology, then 'how' is work practices."

Tom Kelly, the Art of Innovation, IDEO

Managers of IDEO declare their main principle as 'giving more than just style and form to a client concept'. In this sense, they present a design process which includes a set of rules for design. Main advantage of the firm is its multi-disciplinary structure that enables designing various levels of products. The focus point of the overall success lies in sharing the innovative process with its customers through projects and workshops. The main point, however, is the methods they use within these processes. Actually, this is why the firm was selected for the case study.

IDEO use various user-centered design methods in their design process. Some of these methods are very acquaintance; still, some of them are IDEO methods. From here, these methods are going to be inspected and matched with the methods those were selected in the end of the third chapter. This compare is going to be done step by step within the whole process of IDEO.

There are five steps of IDEO design process:

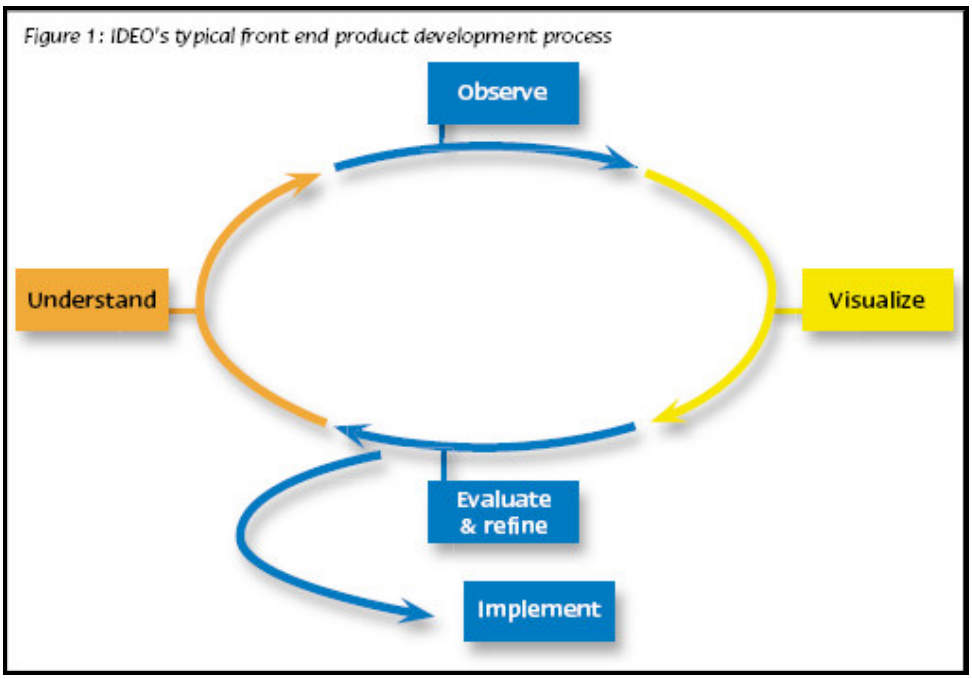


Figure 4.5: IDEO's Design Process (1) (Hytönen, Jarvinen, Tuulenmaki, 2004, p. 21)

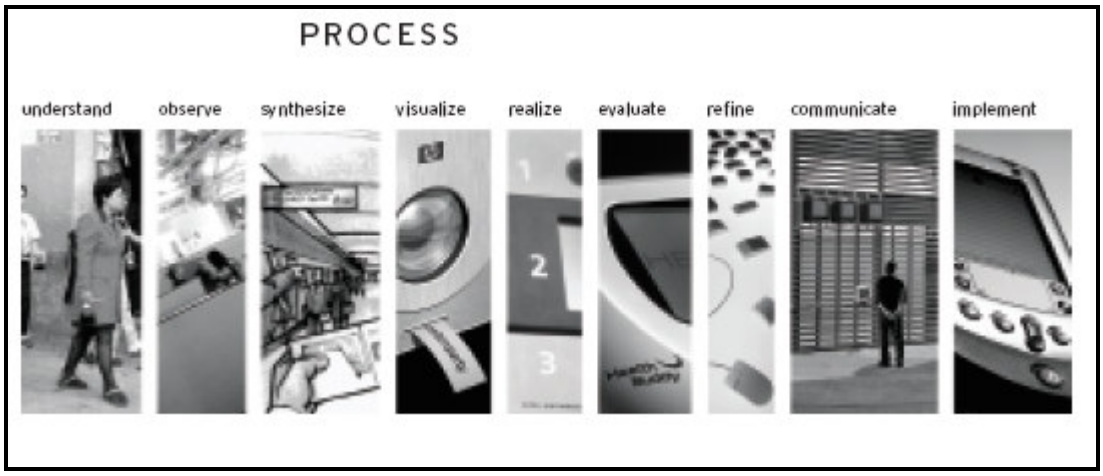


Figure 4.6: IDEO's Design Process (2) (Praxis 5, 1997, pg. 84)

4.2.1 Methods in Action

4.2.1.1 Observation

Figure 4.7: Observation stage

Observation stage is nearly the most important step of the IDEO's design process. The idea in this stage is to understand the people's choices and personal histories by deeply observing them. There are two basic systems that IDEO team uses during the observation. The first one is behavioral observations which help designers to understand the habits of users and the second is verbal descriptions which supplies deeply understanding of user needs from the first hand. Nina Serpiello from IDEO emphasizes that; "understanding a person's motivations, values, and emotions are critically important considerations in successful product design. People communicate about these sensibilities through stories of their experiences"(Serpiello, 2002, p. 1).

In this stage, IDEO works with human specialists and observe people how they interact with the world. The methods those are used during the observation stage are conventional methods, where, focuses on the need to understand the user behaviors in all means. The designers generate concrete representations of the observations that guide the work.

There are two rules that IDEO team has to fit in observation stage such as;

- Go to where people live and work
- Use new technology

These two main rules shape the overall observation step. IDEO team disperses into groups to observe the users in most effective way. They use cameras, recorders, and whatever possible to understand the real needs of the users. In this step, they use seven observational methods to answer the questions of 'what', 'how', 'when', 'where', and 'why'.

Figure 4.8: Observation

IDEO METHODS	PROPOSED METHODS
1. SHADOWING:	*OBSERVATIONAL ANALYSIS*
2. BEHAVIORAL MAPPING:	*LITERATURE SEARCHING*
3. CONSUMER JOURNEY:	*CONTEXTUAL ENQUIRY*
4. CAMERA JOURNALS:	*IDEO METHOD*
5. USER INTERVIEWS:	*USER INTERVIEWS*
6. STORYTELLING:	*VERBAL PROTOCOLS*
7. UNFOCUS GROUPS:	*CO-OPERATIVE EVALUATION*

Table 4.1: Observation Stage-IDEO Methods vs. Proposed Methods

1. Shadowing; This technique response to observational analysis that is defined at the end of the third chapter. In this method the aim is to observe the users while they are using the product.

2. Behavioral Mapping; is similar to literature searching, however, it focuses more on the photographic datum. The aim is to obtain permanent data of usage process.

3. Consumer Journey; responses to contextual enquiry, where, the main idea is to analyze the device-user interaction in the real use environment.

4. Camera Journals; is one of the IDEO's own techniques that is created for gaining visual data such as visual diaries. These diaries help the designers also in the latter stages of the design process to overlap the blanks, if there are, during the process.

5. User Interviews; is a basic tool to understand the real needs of the users. The aim is to gain verbal data by interviewing with the users face to face. Such an interview gives the team invaluable clues about the user-device interaction.

6. Storytelling; is a kind of verbal protocols based on the real experiences of the users. With this method it becomes possible to use multiple disciplines to figure out the product's story.

7. Unfocus Groups; is one of the innovative techniques of the IDEO however it may be related with the co-operative evaluation method. In this technique, a group of people who have different approaches are collected and it is tried to obtain different ideas about the product.

This stage also involves empathic modeling techniques (as defined in Chapter 2) and by the help of such an observation IDEO gains the knowledge of the real problem. For example; during the observation of medical staff using a re-designed pacemaker, IDEO realized that only cardiologists used its advance functions, so they created a two-tier interface making the simpler features easier to access for the majority of users.

During the observation, team members use lists in which all the observation details have written. Such kind of lists help designer in the latter steps to remember the observational research details. In this respect, Kelly emphasizes the importance of interviewing with different and interesting people to reach a greater detail of observation.

According to Megan Pryor, vice president of innovation "IDEO does a remarkable job of taking observations and turning them into opportunities and, eventually, innovations,"(Fredman, 2002, p. 55). Thus, observations which have been turned into ideas lead to innovations at brainstorming sessions.

4.2.1.2 Visualizing by Brainstorming:

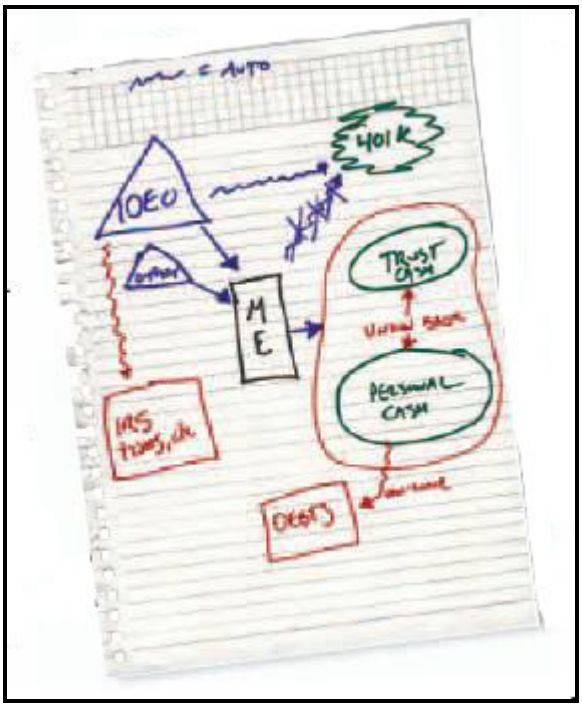


Figure 4.9: Brainstorming at IDEO

Kelly argues in his book, 'The Art of Innovation', that, brainstorming sessions are the most important part of the design process. "Brainstorming is practically a religion at IDEO; Kelley calls it "the idea engine" of the company's culture. These sessions are where IDEO's creativity is most evident, but they're also a manifestation of what can be achieved with the right methodology"(Fredman, 2002, p. 55).

According to Kelly, brainstorming is an art that needs to be practiced often and when performed well can give the team an almost endless amount of good ideas. Brainstorming sessions are usually repeated two or three times in a week by the IDEO

design team. The aim is to generate a full range of ideas in a limited time. Those sessions usually lasts for about one hour according to the level of physical and mental energy.

Starting with a good defined statement of the problem is the origin point in IDEO's brainstorming sessions. Numbering the ideas those are generated during the sessions are also another point to care. According to Kelly, 'numbered lists create goals to motivate participants. You can say, 'Let's try to get to 100 ideas.' Also, lists provide a reference point if you want to jump back and forth between ideas.'

Figure 4.10: Brainstorming Sessions (Newsweek, 2003)

In this step, IDEO uses a method, 'Deep Dive', which is created by the team itself. This method incorporates structured brainstorming sessions which emphasize the creativity of the team and result in a mass of potential ideas. With this method it is intended to identify five main topics such as;

1. Clarifying Objectives
2. Clarifying the Roles
3. Clarifying Tasks And Responsibilities
4. Clarifying Milestones
5. Clarifying the best solutions

For each topic, a method from the Chapter three may reply the needs;

1. Objectives Tree Method & Product Function Analysis
2. Interaction Matrix
3. Task Analysis & Boundary Shifting
4. SWOT & Quality Function Deployment Method
5. Pugh's method & Ranking and Weighting

There are many more methods which are similar to deep dive and used in other fields, however, the first application of this method to product design was done by IDEO. The main aim in this method is to create a new type of powerful creativity tool, resulting in a consultancy able to produce fresh and remarkable results.

Seven main rules dominate during the brainstorming:

RULES for the BRAINSTORMING
1. DEFER JUDGMENT
2. BUILD ON THE IDEAS OF THE OTHERS
3. ENCOURAGE WILD IDEAS
4. GO FOR QUANTITY
5. BE VISUAL
6. STAY FOCUSED ON THE TOPIC
7. ONE CONVERSATION AT A TIME

Table 4.2: Brainstorming at IDEO

1. Defer Judgment: The aim is not to miss any ideas.
2. Build on the Ideas of the Others: The aim is to evaluate ideas by taking the other's views as a reference.
3. Encourage wild Ideas: The aim is to embrace all possible solutions not to miss any good ones.
4. Go for Quantity: The aim is to generate as many useful ideas as possible.

5. Be Visual: The aim is to write down the possible solutions to remember and to discuss them later.
6. Stay Focused on the Topic: The aim is not to call the team's attention on focusing the main subject.
7. One Conversation at a Time: The aim is to take the discussions under discipline.

'Fluency' and 'Flexibility' are the key factors of IDEO brainstorming, where, fluency allows rapid flowing of the ideas and flexibility allows seeing different sides of the problem.

Six surefire ways to kill a brainstorm are defined by the Kelly as;

1. "Let the boss speak first: If the boss gets first crack, then he or she's going to set the agenda and the boundaries, and your brainstormer is immediately limited.

2. Give everybody a turn: Going clockwise around the room may be democratic, but it's not a brainstormer.

3. Ask the experts only: Don't be an "expert" snob. Bring in someone from manufacturing who knows how to build things. Invite a customer service rep with lots of field experience. They may not have the "right" degrees, but they just might have the insight you need.

4. Go off-site: While off-site brainstorming sessions are fine, you want to foster the buzz of creativity so that it blows through your offices as regularly as a breeze at the beach.

5. No silly stuff: It's hard to overestimate what flights of fancy do for a team. They remind everybody that brainstormers aren't like regular work, that anything goes, and that you can have a lot of fun while you solve the problems.

6. Write down everything: Taking notes shifts your focus to the wrong side of your brain. It's like trying to dance and type on your laptop at the same time. Sketch

all you want, doodle to your heart's delight, but leave the note taking to the designated note taker"(Fredman, 2002, p. 57).

Kelley also suggests seven habits for a successful brainstorming:

1. Sharpening the focus
2. Not critiquing emerged ideas
3. Indexing invented ideas
4. Monitoring different stages of 'jumping and building' during brainstorming,
5. Externalizing ideas for others to see
6. Doing mental exercises to 'warm up' the brainstorming group and
7. Getting physical by bringing real material to the brainstorming session or by situating brainstorming physically

Role-playing is the last innovative step of the IDEO that is used during the brainstorming. "Role playing is the practice of group physical and spatial pretend where individuals deliberately assume a character role in a constructed scene with, or without, props.

Figure 4.11: Roleplaying at IDEO

The key differentiator aspects of role playing are:

1. Being 'in the moment' - an individual and group state that enables vivid and focused exploration of the situations and

2. Physicalization - using the entire body to explore generation of ideas that takes "brainstorming" to "body storming." This sort of role playing is similar to the practice of improve theater"(Simsarian, 2003, p. 1012).

4.2.1.3 Evaluating and Refining by Rapid Protoyping:

According to Marion Buchenau from IDEO, "Prototypes are representations of a design made before final artifacts exist. They are created to inform both design process and design decisions. They range from sketches and different kind of models at various levels, 'looks like', 'behaves like', 'works like', to explore and communicate propositions about the design and its context"(Buchenau, 2000, p. 424).

Ilya Prokopoff, head of environmental design for Ideo, defines prototyping as the way of getting the physical early, really early in the design process. "That means we do whatever we can to start understanding what something will be like in the world. We'll cut up a piece of foam in order to understand the size of something and its impact on the space the client will be using it in."

The main aim of prototyping at IDEO is to set an interactive environment for better understanding the problems and deficiencies of the product designed. It is intended to experience "'look and feel' of a product or system that is 'the concrete sensory experience of using an artifact, what the user looks at, feels and hears while using it'"(Buchenau, 2000, p. 424).

Figure 4.12: HUT concept, Design model of concept (Battarbee, 1998, p. 29)

Three IDEO principles of prototyping in this case are:

- Focuse on the issue
- Explore simply, quickly, and then iterate (fail early, learn quickly)

- Model at the lowest appropriate resolution

Figure 4.13: Digital camera interaction prototype (Buchenau, 2000, p. 430)

There are six main rules of prototyping at IDEO;

Rules & Techniques of Prototyping
1. Brainstorming
2. Focus Prototyping
3. Engage the Client
4. Be disciplined
5. Focus
6. Get Agreement

Table 4.3; Prototyping at IDEO

1. Brainstorming: The aim is to sort the unpromising ideas and to focus on the best solutions.
2. Focus Prototyping: The aim is to focus on the key ideas to reach an optimal design solution.
3. Engage the Client: The aim is to involve the users or clients in the process of decision.
4. Be disciplined: The aim is to be strict while selecting the best solution.
5. Focus: The aim is to focus on the output of the solution.
6. Get Agreement: The aim is to take approval from the stakeholders for the application.

The methods those are in reply to prototyping of IDEO from chapter three may be;

1. Physical Models
2. Rapid Prototyping
3. Usability Testing
4. Emphatic Design
5. Testing the Real Environment
6. Taguchi Method
7. MUSIC
8. Probabilistic Design

In this stage, however, the most innovative methods of IDEO, bodystorming, come into being, that is an evaluated version of emphatic modeling and includes testing the real environment. This method is a kind of experiencing the designed product by using the scenarios developed by the team. In this method, usually, an environment is created which resembles to the real use environment of the product. By the help of bodystorming, designers become able to understand the feelings and discomfort of the users that may be arise during the device usage.

Figure 4.14: Bodystorming (Buchenau, 2000, p. 428)

Another innovative method that IDEO team uses during this step is the exploration of unusual situations. "To facilitate the exploration of unusual situations and to open the designers' minds to other customer experiences, they found it helpful to devise and assign specific tasks to each other. They gave each other cards that read, for example: 'pretend that you can't speak English.', 'be hungry, and find something to eat.', 'be friendly and chat to the train staff.' This exercise bridges the gap between real and prototyped experiences. It was a "real setting with real people," but the designers' feelings and behavior were mixed with performance and acting"(Buchenau, 2000, p. 427).

4.2.1.4 Implementing

The aim of the implementation stage for IDEO is to collect the entire employees to create the designed product into the market. In implementation stage, the following rules are valid for IDEO;

1. Tap all resources: The aim is to use all resources to carry out the process.
2. The workforce: The aim is to gather the entire workforce together which is from engineering, sociology, fashion, biomechanics, art therapy, and so on.

At implementation stage the product takes its final shape and prepared for the production and manufacturing. Methods those may reply the needs of this step may be;

1. Concurrent Engineering
2. Performance Measurement
3. Usability Laboratories
4. Hazard Analysis
5. Tolerance Design
6. Assembly Design
7. Standardization and Rationalization

With the conscious of sharing the design knowledge they have, IDEO published a deck to help designers in selecting the right methods during the design process. Fifty one method cards are presented within the 'The Methods Deck' which are divided four main categories such as; Learn, Look, Ask and Try.

Figure 4.15: IDEO Method Cards

Each card within the deck explains a method by a brief story. Of course, this deck does not promise 'how to do' but it intends to help in exploring the new ways of designing.

4.2.2 Medical Device Design at IDEO

IDEO follows the main principles of design approach and process also in medical device design. The firm has its own design group in Palo Alto, California, Silicon Valley, which specially studies on medical devices design.

"As IDEO cofounder Bill Moggridge says, 'If you look at the way technology advances, it almost always sacrifices the user at the cutting edge.' Whether it's on a VCR or a Web-enabled cell phone, 'the most advanced features are kind to electronics but cruel to the user.'"(Hawthorne, 2002, p. 9).

User-centered design has been presented as the key by IDEO while designing medical devices. Medical design group director of IDEO, David Karshmer, emphasizes the growing involvement of user-centered design into medical device design for the past five years. He also points out the importance of human factors researches in this respect.

"Five years ago, device manufacturers tended to focus on feasibility when thinking about product design," says Tad Simons, director of healthcare and life sciences for IDEO (Palo Alto, CA) in a feature. "Now, they're taking a more holistic

view of product design thinking about how the product looks, how it affects work flow, and how healthcare workers and patients use it."

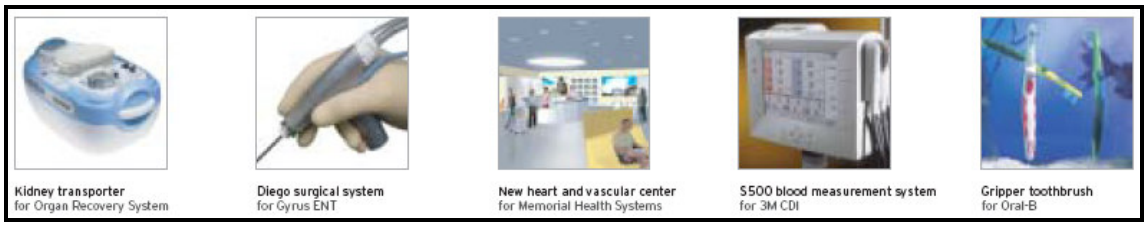


Figure 4.16: Medical device design at IDEO (Metropolis, October 2002, p. 8)

The design logic of IDEO while designing medical devices lies on "looking at the process, at work flow, and asking, 'How can I shape this product to make it easier or faster for the physician to use?'"(Bell, 2003).

The observation stage has been described as the most important stage within medical design by IDEO. In this stage, IDEO works with the human factors specialists for better understanding of use problems. They work with mechanical engineers and ergonomists to get a sense of how the new medical device would work. Also they spend lots of time with the target users, surgeons, nurses, technicians or patients, to understand their needs and habits. They use techniques and methods through understanding the feelings and problems of users, such as direct observation and bodystorming.

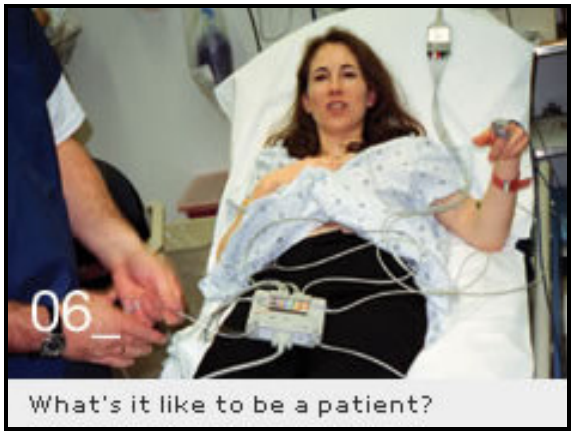


Figure 4.17: Bodystorming for a Medical Device Design Process

"IDEO is at the forefront of a radical shift in the very concept of design, moving from inventing objects to analyzing and reshaping the way environments and customs mold our experiences. At IDEO, designers engage in both the usual brainstorming and

seat-of-the-pants proto-typing—one device used for sinus surgery was mocked up from a marker pen, a film canister and a clothespin—and the sort of field observation Jane Goodall did among the primates of Africa. As CEO Tim Brown puts it, “We think you get nothing from sitting at a computer all day”(Kalins, 2003).

IDEO promise innovational services in medical device design as the other consumer products they have designed. In the light of this innovative approach the firm wins awards nearly in each year. IDEO not only gives good service to customers and users but also shape the future product design.

4.2.3 Homecare

One of the most important areas that IDEO proves itself is the field of home medical equipment design. The firm has four awards on home care equipment in which the innovative designs, user friendly interfaces and ease of use goes to fore.

As a conclusion, the home care devices that IDEO have designed are going to be inspected from the points of the design approach and design priorities.

Figure 4.18: Homecare Devices

4.2.3.1 Humalog/Humulin Insulin Pen for Lilly

1999 Medical Design Excellence Awards Silver Prize

Figure 4.19: Humalog/Humulin Insulin Pen For Lilly (1)

"Because of the need for several insulin injections each day, an easy delivery method can enhance the life of people with diabetes. Eli Lilly saw great potential for a device that allowed users to maintain an active lifestyle by making injections quick and unobtrusive. The result is a simple and safe pen like device that can be carried in a purse or pocket for up to a month."(IDEO).

Since more and more people are suffering from diabetes in each year, design of the insulin injection systems are becoming a very important subject to be dealt with. IDEO have drawn attention to the blanks in the ergonomic and easy to use structure of the existing devices and improved an insulin pen which is the latest version of the innovative injection systems.

Figure 4.20: Humalog/Humulin Insulin Pen for Lilly (2)

The main advantage of the device is the single-unit dose structure since the main thing in the use of insulin injection systems is the amount of the insulin that has been taken in each application. The pen eliminates the need of filling the system for each use and enables several injections just by one syringe.

Another thing to be mentioned about the device is the appearance of the product which gives a high-end product sense and it really does not look like a treatment device.

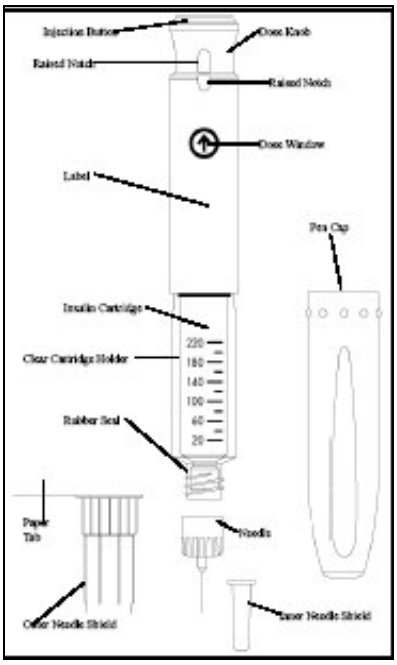


Figure 4.21: Humalog/Humulin insulin pen for Lilly-technical details

IDEO had won a silver prize by Humalog from the Medical Design Excellence Awards in 1999. The juror had commented that the device addresses many conflicting design problems in an inexpensive and unobtrusive manner. They had pointed to the safety controls and the design knowledge of the IDEO about the use process. They soon decided that ‘the developers show they're aware of the broad range of functional impairments that can befall the diabetic, by their ability in combining visual, auditory, and tactile feedback.

4.2.3.2 BodyGem for HealtheTech

2003 IDEA Bronze Prize

Figure 4.22: BodyGem for HealtheTech

"Measuring resting metabolic rate was previously possible only in large, expensive devices found in hospitals and research clinics; now the portable and affordable BodyGem brings this function to the individual through the use of revolutionary oxygen and flow sensor technology"(IDEO).

BodyGem is a metabolism measurement device which measures the resting metabolic rate, oxygen consumption, and the amount of the calories a body burns each day at rest. It meets the basic principles such as portability, lightweight, ease of use and safety by its design.

"The BodyGem began its life as a clinical tool, the brainchild of Healthetech Inc. founder Dr. James Mault. As a cardio-thoracic surgeon at Duke University Hospital, he wanted an easier way to determine how many calories critically ill patients needed while under intensive care. He sought out Morgan Hill-based Abbott Laboratories and biomedical engineer Noel Johnson.

Hospital-based metabolism tests can take hours and cost thousands of dollars. The devices cost $50,000 to make, and the pair figured they could do it less expensively. In 1998, while still working their "day jobs," they hired Palo Alto design firm IDEO to help build a prototype"(Duan, 2001).

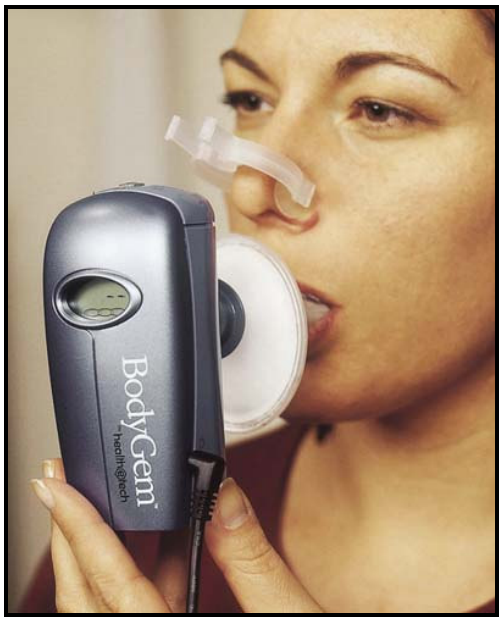


Figure 4.23: BodyGem usage

After then, IDEO developed the concept of the product. “IDEO's human factors experts measured a wide range of face geometries to develop both a mask and a mouthpiece, ensuring proper airflow measuring. The device performs its own internal calibration, and results are displayed immediately. The BodyGem also incorporates an array of special algorithms supporting operation in the uncontrolled environments outside of medical clinics, thus allowing this compact device to be used in homes, fitness centers, and weight-loss clinics. Additionally, after completion of regulatory approval, hospital dietitians and doctors will use the BodyGem to measure the nutritional needs of patients in clinics as well as hospitals”(IDEO).

4.2.3.3 HiRes Auria for Advanced Bionics

2004 IDEA Silver Prize

Figure 4.24; HiRes Auria for Advanced Bionics

"Cochlear implants restore the miracle of hearing to thousands of people who have suffered hearing loss. But no one wants to wear the orthopedic-looking hearing aids that go along with the package, as Advanced Bionics' found out when its own prosthetic appliances started losing market share to a competitor's more attractive product. The firm called upon IDEO to create an improved device that would suit both young and old and create a sharp signature look for the company"(IDEO).

The appearance of the assistive devices has used to be one of the major problems of patients. As stated in Chapter III, home care device users especially elderly people and children tend to use devices those interact with them and they usually build a relationship with their products. The physical appearance of the device therefore becomes an important factor in the name of meaningful relationships. The fact that makes Auria different from the other hearing devices is its attractive design where the system is offering customizable covers that snap on and off to either mask or decorate the device, for both children and adults.

Since one of the most important ingredients of the hearing aids is the quality of the sound; Auria becomes a preferred product with its new low profile, ultra-light headpiece for greater comfort and concealment. Another point about the Auria is the battery life which enables the user to use the device up to nine hours.

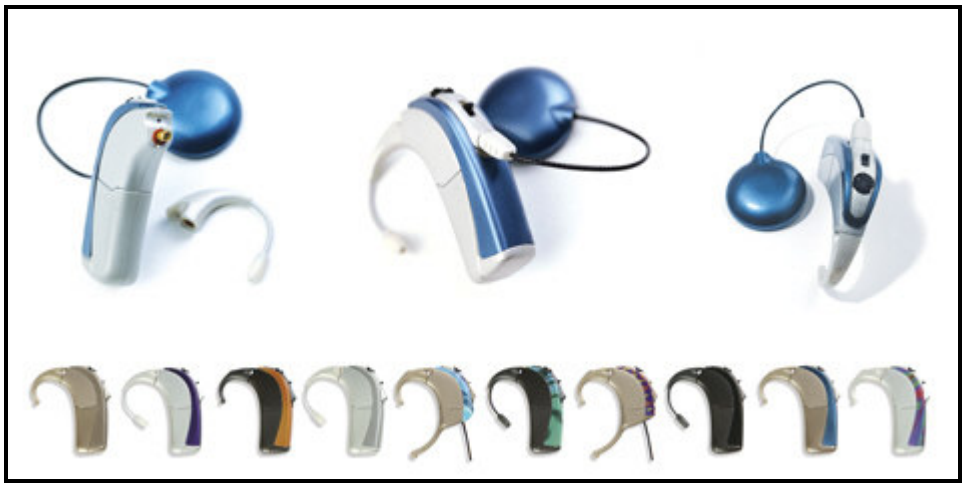


Figure 4.25: Alternative covers for HiRes Auria

Ease of use and user friendly interfaces are also the other impressive features in the design of the device. Ease of use especially important in such devices since they are usually used by the children and elderly and it is usually difficult for such patients to wear full-behind-the-ear processors. Auria also offers an action space interacting by only a switch which controls the programs for different sound environments.

"For teachers and parents of children using the Auria, the Firefly audio earhook, which can fit even the tiniest of ears, gives visual confirmation that the processor is communicating with the implants. For adults who use Auria, a choice of three earhooks provides access to assistive listening devices, cell phones, and consumer electronics. The modularity of the product has allowed Advanced Bionics to minimize the costs of enhancing user options. A better fit with user needs and lifestyles has broadened their market and increased sales. The design has coined an iconic brand image, giving the company a unique position in the market"(IDEO).

4.2.3.4 Breeze CPAP Mask for Puritan Bennett

2004 IDEA Catalyst Honorable Mention

2001 IDEA Silver Prize

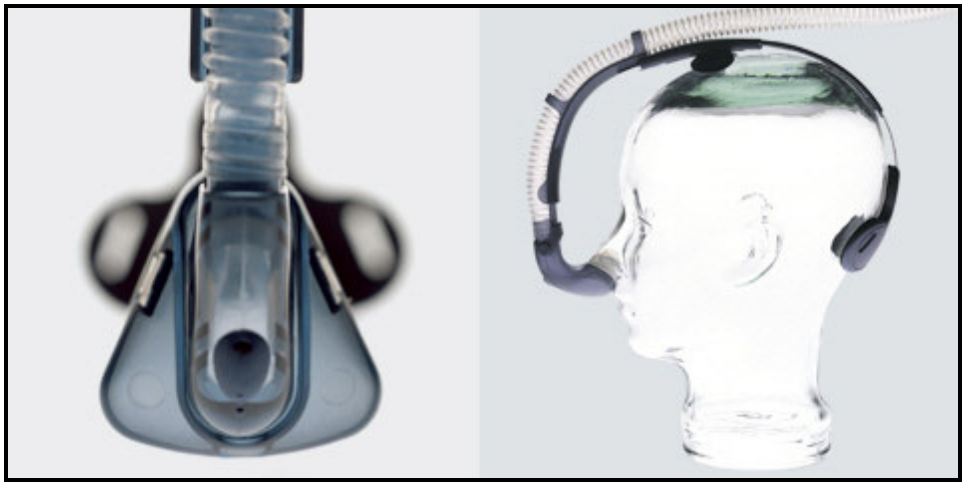


Figure 4.26: Breeze CPAP Mask for Puritan Bennett

"Patients undergo continuous positive airway pressure (CPAP) therapy in the home for sleep apnea or in the hospital for respiratory insufficiency, wearing a mask over the face that allows a ventilator to increase airway pressure. At home, the mask is donned at bedtime and worn while sleeping; in the hospital, doctors use CPAP therapy as an alternative to risky and costly intubation"(IDEO).

There are millions of people who are suffering from sleep apnea. Sleep apnea is a mortal disease which is caused from the muscle relaxation. Muscles at the base of the throat relax while the patient sleeps and they close the airway. This causes the patient not to breathe and it may result by the death of the person. Therefore, a patient who suffers from sleep apnea has to wear a device that keeps the trachea open.

Since the sleep apnea devices are directly applied to human body the ergonomic design appears as the major principle of the design.

Dr. Craig Lawrence explains the design process of Breeze CPAP Mask as; "IDEO worked closely with a medical device manufacturer to develop a product designed to help people with sleep apnea. Several products existed on the market, but all shared a common flaw: They were uncomfortable to wear while sleeping, and many sufferers refused to use them. IDEO set out to develop a product that exceeded the performance of existing products on the market, and that would let a user sleep comfortably. One concept that quickly emerged was to mount the air tube over the

user's head. This idea seemed attractive since it addressed a number of complaints from users. It could locate the tube in a predictable place, keep it from moving around as the user shifted during sleep, and it relieved the weight of the tube, preventing it from pulling at the mask. A series of head-mounted concepts were generated and quickly prototyped at the engineers' desks using commonly found objects and a little creativity. Engineers put prototypes together using the lining of a bicycle helmet, stereo headphones, and pieces of hand-cut plastic in order to try out different ideas. They took them home and slept with them on, waking up to modify them as they encountered problems. These prototypes weren't attractive; however, they did the job and allowed the team to focus in on a winning solution. The final product incorporated a number of concepts from the various prototypes, including a unique cantilever design allowing it to accommodate various head sizes and shapes. The final product was beautiful, but it was a beauty that came from humble beginnings."

4.2.3.5 Health Buddy for Health Hero Network

1999 MDEA Silver

2000 Universal Design

2001 DMAA Best Enabling Technology

2001 ATSP & HIMSS Best Telehealth Vendor

Figure 4.27: Health Buddy for Health Hero Network

"Health Hero Network's system lets health care providers give better care and improve patient comfort by allowing patients to stay connected to their doctors from home. At the center of the system is the Health Buddy, a small tabletop device that asks the patient a series of questions at periodic intervals about such topics as how they feel,

their eating habits, and their medication. The answers are sent to a service center and accessed by a doctor using a web browser to track progress and detect potential problems"(IDEO).

Health Buddy is one of the most important examples of the telemedicine which is defined as the future trend for medicine by Food and Drug Administration. Telemedicine is especially important for patients who suffer from chronic diseases such as asthma and diabetes. These patients may need to monitor their conditions in each hour of the day. Therefore health management is very important for such people. Telemedicine is one of the most promising fields through health management.

What makes the Health Buddy so successful is the design approach which combines the telemedicine technology and user friendly interface. By the help of this device patients are able to transmit their conditions to their doctors and receive information about what they should do. "At periodic intervals the system asks patients a series of questions about their medication, state of well-being, and eating habits and then sends it to a service center for evaluation. The initial target population for the Health Buddy includes patients with heart failure, Parkinson's disease, diabetes, and advanced-stage renal failure"(MDEA). A database collects each patient's records which are very important in the treatment of the chronic diseases.

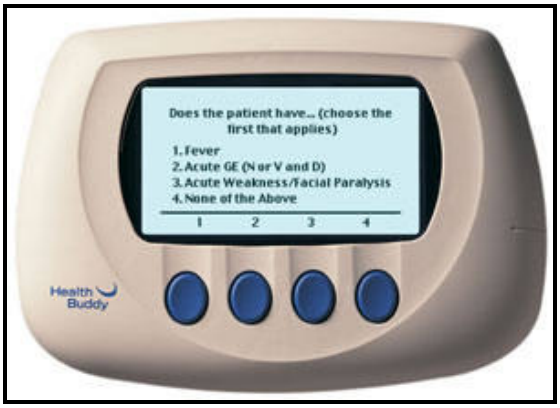


Figure 4.28: Health Buddy-front view

Health Body is also very easy to use since it has four knobs to answer the standardized questions comes from doctor. A patient is able to program and send information by just using these buttons.

Figure 4.29: Health Buddy

4.2.4 Concepts

Figure 4.30: Cd Cover & IDEO Cruose

Figure 4.31: Pepsi Pet

Figure 4.32: Leap for Steelcase Office Chair

Figure 4.33: LifePort Kidney Transporter, 2004 MDEA Gold, 2004 IDEA Silver

Figure 4.34: Ear Ring & The Sports Watch

Figure 4.35: Technojewelry, Concept for wearable technology

Figure 4.36: Interactive Radio Concepts, Digital radio design exploration

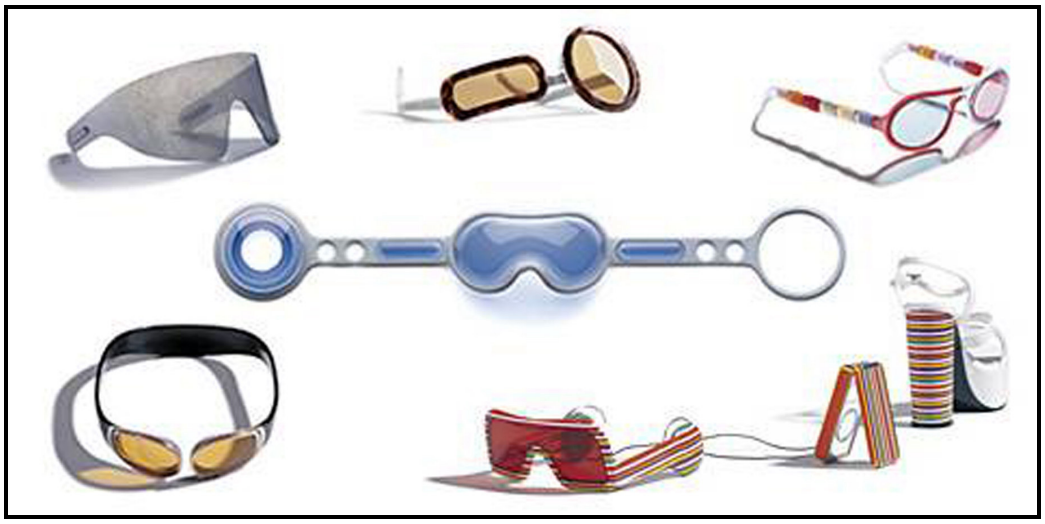


Figure 4.37: Collective Vision-Exploration in Materials for Eyewear

Figure 4.38: Mobile home and business multimedia PC concepts

Figure 4.39: Breakfast concepts-kitchen appliance exploration

Figure 4.40: Identity Card Exploration-Conceptual Business Cards

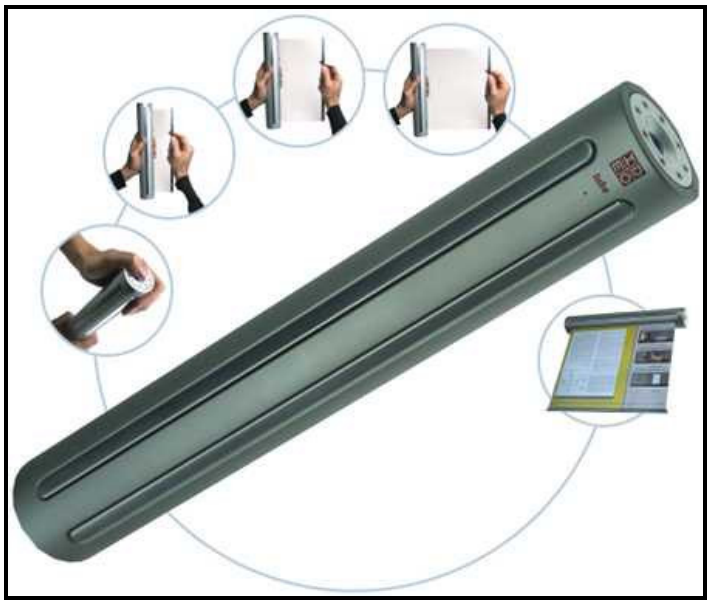


Figure 4.41: On A Roll-Laptop

Figure 4.42: Instant I.D & the Golf Buddy

Figure 4.43: Thin Is In

IDEO continues to design innovative products with innovative approaches and methods. IDEO is deep into state-of-the-art technology, says David Kelley CEO of IDEO. And he adds; “IDEO recently launched Project 2010, a six-month program to evaluate current trends in technology and visualize products 10 years out. Based on a continued evolution of these technologies, a big "if" to be sure, IDEO designed products for work, entertainment, medicine, and sports. Not only are they cool, they are believable. And you will want them. Science-fiction writer Arthur C. Clark envisioned geostationary satellites decades before rockets blasted them into space. Here's another look into the future”(Nussbaum, 2004).

CHAPTER V

CONCLUSION

With this research presented in this thesis, it is tried to add value to the practice of product design and design methods from the point of medical device design.

Integrating product design into the design process of medical devices is one of the most important advantages of the firms in medical market. However there is still lack of use of product design in medical market just as lack of use of design methods in medical device design process. Although some firms understand the impact of 'good design' in increasing the rates of sales, many more of them are still unconcerned of it. In that way or another, it is obvious that, product design has a great effect on the design of new generation medical devices and therefore has to be carefully inspected.

Medical device design and development is, at this rate, going to be one of the most important fields of product design. Future trends are pointing the unimpeded rise of the telemedicine and the design for home environment. This intention to home care and telemedicine is caused from several reasons such as;

- Needs of the patients for more acquaintance environment during their treatment.
- Fees of the hospital treatment which is getting more and more expensive for patients who need periodical care.
- Rise in the number of patients which caused long queues in hospitals.

At this point a great mission is loaded to product design where, one of the most important parts of the job is done by product designers. Since the users of home care devices are untrained people, the attention that must be paid in the design of such devices becomes more and more important. Traditional design approaches, which are once put into practice by doctors, technical people or engineers, become insufficient in the changing conditions of the healthcare. The main subject for better design of medical devices, therefore, lies in recognizing the need for new methods and approaches in product design. These methods may not only solve the problems caused from new

healthcare vision but they may also help designer in creating new ways of innovative usages of medical devices.

The reasons of need for new approaches in the design activity of medical devices can be arranged in order as;

- Users of medical devices alter from untrained patients to skilled technical staff.
- Users of medical devices are much more aware of 'good design'.
- Technological development drives the medical market.
- Capturing the latest trends, as soon as possible, is the key to be alive in medical device market.

Product design with design methods may have great benefits if it is integrated into medical devices. It is obvious that such integration will improve the customer satisfaction and by the help of better designed medical devices, better treatment of patients with minimum error risks may be possible. Product design also has great advantages from the point of manufacturers. Medical devices which are designed with better user-machine interfaces and emotional approaches are likely to increase the sales of manufacturers.

Selection of suitable methods for the design of medical devices, however, quite difficult, especially, for less experienced designers. A designer has to have the knowledge of design methods before starting the design process to minimize the time needed. This is especially important in medical device design, where, medical market has a rapidly evolving structure. At this point, the most useful tools to be benefited are the new product design methods, where, they have the capacity of solving the problems of medical device design. The most important thing in selecting suitable methods for healthcare field, however, is to put the 'user' at the center of the design process, where, there are very small amount of companies that practice user-centered design. Use of human factors and user centered design principles in each step of the design process is the distinguisher side of the medical device design from the other consumer products, since most of those devices are directly applied to human body.

Another point to consider, while selecting suitable methods, is the multidisciplinary structure of the medical device design. It is essential for a product

designer to work in coordinate with other professionals such as doctors, human factors specialists, engineers and so on, during the design process of medical devices. The methods those are going to be selected, therefore, have to be the ability of ensuring right conditions of work between these disciplines.

In this sense, fifty methods from the literature were proposed in this thesis. The selection of those product design methods were founded on the basic principles of human factors and user centered design principles.

REFERENCES

Adams, J. A., *Human factors engineering*, New York: McMillan Publishing, 1989

Alexander, C., 15th printing, *Notes On The Synthesis Of Form*, Harvard Publications, 1999

Allen, A., Business Planning & Technology Development, Benchmarking Medical Design, http://www.devicelink.com/, May/June 2001

Allen, B. E., Caudill, C. D., Hunter, J. S., Howard, R. A., Magee, C. L., Ostrach, S., Rouse, W. B., *Approaches To Improve Engineering Design*, The National Academies Press, 2001

Arcarese, J. S., "Report on Home Use Medical Device Meetings", *The Food and Drug Law Institute*, June 6 & 7, 2002

Aspden, P., *Medical Innovation In The Changing Healthcare Marketplace*, Conference Summary, Institute of Medicine, National Research Council, National Academy Press, 2002

Battarbee, K. and Mattelmäki, T., "Meaningful Product Relationships", University of Art and Design Helsinki, Finland, *Design and Emotion Conference*, Loughborough, England, 1-3 July 2002

Bayazıt, N., *Endüstri Ürünlerinde Ve Mimarlıkta Tasarlama Metodlarına Giriş*, Literatür Yayınları, 1994

Bell, S. L., Medical Device Design: The State of the Art, Medical Device Link, http://www.devicelink.com/mddi/archive/03/02/001.html, 2003

Bras, B. A. and Mistree, F., "Designing Design Processes in Decision-Based Concurrent Engineering", *SAE Transactions Journal of Materials & Manufacturing*, Vol:100, 1991

Bryce, G. R., "Why ergonomics? (Significance Of Ergonomics In Designing Industrial Equipment)", *Plastics Engineering*, Vol:55, May 1999

Buchenau, M., Symposium on Designing Interactive Systems 2000, ACM Press, Brooklyn, NY, August 2000

Burlington, B. D., Human Factors and the FDA's Goals: Improved Medical Device Design, Center for Devices and Radiological Health Food and Drug Administration, 1996, http://www.fda.gov/cdrh/humanfactors.html

Cartier, C., "From Home To Hospital And Back Again: Economic Restructuring, End Of Life, And The Gendered Problems Of Place-Switching Health Services", *Social Science&Medicine*, Volume 56, Issue 11, June 2003

Chun-Heng, H., "Some Phenomena Of Problem Decomposition Strategy For Design Thinking: Differences Between Novices And Expert", *Design Studies*, Vol:22, No 1 , 2001

Committee on Engineering Design Theory and Methodology, "Improving Engineering Design", National Academy Press, Washington, D.C., 1991

Constas, I. and Papadopoulos, D., *Interface-Me: Pursuing Sociability Through Personal Devices*, Springer-Verlag London Ltd, Personal and Ubiquitous Computing, 2001

Corlett, E. N. And Bishop, R. P, "A Technique for Measuring Postural Discomfort", *Ergonomics*, V.9, 1976

Cross, N., "A History of Design Methods, Design Methodology and Relationships With Science", *Series D: Behavioral and Social Sciences*-Vol:71, Kluwer Academic Publishers , 1993

Cross, N., *Engineering Design Methods*, John Wiley & Sons Publications, Third Edition, 2000

Cross, N. & Kruger, C., *Modeling Cognitive Strategies in Creative Design, Computational and Cognitive Models of Creative Design V*, University of Sydney, Australia, 2001

Dain, S., "The Heart Surgery Forum, Normal Accidents: Human Error and Medical Equipment Design", *MD, FRCPC*, Vol:5, Issue:3, 2002

Dean, A., IDEO on Digital Design Tools, http://www.core77.com/reactor/archive.html

Department Of Health And The Design Council, Design for Patient Safety, A System-Wide Design-Led Approach to Tackling Patient Safety in the Nhs, October 2003, http://www.doh.gov.uk /designforpatientsafety.html

"Design Control Guidance for Medical Device Manufacturers", Draft, March 1 1996, This Guidance Relates To FDA 21 CFR 820.30 And Sub clause 4.4 Of ISO 9001 , March 1996

"Design Control Guidance for Medical Device Manufacturers", FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001, March 11 1997

Design Studies 183X: Design Culture, Lifestyle: IDEO, Spring 2004

Dixon, J. R., "Knowledge-based Systems for Design", *Journal of Mechanical Design*, Vol:117, June 1995

Dorst, K., *Describing Design: A Comparison of Paradigms*, PhD thesis, Delft University of Technology: Delft, the Netherlands, 1997

Drake, C., "Human factors: A vital component in product development and launch", *International Journal of Medical Marketing*, Vol. 3, Henry Stewart Publications, pg.9, June 2002

Dreyfus, H.L., *What Computers Still Can't Do*, MIT Press, Cambridge MA., 1992

Duan, M., **"**New device helps tailor calorie intake to match metabolism", *Business Journal*, November 16, 2001

Eekelman, K. B., *New Medical Devices, Invention Development And Use*, National Academy Press, 1988

Ekberg, J., Definitions of Usability, 2000, www.stakes.fi/include/map_text.html

Ensuring a Safe Device-User Interface, FDA Device User Programs and Systems Analysis, http://www.fda.gov/cdrh/humanfactors.html

Forlizzi, J., Hirsch, T., Hyder, E., Goetz, J. "Designing Pleasurable Technology for Elders", *International Conference on Inclusive Design and Communication*s, London, England, April 2001

Fredman, C., The IDEO Difference, Hemispheres-the Magazine of United Airlines, August 2002

Fries, R. C., *Reliable Design of Medical Devices*, Ohmeda Inc. , 1997

Fries, R. C., *Handbook Of Medical Device Design*, Marcel Dekker Inc. , 2001

Gelijns, A. C., *Technological Innovation: Comparing Development of Drugs, Devices and Procedures in Medicine*, National Academy Press, 1989

Gero, J. S. and Neill, T. M., An approach to the analysis of design protocols, http://www.arch.usyd.edu.au/~john/publications/1997.html, 1997

Goodenow, R., Promoting Safety in Medical Device Use, June, 2003, http://www.fda.gov/cdrh/humanfactors/whatis.html

Hanna, K. E., Manning Frederick J., Bouxsein Peter, and Pope Andrew, *Innovation and Invention in Medical Devices*, Workshop Summary, National Academy Press, 2001

Hawthorne, C., IDEO's Design Cure, Metropolis, October 2002

HCT Workshop -- Societal Significant Issues in Home and Self-Care, 1996, http://www.eng.mu.edu/wintersj/HCTWorkshop/HCT_social-issues.htm

Heinzelman, B., "Human factors help engineer better medical devices, *Design News*, June 5, 2000

Hilston, J., Post Gazette, http://www.stetten.com

http://www.fda.gov/cdrh/humfac/doit.html

http://www.humanfactorsmd.com/hfandmedicine_what.html

http://medicaldesignawards.com

Human Factors MD, 2004

Hunziker, J. R., Jones, T. O., *Product Liability and Innovation-Managing Risk In an Uncertain Environment*, National Academy Press, 1994

IDEO official web page, http://www.ideo.com

Jääskö, V. and Mattelmäki. T., "Observing and Probing", In Proceedings of *DPPI, 2003 Conference*

Jones, J. C., 2nd Edition, *Design Methods*, Van Nostrand Reinhold Publications, 1992

Kalins, D., "Design Gets Real (cover story)", *Newsweek*, October 27, 2003

Kelley, T., 2001, The Art of Innovation: Lessons in Creativity from IDEO, America's Leading Design Firm, New York: Doubleday, http://www.theartofinnovation.com

Kirton, M. J., *Adaptors and Innovators, Styles of Creativity and Problem Solving*, Routledge, London, 1994

Klatzky, L. R., Kober, N., Mavor, A., *Safe, Comfortable, And Easy to Use-Improving the Usability of Home Medical Devices*, Report of A Workshop, Committee on Human Factors, National Academy Press, 1996

Lawrence, C., IDEO, Right - Rapid – Rough, Academy Sharing Knowledge, http://appl.nasa.gov/ask/index.html

Lewis, C., "Emerging Trends in Medical Device Technology: Home Is Where the Heart Monitor Is", *FDA Consumer magazine,* May-June 2001

Linden, B., Nicola, L., Sue, R. And Fraser, R., "The Exploration Of Solution Options In Design: A 'Naturalistic Decision Making' Perspective", *5th Design Thinking Research Symposium*, Delft University Of Technology, The Netherlands, 18-20 December 2001

Lopez-Mesa, B., *Selection and Use of Engineering Design Methods Using Creative Problem Solving*, Licentiate Thesis, Department of Applied Physics and Engineering, 2003

McCormick, E. J. & Sanders, M. S., *Human factors in engineering and design*, New York, McGraw-Hill, 1982

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, Guidance for Industry and FDA Premarket and Design Control Reviewers, U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health, July 18, 2000, http://www.fda.gov/cdrh/humanfactors.html

Michael Fioritto's Weblog, May 14 2004, http://fioritto.us/weblog/

Nussbaum, B., Welcome to 2010, special report, BusinessWeek Online, 2000, http://www.businessweek.com:/2000/00_10/design2.htm

Nussbaum, B., The Power Of Design, 2004, http://www.businessweek.com/magazine/content/04_20/b3883001_mz001.htm

Ozog, H., "Risk Management in Medical Device Design", *Journal of Sysytem Safety*, Vol:21, No: 3, 1985

Papanek, V., *Design For The Real World*, Granada Publishing, 1974

Popov, L. S., "Architecture as Social Design: The Social Nature of Design Objects and the Implications for the Profession", *The Journal Of Design Research*, Vol.2, Issue 1, 2002

"Product Design Specification, BME 301-Portable Patient Training Device for Lung Cancer Treatment", Team Members: Thomas Chia–Leader, Jason Ethington–BWIG, Brent Geiger–BSAC, Kawai Chan–Communicator, Advisor: Willis Tompkins, Ph.D., April 30th, 2004

Roozenburg, N.F.M. & Eekels, J., *Product Design: Fundamentals and Methods*, John Wiley & Sons Publications, 1995

Sawyer, D., Do it by design, An Introduction to Human Factors in Medical Devices, Office of Health and Industry Programs, U.S. Department of Health and Human Services Public Health Service Food and Drug Administration Center for Devices and Radiological Health, 1996

Serpiello, N. J., "IDEO, Collage as a Human Centered Research Method for Product Design", *Consumer Product News*, winter 2002

Simon, H.A., *Sciences of the Artificial*, the MIT Press, Cambrigde MA., 1996, 3rd Edition

Simsarian, K. T., IDEO, Take it to the Next Stage: The Roles of Role Playing in the Design Process, San Francisco, CHI 2003: NEW HORIZONS

Stephen, B. W., "Medical Design, High-Stakes Design", *FIDSA, Innovation Summer,* 2003

Stoll, W. H., *Product Design Methods and Practices*, Marcel Dekker, Inc., 1999

The Wall Street Journal, August 15, 2002

Tischler, L. , Six Surefire Ways to Kill a Brainstorm, Web-Exclusives, http://www.fastcompany.com/articles/2001/03/kelley.html, March 2001

Ulrich, T. K. & Krishnan, V., "Product Development Decisions: A View of the Literature", *Management Science*, Vol:47, No:1, January 2001

Vadim, K., Executive summary, A World Leading New Product Design Company, the Art of Innovation, Tom Kelley with Jonathan Littman, 2001, http://www.geocities.com/vadimkot_business

Warren, S., Ph.D. and Craft, R. L., Designing Smart Health Care Technology into the Home of the Future, M.S., Sandia National Laboratories, John T. Bosma, Potomac Institute for Policy Studies, 1999, http://www.eng.mu.edu/wintersj/HCTWorkshop/HCT-pos_SW-futurehome.htm

Wilcox, S. B., Applying Universal Design to Medical Devices, Medical Device & Diagnostic Industry, Copyright ©2003 http://www.devicelink.com/mddi/archive/03/01/006.html

William, A. H., Donald, E. M., and Harvey, R., Future Trends in Medical Device Technology: Results of an Expert Survey, Center for Devices and Radiological Health, http://www.fda.gov/cdrh/ost/trends/toc.html, April 8, 1998

Wilson, B., A Commentary with Analysis, IDEO and *The Art of Innovation:* Brainstorming Techniques for Teams, http://www.wilsonstrategies.com

Winogard, T., *Bringing Design to Software*, ACM Press, 1996

Yao, J., Ryan, S., and Steve, W. "A Wearable Standards-Based Point-of-Care System for Home Use," *3rd Joint EMBS-BMES Conf.* Sept. 2003, Cancun, Mexico

Zaccai, G., Co-Founder Of The International Design Consultancy, An Interview with Gianfranco Zaccai, Design Continuum, http://www.dcontinuum.com/, August 17, 2001