HELSINKI UNIVERSITY OF TECHNOLOGY
Department of Electrical and Communications Engineering

Petteri Mäki

Improving user-centered design with KESSU process model and method definition

A case study at Datex-Ohmeda

Master's thesis

January 27, 2003

Supervisor: Professor Marko Nieminen

Instructor: M.Sc. Päivi Roiha

HELSINKI UNIVERSITY OF TECHNOLOGY THESIS' ABSTRACT

Author and title:
Petteri Mäki

Improving user-centered design with KESSU process model and method definition - a case study at Datex-Ohmeda

Date: Jan 27, 2003 **Number of pages:** 84

Department:
Department of Electrical and Communications Engineering

Professorship:
T-121 Usability research

Supervisor:
Professor Marko Nieminen

Instructor:
M.Sc. Päivi Roiha

Datex-Ohmeda is one of the world's leading medical device manufacturers. The company has had usability activities since the 1980's, and today the level of usability work and the usability process are quite high.

This thesis work describes an enhanced user-centered design process for Datex-Ohmeda and the process of creating it. The new process model is based on the results of KESSU research project. The new model includes a description of the methods used in various stages of product development, what should be researched at each stage and how the design phases relate to each other. The regulations addressing medical device development are also discussed and taken into account while creating the new process model.

The theory part of this thesis presents 17 usability engineering methods and four existing user-centered design process models. In addition the basic theories of usability as well as special aspects of usability in medical field are discussed.

The new user-centered design process was developed by studying first the current state of the company's usability activities. The results of the research presented in this thesis combine the theoretical descriptions of the currently used usability engineering methods and the new KESSU-research based process model. One of the biggest changes to the current working practices was the user task design phase. The new phase was also tested in practice and found to be useful.

Keywords:
User-centered design, process model, KESSU research project, usability engineering method

TEKNILLINEN KORKEAKOULU DIPLOMITYÖN TIIVISTELMÄ

Tekijä ja työn nimi:
Petteri Mäki

Käytettävyysprosessin kehittäminen KESSU-mallin ja metodologian määrityksen avulla – tutkimus Datex-Ohmedassa

Päiväys: 27. tammikuuta 2003 **Sivumäärä:** 84

Osasto:
Sähkö- ja tietoliikennetekniikan osasto

Professuuri:
T-121 Käyttöliittymät ja käytettävyys

Työn valvoja:
Professori Marko Nieminen

Työn ohjaaja:
DI Päivi Roiha

Datex-Ohmeda on maailman johtavia lääketieteellisen laitteiston valmistajia. Sillä on ollut käytettävyyden alan toimintaa aina 1980-luvulta asti, ja menetelmät sekä käytettävyyden prosessi ovat nykyisellään varsin kehittyneet.

Tämä diplomityö kuvaa Datex-Ohmedalle kehitetyn parannetun käyttäjäkeskeisen tuotekehityksen prosessin, sekä sen kehittämisen vaiheet. Uusi prosessimalli pohjautuu KESSU-tutkimusprojektin tuloksiin. Malli sisältää kuvauksen siitä, mitä menetelmiä tulisi käyttää missäkin tuotekehityksen vaiheessa, millaisia asioita tulisi eri vaiheissa selvittää sekä tiedon siitä, kuinka vaiheet suhtautuvat toisiinsa. Myös lääketieteellisen alan tuotekehitystä ohjaavat säädökset on huomioitu uutta prosessia suunnitellessa.

Työn teoriaosa esittelee 17 käytettävyystyön menetelmää sekä neljä jo olemassa olevaa käyttäjäkeskeisen tuotekehityksen prosessimallia. Lisäksi esitellään lääketieteellisen alan käytettävyyteen liittyviä erityispiirteitä sekä käytettävyyden teoriaa.

Uusi käytettävyyden prosessi on kehitetty tutkimalla ensin yrityksen käytettävyystyön nykytila. Tutkimuksen tulokset yhdistävät yrityksen nykyisin käyttämän metodiikan teoreettiset kuvaukset sekä KESSU-prosessimallin pohjalta kehitetyn uuden prosessimallin. Eräs uuden prosessimallin suurimmista muutoksista nykytilaan, käyttäjän tehtävien suunnitteluvaihe, testattiin myös käytännössä ja todettiin toimivaksi.

Avainsanat:
Käyttäjäkeskeinen tuotekehitys, prosessimalli, KESSU-tutkimus, käytettävyystyön menetelmä

Acknowledgements

This thesis was written as a full-time work for Datex-Ohmeda. I wish to thank the usability team leader Virpi Nummijoki for supporting me in my research, for acquainting me with the company and its practices and for always having time to answer my questions.

I also wish to thank my supervisor, Marko Nieminen for providing me valuable ideas and suggestions, and my instructor Päivi Roiha for organizing the research with me and giving important and practical advice.

Special thanks for Sirpa Riihiaho, who commented my work very thoroughly and gave me lots of comments and ideas on structuring and sharpening my writing. I'm also grateful to Timo Jokela, who provided me with important material to work with.

I have received lots of support, advice and inspiration from my fellow usability students. I thank you all and wish everyone strength to your own research. You know who you are.

Last, but not least, I wish to thank my family and friends for support, understanding and for just being there. I couldn't have made it this far without you.

Helsinki, 27.1.2003 Petteri Mäki

Contents

Abbreviations

AAMI	*Association for the Advancement of Medical Instrumentation*. U.S. organization devoted to increasing the understanding and beneficial use of medical instrumentation.
ANSI	*American National Standards Institute*. A non-profit organization that administers and coordinates the U.S. voluntary standardization and conformity assessment system.
DHF	*Design History File*. A collection of documents created during a product development process.
FDA	*Food and Drug Administration*. A regulatory organization of U.S. government that monitors food and medical field product development and safety.
HCD	*Human-Centered Design*. A product design ideology that emphasizes the role of the user in the center of the design efforts.
HCI	*Human-Computer Interaction*. A discipline concerned with the design, evaluation and implementation of interactive computing systems for human use and with the study of major phenomena surrounding them.
IEC	*International Electrotechnical Commission*. A global organization that produces standards for electrical, electronic and related technologies.
ISO	*International Organization for Standardization*. A network of regional standardization organizations that produces standards for technical field.
KESSU	A research project on user-centered design, which was conducted by researchers from Oulu University and Helsinki University of Technology in association with Finnish companies.
SME	*Subject Matter Expert*. A person who is knowledgeable of the researched task and context.
UCA	*Usability Capability Assessment*. A way to evaluate the current state of usability efforts inside a company.
UCD	*User-Centered Design*. A synonym for HCD.
UI	*User Interface*. The part of a system that interacts with the user.
UIH	*User Interface Handbook*. A guideline at Datex-Ohmeda, which states how the user interface should look like and function.
UML	*Unified Markup Language*. A general-purpose notational language for specifying and visualizing complex software, especially large object-oriented projects.
UPA	*Usability Performance Assessment*. Usability capability assessment method developed in KESSU project
VTT	*Valtion Tieteellinen Tutkimuskeskus*. An independent Finnish research institute that carries out technical and technoeconomical research and development work.

1 Introduction

This thesis presents a process of improving an existing user-centered design (UCD) process. It involves a description of a research, which aimed to understand the current situation, the new model and its development process description, and a small study to validate the most notable changes proposed by the new model. In shorter terms this thesis describes the development process of a process model.

The process model used as a reference for the new model is called KESSU UCD process model. It is the newest of the usability process models, and offers the best opportunities for usability capability assessments. The KESSU model has been developed in a close relation with business world, and therefore seems like a good and already tested choice.

This thesis was written during summer and autumn 2002 for Datex-Ohmeda. Datex-Ohmeda is a medical device manufacturing company, whose main products are patient monitoring systems and anesthesia machines. Datex-Ohmeda uses the results presented in this thesis to improve and harmonize its current usability efforts. The clarification of methods used in usability engineering work is especially important to the company along with the fact that with the new process model based on KESSU the usability capability assessments will be more effective.

From a scientific point of view this thesis can be seen as a new iteration round for the KESSU model, although the process model is only a part of the total user-centered design process proposed by this thesis.

The most important addition to the existing KESSU model is the consideration of methods in addition to the theoretical process model. The combination of methods and process model is essential to any company that plans to do any usability activities, and without the backbone of usability engineering methods the process models are usually more or less inefficient and doesn’t help in actual usability work.

The purpose of this first, introductory chapter is to present the objectives, scope and structure of this work.

1.1 Objectives of the thesis

The main thing to be done in this work is **a UCD process description,** which combines the descriptions of:

1. The needed **UCD process model** and
2. the use of usability engineering **methods**.

The company is interested in **clarifying the current use of the usability engineering methods.** Therefore this thesis describes only those usability methods that are already in use iat Datex-Ohmeda. This posed no problem to the literature research or to the future process model, because the variety of methods in use in the company was large enough.

Implementing the KESSU process model was chosen for two reasons. First, it helps the usability capability assessment inside the company by providing a good reference model that can be used as the basis for the evaluation process. Second, it helps to improve the quality of the usability process by providing a modern and tested process model. The usability capability assessments require that the model remains as close to the original KESSU model as possible to ease the assessment procedure. The quality of the usability process is improved by **finding the most problematic aspects of the current process** and concentrating on improving them.

The objectives of this thesis are summarized in figure 1 below.

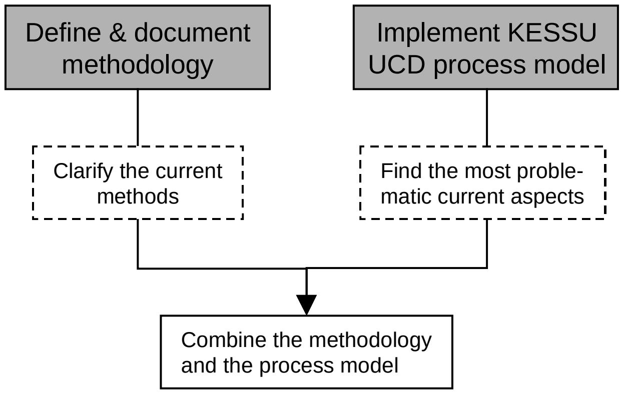

Figure 1: The objectives of this thesis

In more detail the objectives require that a clear description of the phases of design, the methods used in user-centered design and a guideline on documentation are written. Most of the method descriptions will be done in the theory part of this thesis, but the notes on implementing the methods to Datex-Ohmeda will be found in the practical part. The guideline on documenting the usability engineering efforts and results is presented as part of the whole user-centered design process model by describing the deliverables of every phase of the model.

In summary, the **objective** of this thesis is to create a new user-centered design process description for Datex-Ohmeda, which:

- Identifies and describes all the necessary **phases of design**;
- Describes the use of usability engineering **methods** within each phase;
- Gives an understanding of what should be **documented** in each phase;
- Enables the **easy use of usability capability assessments** in the future.

1.2 Scope of the thesis

The **scope** and restrictions are addressed in the following. This thesis is intended to give a general view of the user-centered design process adapted to the needs of a medical device manufacturer. Thus, as the scope of the thesis is wide, it cannot go into detail in all things. Therefore this work does **not** describe the following things:

- Detailed descriptions of every usability engineering method used;
- Document templates to the phase deliverables;
- How the user-centered design process model is integrated to the rest of the product development.
- How the results of this thesis are realized in the company

A thorough analysis of every aspect of every usability engineering method mentioned is not possible within the scope of this work. Thus, a general description of the method as well as the most important issues concerning the use of the method in Datex-Ohmeda are presented.

The deliverables of every phase are described in general level. It is assumed that it is enough to describe the contents of every deliverable, not necessarily going into more detailed level, such as document templates. The deliverable templates can be developed later inside the company.

Companies usually have more than one process model to cover the different aspects of product development. The different models cover the whole design activity from the aspect of a single profession, for example mechanical or electrical engineering. This thesis does not concern any other process models than user-centered design or the integration of the new process model with the existing process models of other principles.

1.3 Structure of the research

The two parts of the research behind this thesis, the new UCD process model and the method descriptions, were created in opposite ways. A literature study was used as the basis for the new process model creation. After the literature research the model prototype was created and adapted to Datex-Ohmeda.

The methods study was conducted the other way around. A study on the company's current methods was done first to find out the methods that are currently known and used. After the inquiry the theoretical descriptions were written according to the literature sources, and finally some comments were added on the adaptation of the theories to Datex-Ohmeda.

The two strands of research were combined by inserting the methods to the process model. This combined model went through a few iteration rounds before its final form. The final form can be seen in chapter 6.

1.4 Structure of this thesis

This thesis presents a UCD process model and methods for medical device development. It has two parts: theory and practice. The **theory part** consists of the ideas of others, it's been created on the basis of a literature study. The **practical part** consists of a description of the research methods as well as the results of the research conducted.

1.4.1 Theory part

Chapter 1 presents the topic of this thesis, its scope and a short description of what was done to create this work.

Chapter 2 is a basic introduction to usability. It presents the core concepts of usability engineering profession and gives background to the study by giving short descriptions of KESSU research project and the current state of usability in the medical device manufacturing field.

Chapter 3 includes theories on different kinds of UCD process models. Three general models and two process models from medical standards are presented and discussed.

Chapter 4 describes usability engineering methods. The method descriptions of this chapter are used as the official Datex-Ohmeda usability methods with a few modifications introduced with the new process model in chapter 6.

1.4.2 Practical part

Chapter 5 presents the research on the current state of usability at Datex-Ohmeda as well as its results: the UCD process and methods used in the company at the time this thesis was written. The process model is described in some detail, and methods currently used are discussed. The main areas that are in need to be improved are described.

Chapter 6 presents the main result of this thesis: the company's new UCD process model and the methods associated with each of the phases. The iterative process of developing the new model is also described.

Chapter 7 explains what was done to validate the new UCD process model.

Chapter 8 includes the discussion on the work done and thoughts on the future of the model created.

2 Background

This section includes a basic introduction to usability and concepts related to it. The definition of usability as it is stated in the ISO standard 9241-11 is presented with comparisons to other sources defining usability. The concepts of usability engineering and user-centered design are also explained in detail relevant to this work. The last subsection includes considerations on usability and its application in medical product development.

2.1 Definitions of usability

The term usability has several definitions depending on the author. All the definitions try to convey the same message and usually there are just small differences. This subsection presents the views of the most well known sources of usability definitions, ISO and Jakob Nielsen.

Usability is defined by an ISO standard as ”The extent to which a product can be used by specific users to achieve specified goals with effectiveness, efficiency and ease of use” (ISO 1998). The definition states that usability is always context- and user-dependent. It is divided into three main areas (ISO 1998):

- **Effectiveness**: ”Accuracy and completeness with which users achieve specified goals.”
- **Efficiency**: ”Resources expended in relation to the accuracy and completeness with which users achieve goals.”
- **Satisfaction**: ”Freedom from discomfort, and positive attitudes towards the product.”

Jakob Nielsen sees the concept of usability as a part of the total system acceptability, practical system acceptability and system usefulness (Nielsen 1993). The position of usability in his conceptual field can be seen in the figure 2.

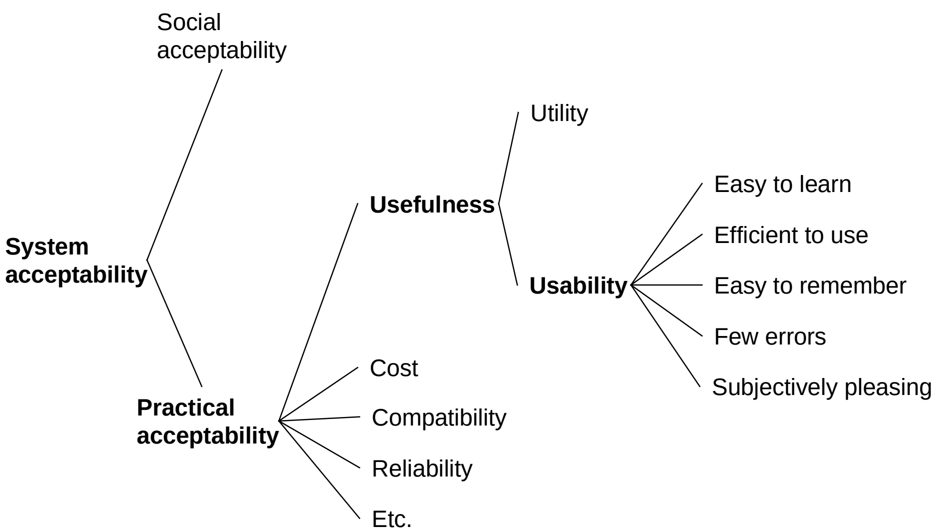

Figure 2: Usability as a part of system acceptability (Nielsen 1993)

As seen in the figure 2, Nielsen defines usability as a combination of five characteristics (Nielsen 1993):

- **Learnability**: “The system should be easy to use so that the user can rapidly start getting some work done with the system.”
- **Efficiency**: “The system should be efficient to use, so that once the user has learned the system, a high level of productivity is possible.”

- **Memorability**: “The system should be easy to remember, so that the casual user is able to return to the system after some period of not having used it, without having to learn everything all over again.”
- **Errors**: “The system should have a low error rate, so that the users make few errors during the use of the system, and so that if they do make errors they can easily recover from them. Further, catastrophic errors must not occur.”
- **Satisfaction**: “The system should be pleasant to use, so that users are subjectively satisfied with using it; they like it.”

Looking at the specifications above, usability can be summarized *as ease of use and learning, high efficiency and productivity, low error rate and user satisfaction.* This specification is used throughout this thesis.

As can be seen from the definitions, usability as a multi-dimensional aspect is a difficult thing to control in product development. Some of the demands that the different aspects lay on usability may contradict with each other, so it’s hard to design a product that is “totally usable”. Usually the aspects of usability must be prioritized.

2.2 Usability engineering and user-centered design

Usability engineering and user-centered design are both commonly seen as processes in which usability of the products’ user interface is enhanced and assessed with different methods which depend on the product development phase and on the information needs of the design team.

Usability engineering is a collection of activities of ensuring usability in product development. It is an ongoing process throughout the design, and ideally continues after the launch of the product. Jakob Nielsen has described usability engineering as “…a set of activities that ideally take place throughout the lifecycle of the product, with significant activities happening at the early stages before the user interface has even been designed” (Nielsen 1993). Deborah A. Mayhew agrees with Nielsen: “Usability engineering is a discipline that provides structured methods for achieving usability in user interface design during product development” (Mayhew 1999). The methods used in usability engineering is discussed in chapter 4.

User-centered design, UCD, is often seen as a synonym for usability engineering, although it’s not the same thing. UCD is more like a design philosophy and a state of mind while usability engineering refers to a use of a more or less defined set of usability methods. User-centered design principles can be accomplished by the use of the usability engineering.

User-centered design stresses the fact that a product is designed for a real user. It makes users the center of the design process and tries to make sure that their needs are included in the design process. The best known source for the definition of UCD is the ISO standard 13407, which states that the incorporation of user-centered design (or human-centered design, as the standard calls it) is characterized by following things: (ISO 1999)

- The active involvement of users and a clear understanding of user tasks and task requirements;
- an appropriate allocation of function between users and technology;
- the iteration of design solutions;
- multi-disciplinary design.

The same standard also emphasizes that the human-centered design process should start at the earliest stage of the project. (ISO 1999)

Constantine and Lockwood define Usage-Centered Design with five key elements: (Constantine & Lockwood 1999)

- Pragmatic design guidelines

- Model-driven design process
- Organized development activities
- Iterative development
- Measures of quality

This summarizes well the idea of UCD*: a well documented and organized iterative project, which has clear goals and a defined structure*.

In User-centered design user research, iterative design and usability evaluations done with interface prototypes are seen as a basis for all product development activity. These basic building blocks of UCD and their relations are illustrated in figure 3.

As Nielsen points out in his description of usability engineering, many of the most important usability engineering methods, for example user observations and interviews, focus on the early stages of product development. This activity is commonly known as **user research**. It's main goal is to familiarize the designers with the product user needs, tasks, use context and all the other factors that are necessary to build the product for the user studied in the research.

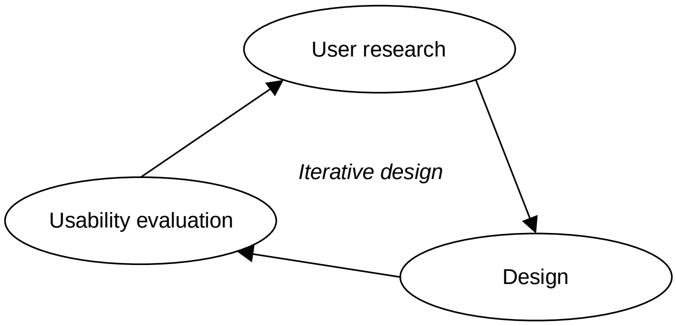

Figure 3: The building blocks of user-centered design

Iterative design and **usability evaluations** refer to a way of conducting product development, which is usually described in a form of a cyclic model. Designing a product in an iterative or cyclic way means that development team creates product prototypes, which are continuously refined after different forms of testing or other studies. The idea in the refinement is that if the design doesn't meet the predefined requirements set for it, it's designed and tested again until all the set objectives are met.

Different process models defining user-centered design processes further from figure 3 are presented and explained in chapter 3.

2.3 KESSU research project

This thesis work is partly based on the results of the KESSU research project done by scientists from Oulu University and Helsinki University of Technology in association with various Finnish companies. The project ends in the end of 2002, so it is still ongoing while this thesis was written. The research problem of the KESSU project is to learn how to perform an efficient ad useful current-state analysis of user-centered design (Jokela 2001).

The KESSU project worked iteratively. This means that the theories created during the research were tested in the participating companies and then developed further based on the experiences of the field tests.

The main result of the KESSU research is a new usability capability assessment approach. This approach is briefly introduced in the next section. The more interesting result for this thesis was the user-centered design reference process model, which was a side product of the usability capability assessment research. The process model is used as the basis for the new Datex-

Ohmeda process model. The KESSU UCD process model is discussed in more detail in subsection 3.2.3.

2.4 Usability capability assessment

As can be seen from the objectives set to this work (see section 1.1), one of the goals of this work is to develop a user-centered design process model, which would allow easy usability capability assessment (UCA). The aim of this subsection is to give the reader a view of what these assessments are and how they relate to usability activities.

Usability capability assessments are performed to identify the **current state of user-centeredness** in product development. The results are commonly presented in a form of a **capability profile**. Each process in the UCD process model is given a capability rating, which identifies its level of user-centeredness. (Jokela 2001)

Assessment is usually carried out by a team of usability experts. The assessment procedure typically starts with the definition of the inspection plan, which is introduced to the project organization in a briefing. The actual assessment consists of gathering and analyzing documents and carrying out interviews, which are usually the most characteristic part of the process. With the interviews the assessment team tries to find aspects of the organization which have impact on UCD processes. The data gathered depends on the UCA approach chosen. The data is then analyzed and interpreted using a UCA model as a reference. The results are then reported back to the target organization. (Jokela 2001)

Usability capability assessments can be used for two kinds of purposes: they can provide **a basis for improving UCD** in the company or give a **certification** that the organization can produce usable products (Jokela 2001). When used to improve UCD processes the assessment identifies weak points in the user-centered design processes of the company. A usability capability assessment done for a certification is often requested by a third party requiring evidence that an organization can produce usable products.

The KESSU project (Jokela 2001, Jokela 2002) that studied usability capability assessments defined the *capability areas* to study in UCA as *UCD infrastructure*, *implementation of UCD* and *business management commitment to usability*. In his doctoral thesis Timo Jokela describes them the following way (Jokela 2001):

- **UCD infrastructure**: “the extent to which the organization has resources to effectively and efficiently plan and implement high quality UCD in product development projects.”
- **Implementation of UCD**: “the extent to which UCD is planned and implemented in product development projects in terms of effectiveness, efficiency and quality.”
- **Business management commitment**: “the extent to which business management creates a demand for usable products and commitment to the development of a UCD infrastructure.”

The usability capability areas described briefly above belong to a model called **KESSU usability performance assessment** (UPA). It differs from the other UCA models by *addressing issues on substance of UCD processes instead of their management*. In KESSU UPA, the UCD activities currently performed are determined first. Next, their quality and integration are measured. Quality reveals how credibly, efficiently and professionally the activity is performed. Integration reveals whether an outcome truly has an impact on designs. (Jokela 2001)

The UCD process model will be subjected to usability performance analysis regularly, so it should comply with the measurement principles as well as possible.

2.5 Medical product development and usability

Usability engineering on medical device development is recognized to be of great importance because design-induced errors in the use of medical devices can lead to patient injuries or even deaths (Sawyer 1996). Although the situation has gotten better from earlier days, still in U.S.

more than 100 patients died in anesthesia due to equipment use error in 1994 (Burlington 1995). Important issues on reduction of errors in medical field are improvements in training and work schedules, but more importantly the design of devices and containers used in medical care. The latter are important because good design increases the chance of self-detection of errors (Senders 1994).

Patients' lives depend on the combination of machinery and people around them. This has caused several organizations to take action to steer the medical device suppliers' product development to more user- and usability-aware direction. These organizations include ISO and IEC globally, European Union, and Food and Drug Administration (FDA) with the Association for the Advancement of Medical Instrumentation (AAMI) in the U.S.

EU has issued medical device specific standards, but nothing that would concern User-centered design processes or general usability issues discussed in this thesis. In the United States **FDA quality regulations for medical systems development** (FDA 2002) were introduced in 1997 to ensure that all medical device manufacturers who sell their products in the U.S. have to follow specific *design controls* in their product development. Since nearly half of the world's medical device market is in Northern America, the FDA regulations must be taken into account by virtually every medical device manufacturer. None of the design control areas refer directly to usability engineering, but additional FDA guidance (Sawyer 1996, FDA 1997), has made it clear that usability engineering is a major aspect in keeping the medical electrical devices easy to use and most importantly safe. The design controls' effect on user-centered design is described in subsection 3.2.4.

Naturally, in comparison to the general view of usability and its processes described in previous subsections, the **medical usability standards emphasize strongly on safety**. This emphasis can be seen in the definition of usability in the IEC draft standard 60601-1-6: "Attribute of the medical electrical equipment that characterizes the time taken to become acquainted with the system and its operation and how easy it is to remember its operational details, its effectiveness, efficiency and freedom from discomfort, and positive attitude towards the use of the medical electrical equipment for the operator or service personal performing the their task and *which can affect the safety for the patient, operator or other persons*." (IEC 2002)

Safety emphasis is also noticeable in the definition of usability engineering in the same standard: "The application of knowledge about human behavior, abilities, limitations, or other characteristics to the design of medical electrical equipment, devices, systems, tasks, jobs, or environments *to achieve safe and efficient and effective use.*" (IEC 2002)

When considering the status of user-centered design in medical device development it is clearly seen that it's better than in most of the other information technology product development. The reason for this is partly the same as in all specialized systems development: **the users and their environment are specialized to a high degree**, and no engineer can design a product for them without the help of the medical care professionals. In a way this has forced the medical device development companies to user-centered design: listening to the users' opinions and to implementing methods to study and understand the users' needs, tasks and environments.

3 UCD process model theories

This chapter introduces different process model theories. First of all the concept of a process model is introduced briefly, after that the models are discussed in some detail.

The first three theories introduced are general process development models which means that they have been designed to be used in any kind of product development. The last model is from an IEC medical device development standard, and should therefore be taken into account while discussing process models in medical product development.

The most important models of this chapter are the ISO process models and especially the KESSU model, because the new process model presented in chapter 6 is based largely on them. Regulatory effects of IEC standard and the model described in it are also discussed in the light of how they affect medical process models.

3.1 What is a process model

Process models are descriptions of the workflow in a product development process. They show what should be done during product development on a high level of abstraction. Usually the models can be divided into two categories: **waterfall** and **iterative**.

A typical **waterfall model** is shown in figure 4. The model is clearly linear, with the output of the each development phase serving as the input for the next one. Usually even though this model is used, the phases overlap and sometimes the design team is forced to go back, for example to software design to find a correction for a bug found in unit testing. Although these models are somewhat simplified they are used widely as basic models for product design.

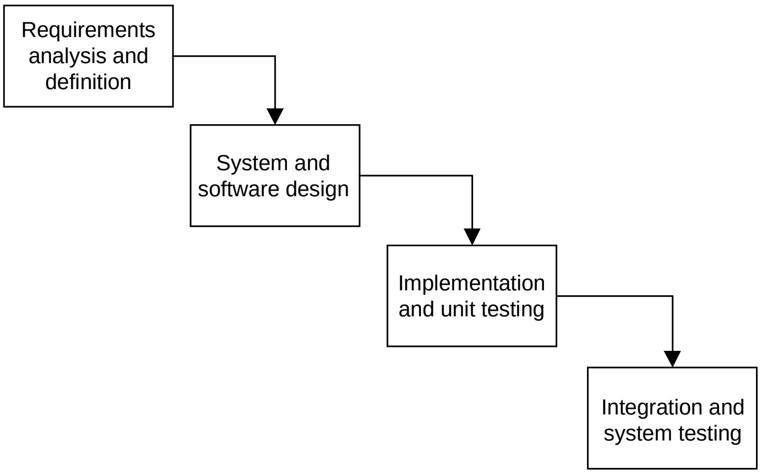

Figure 4: A traditional waterfall process model of software design (Sommerville 1989)

An **iterative model** shows more clearly the somewhat parallel nature of product development. The model encourages iteration during the product development by redoing some or all the phases to achieve better results. An example of the iterative process model can be seen in figure 5.

The model of figure 5 shows a star-like model in which the usability evaluation is on a central role. It can receive information from any one of the other activities and deliver the results from one activity to another. This star-like model represents well the core ideas of iterative design: **the product development doesn't necessarily start from a certain phase** (although it can often be the case), and often the **phases do not happen sequentially but in parallel**.

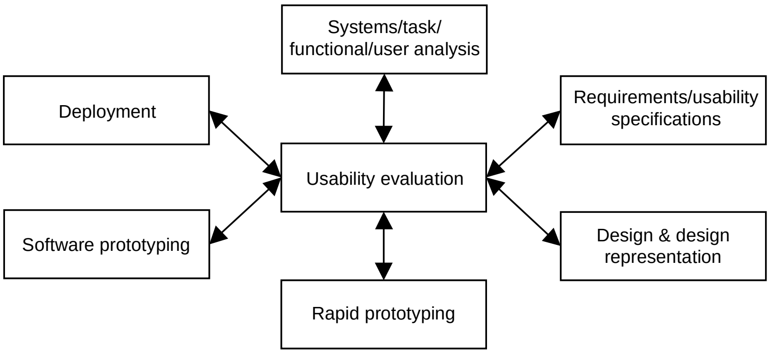

Figure 5: An iterative process model (Hartson & Hix 1993)

Another common way to represent iterative processes is to draw them **cyclic**. An example of this can be seen in the introduction of UCD, in figure 3. The idea is the same as in the figure 5 above: the phases of design interact more freely and the phase order is not as strictly fixed as in waterfall models.

All the process models described in the following section are iterative by nature, as the description of user-centered design in section 2.2 suggests.

3.2 Existing UCD process models

This section is intended to give an understanding of existing process models. It describes process models by ISO, Jakob Nielsen and KESSU project. Additionally the upcoming IEC user-centered design standard for medical devices and the requirements for medical device development by FDA are addressed.

3.2.1 ISO 13407 and ISO 18529

The International Organization for Standardization has created two standards for human-centered design processes, ISO 13407 and its extension and formalization ISO 18529. They both describe the same iterative core process, but ISO 18529 gives a wider vision of the UCD process management and support and goes into greater depth in describing the practices associated with the stages of the model. ISO 13407 process model is examined first because it describes the basis and the most important aspects of the UCD process. The additions in ISO 18529 are discussed after that.

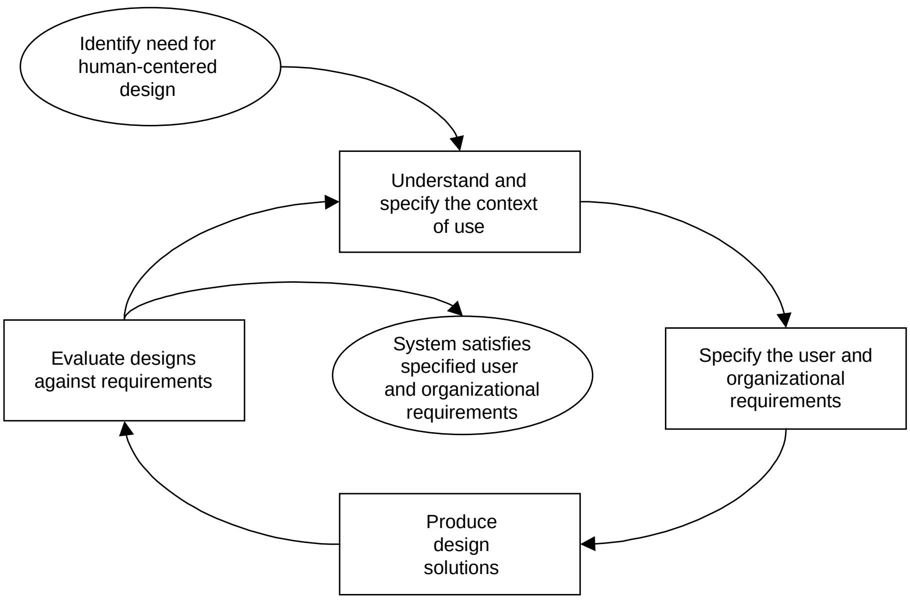

Figure 6: ISO 13407 human-centered design process model (ISO 1999)

The **ISO 13407 process model** is designed to be **method-independent**, which means that the phases in the model have no built-in usability engineering methods. Only the general outcomes of the stages are described, not the means of deriving them.

The process model has four stages of human-centered activity (ISO 1999):

1. Understand and specify the context of use;
2. specify the user and organizational requirements;
3. produce design solutions;
4. evaluate designs against requirements.

Before the four actual stages of activity (marked as boxes in figure 6) the model has a phase called "**Identify need for human-centered design**". It means that the whole organization should commit itself to this process and sufficient resources in time and effort should be allocated to support human-centered design.

This stage also includes the planning needed to implement the following activities. The standard says the plan should identify at least the human-centered design activities described in the model, how to integrate them into product development, people and organizations responsible for human-centered activities, procedures for maintaining communications and documentation, appropriate milestones and suitable time scales to allow feedback and design changes. (ISO 1999)

The four activity stages are described in more detail in the following.

Understand and specify the context of use

This activity stage aims to the understanding of characteristics of the users, tasks and the organizational and physical environment, which define the context in which the product is used. (ISO 1999)

The **characteristics of intended users** include knowledge, skill, experience, education, training, physical attributes, habits, preferences and capabilities. (ISO 1999) It may also be necessary to define several different types of users, if their characteristics vary considerably.

The **tasks** that users are to perform mean the goals of the users. The characteristics of the tasks that can influence usability should be described, e.g. frequency and the duration of performance. (ISO 1999) The issues on health and safety of users, as well as allocation of tasks between man and the machine should be documented as well.

The **environment** means the hardware, software and materials to be used. Relevant characteristics of physical and social environment should also be described. These can include technical, physical, ambient, legislative or cultural environment details as necessary. (ISO 1999)

The **output of this activity is a context of use description**, which should (ISO 1999):

- specify the range of intended users, tasks and environments in sufficient detail to support design activity;
- be derived from suitable sources;
- be confirmed by the users or if they are not available, by those representing their interests in the process;
- be adequately documented;
- be made available to the design team at appropriate times and in appropriate forms to support design activities.

Specify the use and organizational requirements

In human-centered design the activity of specifying the use and organizational requirements should be extended to create an **explicit statement of user and organizational requirements in relation to the context of use description**. Following aspects should be considered to identify relevant requirements (ISO 1999):

- required performance of the new system against objectives;
- statutory or legislative requirements, including safety and health;
- cooperation and communication between users and other parties;
- users' jobs (allocation of tasks, well-being, motivation);
- task performance;
- work organization;
- management of change (training, personnel involved);
- feasibility of operation and maintenance;
- human-computer interaction (HCI) design.

The tasks with the system being designed should be divided into those made by humans and those performed by technology. All requirements defined in this activity should be described in terms that permit subsequent testing and confirmation. (ISO 1999)

The **output of this activity is a specification of user and organizational requirements**, which should (ISO 1999):

- identify the range of relevant user and other personnel in design,
- provide a clear statement of human-centered design goals,
- set appropriate priorities for different requirements,
- provide measurable criteria against which the emerging design can be tested,
- be confirmed by the users or those representing their interests in the process,
- include any statutory or legislative requirements, and
- be adequately documented.

Produce design solutions

This stage of activity produces designs drawing on the established state of the art, the experience and knowledge of the participants and the results of the context of use analysis. (ISO 1999)

The process of producing design solutions involves the activities of (ISO 1999):

- using existing knowledge to develop design proposals with multi-disciplinary input;
- making the design solutions more concrete using simulations, models, mock-ups, etc.;
- presenting the design solutions to users and allowing them to perform tasks (or simulated tasks);
- altering the design in response to the user feedback and iterating this process until the human-centered design goals are met;
- managing the iteration of design solutions.

Using existing knowledge to produce design proposals means that the existing knowledge on ergonomics, cognitive psychology, psychology and product design should be used in the process of creating designs. This knowledge can be found from internal user interface style guides or marketing information. General standards and guidance on ergonomics and human factors should also be referenced. (ISO 1999)

Making the design solutions more concrete means the use of different types of prototypes to communicate the product idea more efficiently. This also reduces the cost of reworking the final product in case of revisions. A prototype can be anything between a pencil sketch and a complex computer simulation. (ISO 1999)

Presenting the design solutions to users and allowing them to perform tasks is a way to gain feedback from the users. In an early stage of development this could involve presenting users with sketches of screen images of what product or system would look like and asking them to try them out in a realistic context. This way some aspects of the design can easily and inexpensively be assessed. Some prototypes are just used to explore different solution possibilities. (ISO 1999)

The most important aspect of prototypes is that they can be used to collect user feedback.

Altering the design in response to the user feedback and iterating this process until the human-centered design goals are met means that the process is iterative (see the description of UCD in section 2.2 and section 3.1). The prototype is refined during the iteration enabling more and more realistic use contexts. (ISO 1999)

Managing the iteration of design solutions is basically a notion that activities in the prototyping phase should be adequately recorded. The records should contain at least (ISO 1999):

- the sources of existing knowledge and standards used, with an indication of how they have been incorporated (or why they have not been followed, if appropriate),
- the steps taken to ensure that the prototype covered key requirements and followed good practice, and
- the nature of the problems identified and the subsequent changes to the design.

The **outputs** of this stage are the developed prototypes and their documentation.

Evaluate designs against requirements

Before any evaluation is made it's essential to develop an **evaluation plan**, which identifies the relative aspects of the following (ISO 1999):

- the human-centered design goals;
- who is responsible for the evaluation;
- what parts of the system are to be evaluated and how they are to be evaluated;
- how evaluation is to be performed and the procedures of carrying out the tests;
- resources required for evaluation and analysis of results and access to users;
- scheduling of evaluation activities and their relation to the project timetable;
- feedback and use of the results in other design activities.

Evaluation should take place at all stages of system life cycle and it's important to start as early as possible. The standard states that "Evaluation can be used to **provide feedback to improve the design**, to **assess whether objectives have been achieved** or to **monitor long-term use of the product or system**." (ISO 1999)

If **providing feedback to improve design** system is tested for new design ideas or to find problems in current solution. Evaluation goals should reflect one or more of the objectives below (ISO 1999):

- to assess how well the system meets its organizational goals;
- to diagnose potential problems and identify needs for improvements in the interface, the supporting material, the workstation environment or the training proposals;
- to select the design option that best fits the functional and user requirements;
- to elicit feedback and further requirements from the users.

Expert evaluations can be used to diagnose major problems but they are not a guarantee for a successful system. User-based evaluation is the preferred choice, especially cooperative evaluation, where the evaluator discusses the problems with the user as they occur. (ISO 1999)

If **assessing if objectives are met** the evaluation can be used to demonstrate that a particular design meets the human-centered requirements or to conform that the design solution meets the requirements of standards.

If **monitoring long-term use of the product or system** there should be a plan and a process to gather and analyze data from the system. Long-term monitoring is important because some effects of interaction with a product can be recognized only after a period of time.

The **output of this stage is an evaluation report**.

Additions to ISO UCD process model in ISO 18529

In comparison to the ISO 13407 the ISO 18529 describes the UCD process model in a more detailed manner. The ISO 18529 model introduces more detailed activity descriptions called **practices**. The process model is still **method-independent**, it just describes the activities of each stage in more detail. The practices are not described in this thesis, but they can be found from chapter 6 of the ISO standard 18529 (ISO 2000).

The components of the ISO 18529 model can be seen in figure 7. The **processes** mentioned in the figure 4 mean the stages of activity presented in ISO 13407 description above and the few extra stages described in more detail below. In the following text the stages of action will be referred to as processes.

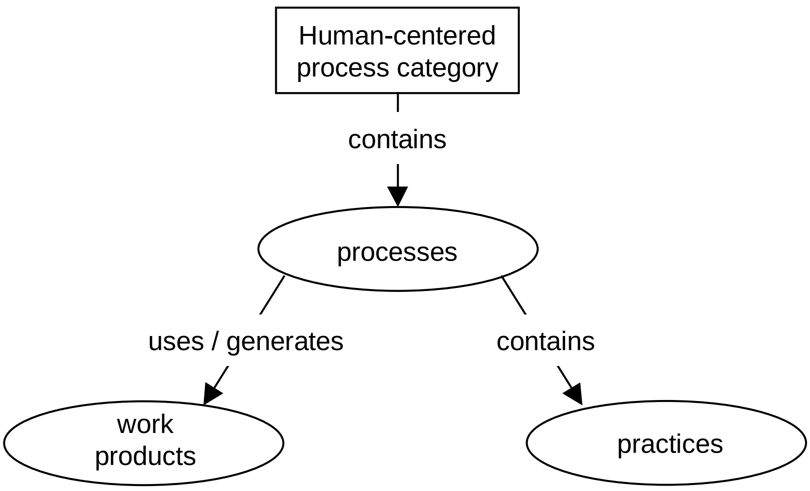

Figure 7: Entity relations in ISO 18529 (ISO 2000)

ISO 18529 expands the human-centered design scope to include the supporting activities of managing the HCD process, its inclusion in strategy and operating of the system. The four processes described in ISO 13407 still form the core of the product. The ISO 18529 process model can be seen in figure 8.

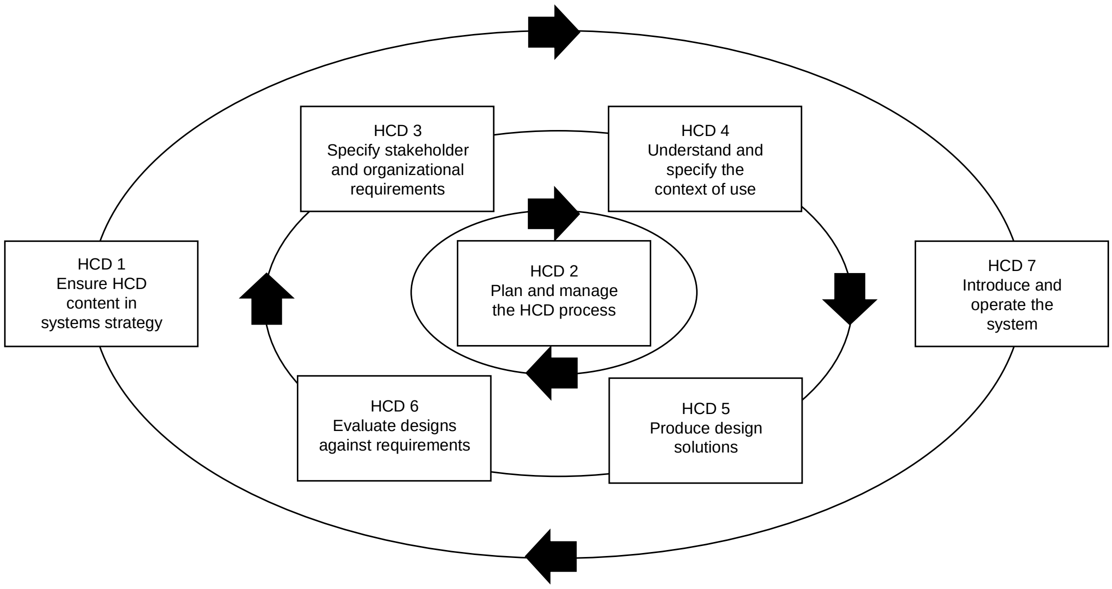

Figure 8: ISO 18529 human-centered design process model (ISO 2000)

The processes HCD 3 – HCD 6 are the same as in ISO 13407. They form a tight loop at the core of the system development. HCD 2 covers management and control of human-centered activities by using the information created by HCD 3-6 loop. It also connects the human-centered lifecycle to other processes in system development. HCD 1 connects the human-centered lifecycle to higher management processes, looks to the future of systems and sets goals to HCD 3-6 cycle. HCD 7 is concerned with the use of the system. It connects the HCD processes to the support phase of the system lifecycle. (ISO 2000)

In ISO 18529 the processes are described through their purpose, a set of base practices and a result of successful implementation of the process. The three new processes are described in the following by their purpose and results.

HCD 1: Ensure HCD content in systems strategy

The purpose of the process HCD 1 is to establish and maintain a focus on stakeholder and user issues in each part of the organization, which deal with system markets, concept, development and support. As a result of successful implementation of this process (ISO 2000):

- marketing will take account of usability, ergonomics and socio-technical issues;
- systems will be targeted to meet users' needs and expectations;
- planners will consider stakeholder and organization requirements in setting out system strategy;
- systems will be more responsive to changes in users;
- the enterprise will be more responsive to changes in its users;
- systems are less likely to be rejected by the market.

HCD 2: Plan and manage the HCD process

The purpose of the process HCD 2 is to specify how the human-centered activities fit into the whole system lifecycle process and the enterprise. As a result of successful implementation of this process (ISO 2000):

- the project plan will allow for iteration and incorporation of user feedback;
- resources will be allocated for effective communication between the design team participants;
- potential conflicts and trade-offs between human-centered and other issues will be reconciled;
- human-centered processes will be incorporated into quality systems, procedures and standards;
- human-centered issues will be supported and promoted within the organization.

HCD 7: Introduce and operate the system

The purpose of the process HCD 7 is to establish the human-system aspects of the support and implementation of the system. As a result of successful implementation of this process (ISO 2000):

- the needs of the stakeholders of the system will be communicated to the project;
- the management of change, including the responsibilities of users and developers, will be specified;
- the support requirements of end-users, maintainers and other stakeholders will be addressed;
- there will be compliance to health and safety procedures;
- local customization of the system will be supported;
- user reactions will be collected and the resulting changes to the system reported back to stakeholders.

Discussion on ISO UCD process models

ISO UCD process models offer a very general basis for usability work. Their main advantage is method-independence, which allows them to be adapted to a variety of environments and business cultures. They can be complemented with more usability engineering method centered process models to add substance to the four key processes. One of these process models is Nielsen's usability engineering lifecycle, which is introduced in the next subsection.

By introducing practices the ISO 18529 defines the processes more rigidly than ISO 13407. This can be seen both as an advantage and a difficulty. On the other hand it clarifies the nature of the processes and steers their outcomes to the right direction, but on the other hand it makes the process model less flexible by stating explicitly what should be studied. The practices are not described in this thesis because they are not a part of the final process model described in chapter 6.

The generality of the ISO process models requires expertise from the usability practitioners who implement the process models. There are no clear method indications and the models must be implemented on case-by-case basis.

3.2.2 Nielsen's Usability engineering lifecycle

Jakob Nielsen introduces his view of the user-centered design process model in his book Usability Engineering. In this model Nielsen presents an **eleven-step process with an iterative design part**. The design phases are (Nielsen 1993):

1. Know the user
2. Competitive analysis
3. Setting usability goals

4. Parallel design
5. Participatory design
6. Coordinated design of the total interface
7. Guidelines and heuristic evaluation
8. Prototyping
9. Empirical testing
10. Iterative design
11. Collect feedback

Not all the phases in the list above are actually real phases in the process model. The phases 6 and 7 can be combined with the 8th phase to form a wider prototyping phase. The 10th phase, iterative design, is actually an activity, which applies to the whole design, not just a single phase. Iterative design mainly concerns the participatory design, prototyping and empirical testing phases.

An illustration of Nielsen's usability engineering lifecycle with the modifications above can be seen in figure 9.

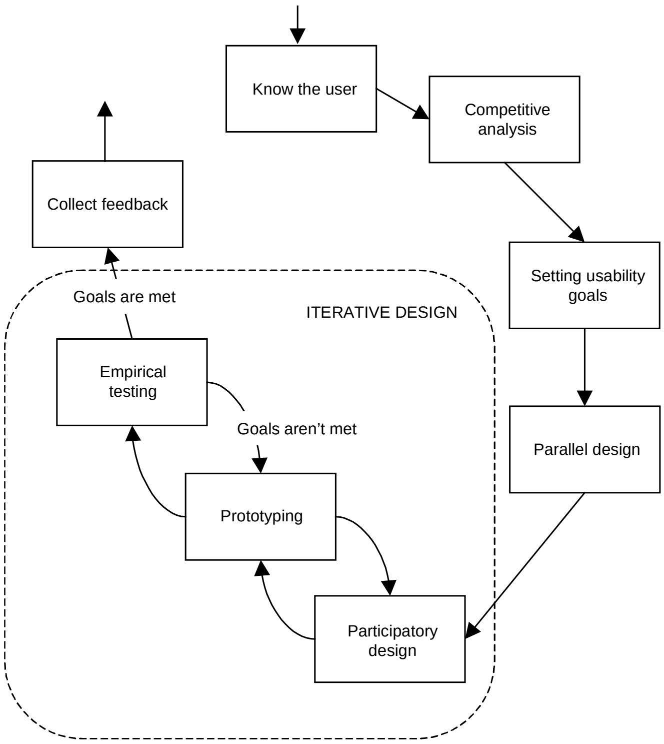

Figure 9: Nielsen's usability engineering lifecycle

Nielsen himself divides the lifecycle model further into three phases: **pre-design phase, design phase and post-design phase**. (Nielsen 2001) The pre-design phase consists of getting to know the users, competitive analysis and setting usability goals (phases 1 to 3 in figure 9), design phase consists of parallel design, participatory design, prototyping and empirical testing (phases 4 to 7 in figure 9) and post-design phase consists of collecting feedback (phase 8 in figure 9).

In the following the original 11 phases of Nielsen's usability engineering lifecycle are introduced and explained how they fit the figure 9 description of usability engineering lifecycle if it's not apparent from the figure.

Know the user

The first step in the usability process is to study the user and the use of the product. First of all, the **user should be clearly defined**. Relevant factors such as work experience, educational level, age and previous computer experience should be researched. The users' **environment**, both social and physical, needs to be known as well. (Nielsen 1993)

Nielsen strongly emphasizes that the studies shouldn't solely base on what the users say. More weight should be placed on the things they do. Because of this he reminds to keep the interviews as concrete as possible, by asking the users to show examples of how they do the things they talk about. Observing the actual work being done is essential.

Nielsen sees **task analysis** as an essential part of knowing the user. Nielsen states that with task analysis "The user's overall goals should be studied as well as how they currently approach the task, their information needs, and how they deal with exceptional situations" (Nielsen 1993). Users' model of the task should be identified, because it can reveal sources for metaphors to the interface being designed and difficult parts of the current interface, which can be improved in the future design (Nielsen 1993). Task analysis as a usability engineering method is explained in more detail in subsection 4.4.

By doing task analysis the information received is usually concentrated on how the tasks are done, but the reason for each action is not studied. Nielsen suggests **functional analysis** for finding out the actual functional reason behind the action seen in task analysis. In functional analysis the actions, which are required are separated from those, which are merely changeable surface procedures. (Nielsen 1993)

Competitive analysis

Nielsen says that the **competing products can be treated as prototypes for new design**. They can be studied the same way as ones own prototypes: with heuristic evaluations and usability tests. They are already fully implemented, so conducting tests with them is fairly easy. If several different products exist, a comparison between them should be made to separate good design solutions from bad ones. (Nielsen 1993)

Setting the usability goals

When setting usability goals it's essential that the **aspects of usability desired are identified** (see section 2.1). Usually not all of them can be satisfied with one product, so priorities have to be made clear. **Usability metrics** has to be planned to measure the usability goals selected. (Nielsen 1993)

Nielsen suggests that in addition to **specifying a minimum level of each usability attribute** measured, some other levels can be specified as well. Other useful levels to be defined are the current level and the planned, ideal level of performance. (Nielsen 1993)

At this point Nielsen suggests a **financial impact analysis** to be made. Its idea is to calculate the worth of increased usability of the product being developed by estimating the decline in various costs with the new system. (Nielsen 1993)

Parallel design

Parallel design means that several different design teams work on the same subject. At some point the designed interfaces are gathered together and the **best solutions are merged into a single design**. The advantage of parallel design is that more different design solutions can be explored before settling to one design, which is developed further iteratively. Figure 10 describes the relation between parallel and iterative design.

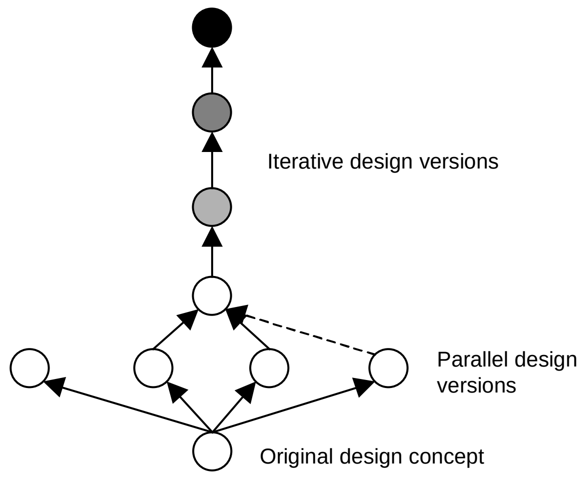

Figure 10: Parallel and iterative design in usability engineering lifecycle (Nielsen 1993)

Nielsen points out that it's imperative that the design teams work independently, because the idea of this phase is to generate as many ideas as possible. Usually the ideas are combined before the first prototypes are created, but sometimes it might be useful to make prototypes of the few most interesting ideas, if they are fundamentally different enough. (Nielsen 1993)

If the designed product is totally new, the parallel design phase is more important than in the case where there are already competing products in the market. This is due to a fact that the competitor analysis described earlier acts as a parallel design phase, where the best and worst sides of other manufacturers' products are analyzed. Still Nielsen suggests a few parallel designs, even though the competitor information is available. (Nielsen 1993)

Another way to look at the parallel design is the **parallel diversified design**. It differs from parallel design by assigning different design problems to different designers. The best proposals of every design problem are then combined into the product. Nielsen states that "By explicitly directing the design approach of each designer, diversified parallel design drives each of these approaches to the limit, leading to design ideas never have emerged in unified design." (Nielsen 1993)

Participatory design

By participatory design Nielsen means the **involving users in the actual design** work. The users can often come up with aspects that the designers haven't realized to be important. They are especially good in detecting mismatches between users' actual task and the developer model of the task. Users participating in product development are sometimes called *subject matter experts* (SME). (Nielsen 1993)

Because the **users are not designers** the best way of including them in design is by preparing different types of prototypes and asking for opinions. The design proposals should be kept as concrete as possible. It's also important to remember that users who are involved in the design process long enough become somewhat designers themselves. This is why the SME:s involved in design should be changed from time to time to ensure fresh views of the product prototypes. (Nielsen 1993)

Coordinated design of the total interface

Nielsen sees **consistency** as one of the most important usability characteristics. Consistency should apply to all media, not just the interface itself. (Nielsen 1993)

Consistency between different product generations is important, so products should always function in the same manner as their predecessors. A good way to ensure this is to develop **corporate user interface standards**. Of course it should be remembered that there are other usability criteria too, and sometimes they outweigh the desire for consistency over product generations. (Nielsen 1993)

To provide consistency it's good to have some kind of an **authority** to monitor and control the various aspects of user interface design. It's also important that the design teams share the same understanding of the UI design principles. This can be established by the **extensive use of examples in forms of prototypes and design guidelines**. (Nielsen 1993)

When looking at the figure 9, it can be seen that this activity is relevant in all the design phases (phases from parallel design to empirical testing), because all the design must be done aiming to a consistent result.

Guidelines and heuristic evaluation

Different types of design guidelines can be divided into **general, category-specific and product-specific** guidelines. General guidelines apply for all user interfaces, category-specific to certain types of interfaces (Windows applications, for example) and product-specific guidelines are created for each interface individually, usually during the product development (Nielsen 1993). Guidelines are discussed further as the method theories are introduced in subsection 4.5.

The guidelines are a good basis for **heuristic evaluation**, which is described in more detail in section 4.8.1. The general idea is that the general guidelines are broken down to category-specific rules, which are in turn transformed into product-specific guidelines, which allow the implementation of heuristic evaluation according to them. (Nielsen 1993)

Guidelines and heuristic evaluations can be applied during the whole design phase. This is the reason why this phase is blended to all the design phases (phases from parallel design to empirical testing, see figure 9).

Prototyping

According to Nielsen as early prototyping as possible is necessary, because the **users involved in the design process do not understand abstract specifications as well as concrete prototypes**. He sees prototyping as the main way to test the user interface with actual users. The longer the creation of the prototypes takes, the less information can be gathered from the users. (Nielsen 1993)

Prototyping aims to save time and costs in product development as well as to implement the user point of view to the design as early as possible. The reductions in time and cost are achieved by cutting down the number of features or the level of functionality the features have. If the reductions are done mostly on the expense of the number of features, the prototype is called a **vertical prototype**. If the level of functionality is reduced it's called **horizontal prototyping**. (Nielsen 1993)

Vertical prototyping generates a prototype with only a few of the features doing something, but doing that in a detailed and accurate way. By vertical prototypes small sections of the whole system can be tested in detail. (Nielsen 1993)

Horizontal prototyping results in a prototype of the whole user interface, but with a minimal number of working features. The main advantage of horizontal prototyping is that they can be created fast and in the earliest stages of product development, because they don't need functionality to be implemented. (Nielsen 1993)

If both the range of features and the level of functionality are reduced in the prototype, the result is a **scenario**. The scenario works only if the user follows a specific path. Scenarios are very easy and inexpensive to build, but not very realistic. Scenarios can be used either as tools for communicating and understanding how the users will interact with the system, or as early prototypes to collect user feedback of the system. (Nielsen 1993)

Scenarios and prototyping as usability engineering methods are described in more detail in sections 4.6.1 and 4.7.

Empirical testing

Empirical testing means **user interface evaluations involving the users.** Empirical tests are closely connected to the previous phase of prototyping, because the main idea of prototypes is to collect feedback from the users. This is usually done by measuring the interface against the usability goals set in the beginning of the product development. (Nielsen 1993)

Empirical evaluations (or usability tests, as they are more commonly called) are described in more detail in subsection 4.8.4.

Iterative design

Iterative design is based on the design phase described in the previous subsection**. When the goals set in earlier phases and measured in user tests are not met, redesign and a new interface version is required**. Usually a design process involves several design-test –loops. Nielsen reminds that it's important to test the prototype again after the problems found in the previous iteration have been solved, since new ones can emerge from the revisions made to the design. (Nielsen 1993)

On the other hand it may not be feasible to involve users to test every new feature of every design made. Sometimes expert reviews can assess the usability of the design well enough.

Nielsen encourages designers to capture the **design rationale** for later reference. Design rationale shows in a form of a chart why the design solutions were made in the first place. It is easy to forget the reasons of interface design decisions, especially if several iterations are made and the details of the design changed several times. Nielsen states that "…it is helpful to know the reasons underlying the original design so that important usability principles are not sacrificed to attain minor objective." (Nielsen 1993)

Collect feedback

After a product is released it's important to monitor its use in the field. The feedback serves as a basis for the future versions the same way as the competitor analysis. In a way the product is a prototype for future products.

Sometimes feedback can be gathered as a part of standard marketing studies, sometimes it's useful to do specific studies on usability issues alone with the same techniques as in task analysis phase. An important channel of information is the feedback of users. It can be in the form of complaints, modification requests or even calls to help lines. Problems with learnability can be gathered from the instructors who teach the system on their courses. (Nielsen 1993)

Discussion on usability engineering lifecycle

In addition to the 11-step model described in previous subsections, Nielsen also suggests an **overall usability plan**, which should contain information on what usability activities the development process contains. In addition overall usability plan, **each of the methods used should have an own, explicit plan** showing what should be done with the method and how. Before using any usability engineering methods Nielsen advises to **pilot test** them first. By using 10-15% of the total effort on each method to test its details will result in better quality results obtained with the rest of 85-90% of the effort. (Nielsen 1993)

As can be seen from the description of the Nielsen's model, the usability engineering lifecycle is very **method-centered** thus differing from the method-independent ISO models described before. Although Nielsen's model is as general as ISO models in many ways, Nielsen's book's preface reveals clearly that it's written mainly to computer systems designers.

The **main downside** of Nielsen's model is that it doesn't suggest how the findings of each phase should be documented or communicated. From this point of view his views can be seen as complementary to the very high level definitions of the ISO UCD process models, which clearly define the required outcomes. While the ISO model is used as a standard or guideline for operation, Nielsen's model is more of a down-to-earth **usability practitioner's manual or reference**.

3.2.3 KESSU UCD process model

KESSU User-centered design model is described in Timo Jokela's doctoral thesis (Jokela 2001), and in more detail in his article "A Method-Independent Process Model of User-Centered Design" (Jokela 2002). KESSU was originally the name of the project in which the model developed, and Jokela doesn't mention KESSU anymore in his more recent article (Jokela 2002). To clarify things and distinguish the model from other UCD process models, Jokela's model is called KESSU UCD process model in this thesis.

KESSU UCD process model was designed using the ISO 18529 standard (ISO 2000) as a basis. It is intended to be a **method-independent** process model, which can be used as a basis for **usability maturity evaluations**. Actually the process model evolved alongside several usability maturity evaluations. KESSU UCD process model **doesn't describe any practices** the way ISO 18529 does. The processes in the KESSU model are defined through their outcomes, **concrete deliverables**.

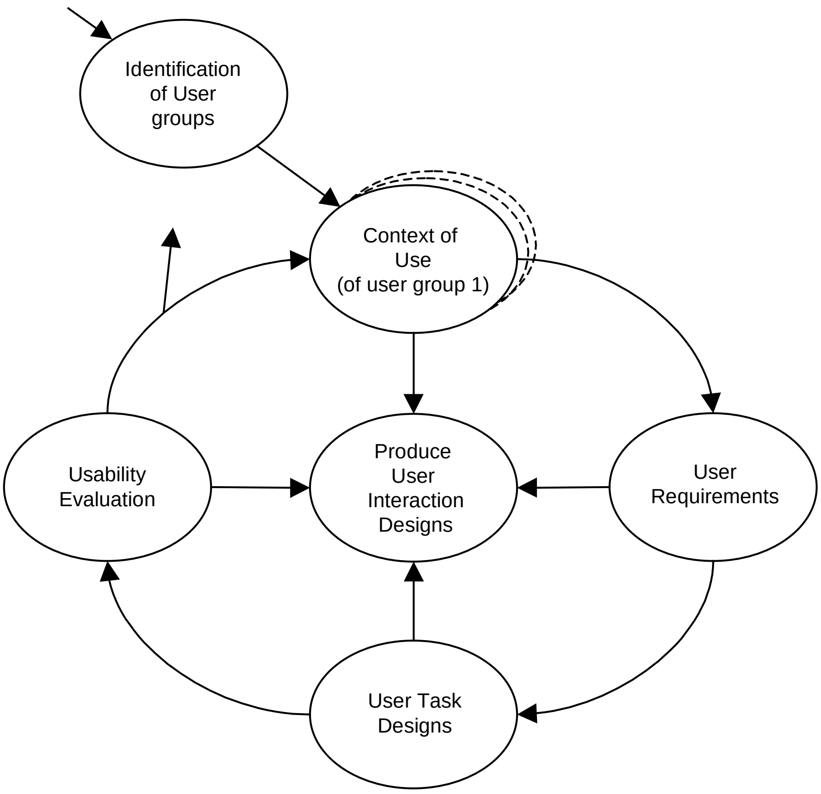

Figure 11: KESSU UCD process model (Jokela 2001)

The KESSU UCD process model can be seen in figure 11. It has six processes in contrast to the four core processes of ISO 18529 (HCD 3-6, figure 8). In the following these six processes are described.

Identification of User Groups

The **purpose** of the Identification of User Groups process is to identify the different user groups: who are the potential users of the product or system. (Jokela 2002)

The **outcomes** of the process are (Jokela 2002):

- *User group definitions*. User groups are named and their approximate sizes are determined.
- *User characteristics.* The characteristics may include knowledge, language, physical capabilities, anthropometrics, psychosocial issues, motivations in using the system, priorities, etc.

Context of use (of user group N)

The **purpose** of the Context of Use of User Group ‘N’ process is to identify the characteristics of the users, their tasks and the technical, organizational and physical environment in which the product system will operate. (Jokela 2002)

In comparison to the ISO 18529 the Context of Use process has now two deliverables instead of one (see section 3.2.1). The **outcomes** of this process are Context of Use of the Old System and Context of Use of the New System.

Context of Use of the Old System is about describing the use of the current system as relevant for designing the new one. It has the following parts (Jokela, 2002):

- The **user accomplishments** related to the old product are identified and documented. The accomplishments should be described in terms of user and organizational activities.
- The user **tasks** that users perform to achieve the accomplishments are described and documented.
- The real operational **environment** of the product, including the factors that affect the performance of users, is described.
- The **non-functional attributes** of tasks should be identified and documented. The attributes may be for example: frequency, duration of performance, criticality for errors, identification of problems and risks that users meet when performing their tasks.

Context of Use of the New System is about describing the context of the product under development. Its main function is to highlight the differences between the old and the new contexts. The outcome has the following parts (Jokela 2002):

- The **user accomplishments** related to the product are identified and documented. Especially the differences to the existing context of use are identified.
- The real operational **environment** of the product, including the factors that affect the performance of users, is described.
- The **non-functional attributes** of the tasks should be identified and documented the same way as in the Context of Use of the Old System.

User Requirements

The **purpose** of the User Requirements process is to define usability and user interface design requirements for the product. The process uses context of use information and business goals as **inputs**. (Jokela 2002)

The **outcomes** of the process are (Jokela 2002):

- *Usability requirements*. Usability requirements are determined and documented. Usability requirements mean the performance of the product against the context of use.
- *UI Design Requirements*. Guidelines and restrictions that should be considered when the UI is designed should be identified and documented. These are typically heuristics, style guides or project standards.

The idea of usability requirements is that they are measurable, for example in terms of efficiency, effectiveness and satisfaction stated in ISO 9241-11 (ISO 1999).

User Task Design

The **purpose** of the User Task Design process is to design how users would carry out their tasks with the new product being developed. (Jokela 2002)

In this stage the user actions the product will support are decided and the scenarios for each activity are developed. In this phase no design of user interface elements is done, only the task order and objectives are defined. Special interest should be placed on those activities with usability requirements placed on them. (Jokela 2002)

While discussing the differences between user task design and user interaction designs Jokela says: "User task design is a characteristic activity of UCD while user interaction design is always performed as user-interface elements are developed – even if there is no user-centeredness in the process." (Jokela 2002)

The **outcome** of this process is (Jokela 2002):

- *User Task Descriptions*. The tasks relating to how a user plans to use the product to achieve the goals are described and documented. The tasks should also be designed in relation to such tasks as user documentation and user training.

Produce User Interaction Designs

The **purpose** of Produce User Interaction Designs process is to design those elements of the product the user interacts with. Besides the user interface, this process includes also the design of user documentation, training and other support. (Jokela 2002)

Produce User Interaction Designs has a special role among the processes of KESSU model. It creates concrete designs while the other processes support the design process. (Jokela 2002)

The **outcomes** of this process are (Jokela 2002):

- *User Interface*.
- *User Documentation*.
- *User training*.
- *Other relevant outputs*. Other relevant outputs might be packaging, user support procedures, etc.

Usability evaluation

The **purpose** of this process is to evaluate the product against the requirements in terms of the context of use. Usability evaluation in this process model means those usability studies that concern task performance. Other analyses (heuristic evaluations, style guide checks) are done in the Produce User Interaction Designs process. (Jokela 2002)

The **outcomes** of this process are (Jokela 2002):

- *Formative Usability Evaluation Results*. The collection of qualitative feedback on the product.
- *Summative Usability Evaluation Results*. The report of tests against all the usability requirements defined in Usability Requirements process.

Discussion on KESSU UCD process model

As can be suspected the KESSU model has a lot in common with ISO process models. This makes it easier to adapt to the model, since the ISO models are already widely used. The enhancements made to KESSU make it easier to understand and stress the aspects of User-centered design that are not normally very visible: user task design and the possibility of multiple user groups.

KESSU model defines the processes through concrete outcomes, while the ISO 18529 also uses the base practices for definition purposes. Another main difference in comparison to the ISO 18529 is the number of design processes. KESSU model concerns only the core processes of UCD and leaves out the supporting processes HCD 1, 2 and 7 (see figure 8).

The "produce design solutions" –process from ISO 18529 is split into two processes: "produce user interaction designs" and "produce user task designs". This was done because the design team wanted to emphasize the fact that in UCD the design is not merely about layout design but more of designing larger tasks and their hierarchies. (Jokela 2002)

The another process split in KESSU process model is the division of "Context of Use" into "Identification of User Groups" and "Context of Use of User Group N". This was done to emphasize the fact that there can be more than one user group and context of use. (Jokela 2002)

The KESSU UCD process model is more demanding to the practitioner than ISO 18529 to which it is based on. The absence of base practices of the processes means that the person applying the model should have a clear understanding on what the relevant information is in each phase and how to acquire it.

Generally, even though Jokela says the KESSU project was based on ISO 18529, the process model clearly has more in common with the ISO 13407 definition. Like ISO 13407, the KESSU model concentrates on the central processes and tries to define the essence of UCD instead of trying to document each phase thoroughly. It is left to the practitioner.

3.2.4 Medical UCD process model standards and constraints

This subsection discusses the UCD process models used in medical device manufacturing standards. FDA has also introduced special design controls, which affect the usability engineering work by dictating some of the working practices in medical device design. They are also discussed in this subsection.

IEC 60601-1-6 and AAMI HE74:2001

The process model seen in figure 12 is described in the International Electrotechnical Commission standard draft 60601-1-6 (IEC 2002), which aims to ensure patient and operator safety by describing and enforcing a usability engineering process and the accompanying methods. **When the standard draft becomes final, it requires a usability engineering process to be utilized by all medical electrical equipment manufacturers**. By usability engineering process the standard means the same thing as user-centered design process.

The user-centered design process of IEC 60601-1-6 has its roots in risk analysis, and the whole standard concentrates on ensuring the patient safety by enforcing a process model which includes both usability engineering and risk analysis influences.

Figure 12 displays the process model described in the appendix of the IEC 60601-1-6. It has the same basic components as the other models seen in the preceding chapters: iterative design, requirements analysis based on user research and usability evaluations. Therefore the stages of IEC 60601-1-6 model are not discussed here in further detail. They are presented in earlier subsections in this section.

AAMI has developed a very similar standard HE74:2001 (ANSI/AAMI 2001), which is already in use in the United States. It uses exactly the same process model seen in figure 12, and is virtually the same standard as the IEC standard (IEC 2002).

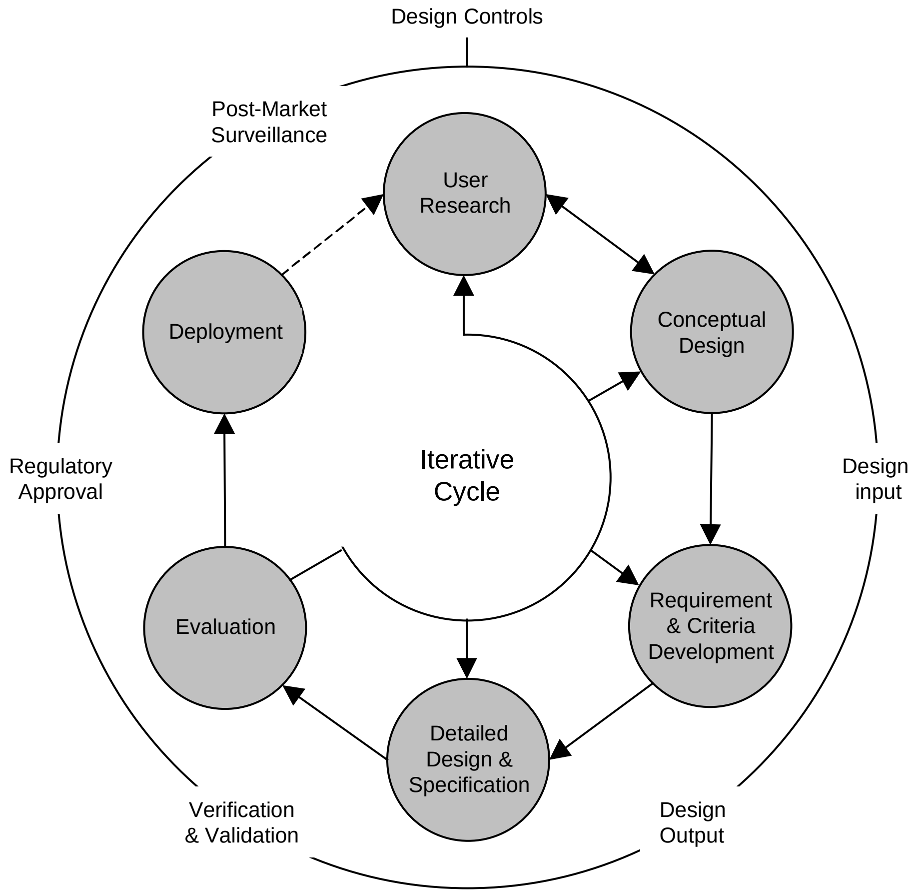

Figure 12: IEC 60601-1-6 and AAMI HE74:2001 User-centered design process model (IEC 2002, ANSI/AAMI 2001)

Constraints to medical device product development

Some of the **design controls required by FDA** (see section 2.6) and other outside constraints are displayed in their respective places in IEC 60601-1-6 process model in figure 12. The first three, design input, design output and verification & validation are based on the design controls. FDA documentation describes the design control requirements concerning user-centered design the following way (FDA 2002):

- **Design and development planning**. Plans that describe the design activities and define responsibilities for implementation have to be established and maintained.
- **Design input**. Procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and the patient, have to be established and maintained.
- **Design output**. Procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements have to be established and maintained.
- **Design review**. Procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

- **Design verification**. Design verification shall confirm that the design output meets the design input requirements.
- **Design validation**. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.
- **Design history file**. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance to the approved design plan and the requirements of this part.

In practice these design controls mean the following things:

- A **usability plan** has to be created and followed. (Design and development planning)
- **User research** has to be done and documented. (Design input)
- **User requirements** have to be specified in a way that the design **can be measured** against them. (Design output & Design verification)
- User interface design has to be **reviewed** at appropriate stages. (Design review)
- **Usability testing** has to be arranged. (Design validation)
- All the user interface design activities have to be **documented** and archived. (Design history file)

The last two stages on the outer ring of figure 12 are regulatory approval and post-market surveillance. They mean that the **medical device manufacturer has to get a permit from an official source before they can launch a new product**. The official sources are FDA in U.S. and EU in Europe. To get the permission the medical device has to be handed over to authorities for a thorough test.

Post-market surveillance means that the **manufacturers are required to keep records of user feedback and accidents** that have happened while using the devices they manufacture. Hospitals, health centers and medical device manufacturers are obliged to report the incidents which involve patient injury or death due the use of medical equipment directly to the FDA. (Hyman 1994, Gross 1995)

FDA officials audit medical device manufacturers by studying their documentation of product development (the design history file) and by interviewing the employees. In addition the **EU requires product to be tested against product-specific standards**, which is done in Finland by VTT. These activities affect product development on the general level only by requiring an adequate level of documentation from all the development projects, which is already required by FDA design controls.

3.3 Conclusions

This chapter presented four process models: ISO 13407 combined with ISO 18529, Nielsen's usability engineering lifecycle and the KESSU process model. In the final subsection the process model of an upcoming IEC medical standard was introduced and the constraints of User-centered design in medical field were discussed.

ISO process models function as the core UCD models. They are method independent and general, allowing their integration to almost any product development process. They are the most widespread UCD process models, and serve as a basis for most of the other models. Their downside is that they are a bit too general, and don't offer much guidance on their implementation.

Nielsen's usability engineering lifecycle concentrates more on methods than the other models in this chapter. It can be used as a practical guideline for the application of usability engineering methods. Complemented with some other process model it can form a good combination of practicality and theory.

The KESSU process model is the newest and most modern of the UCD process models presented in this chapter. Because it has evolved as a side product of usability maturity assessment studies the model is easily applicable as a basis in maturity evaluations. It doesn't have any base practices the way ISO 18529 has; it defines the processes entirely through their deliverables. The definition of processes through their outputs enables easy adaptation of any methods necessary.

IEC 60601-1-6 and FDA design controls give mandatory constraints for any UCD process model in the field of medical technology. They have to be followed if the company wishes to pass the regulatory audits of FDA officials.

4 Usability engineering methods

This chapter describes the usability engineering methods needed in the descriptions of the current usability activities in chapter 5 and the new process model in chapter 6.

During each description the theory of the method is presented, and positive and negative aspects are considered as well as a typical form of reporting the results. Comments on adapting the usability engineering methods described in this chapter to Datex-Ohmeda are given in section 6.11 while describing the new user-centered design process combined with the methods.

4.1 Interview

In this work all the methods used to communicate with the user and ask him questions to gain knowledge are considered to be interviews. Interview is not usually done in the context where the product is used.

Three different interviewing styles, personal interview, focus group and questionnaire, are described below.

4.1.1 Personal interview

Personal interview is the most common type of interview. In a personal interview the interviewer asks questions from the interviewee according to a predetermined plan. They are typically used in the beginning of a product development project to study the users, the tasks and the context of use of the future product. They can also be used in conjunction with other usability engineering methods, such as usability tests (see subsection 4.8.4) or task analysis (see subsection 4.4).

Personal interviews are divided into unstructured, semi-structured and structured interviews.

Unstructured interviews have only a set of general questions and no structure. The discussion can lead to anywhere depending on what the interviewee says (Faulkner 2000). Unstructured interviews are applicable in very early phases of product development when the area of study isn’t clear. Generally unstructured interviews are not very useful in usability engineering because of their unpredictable and unorganized nature.

Structured interviews follow a strict path of preset questions with defined answer possibilities. The interviewer asks the questions and the interviewee answers them. In comparison to the unstructured interview this method has much more rigid structure and there are no possibilities to follow interesting topics of conversation if the set of questions doesn’t cover them.

In the middle of the two interviewing methods presented above is the **semi-structured** interview. It is a combination of both the styles above: the interview has a structure and the main questions are defined beforehand, but during the interview the conversation can focus on interesting topics even if they are not in the interview plan. The semi-structured interview is the most useful form of interview in usability engineering.

A basic set of semi-structured interview questions for studying the user and his tasks is presented below: (Nielsen et al. 1986)

1. What do you do?
2. Why do you do this?
3. How do you do it? (repeat for subtasks)
4. What causes you to do this?
5. What is the result?
6. What errors occur?

7. How do you correct these errors?

The **advantages** of the personal interview method are the interviewer's ability to see and interpret the interviewee's reactions and tones of voice as well as the method's familiarity to almost everyone. The latter can also be seen as a **weakness**: because everyone can make a conversation doesn't mean that everyone can conduct a fruitful interview. It is easy to ask leading questions and make the interviewee say things that the interviewer wants to hear (Preece 1994, Nielsen 1993). Interview also often requires domain specific knowledge in order to know what to ask, and people usually do different things than they say (Maguire 1997, Nielsen 1993).

It is useful to record the interviews for later transcription. This makes it easier to return to the interesting parts and to include direct quotes from the interview to the report (Nielsen 1993).

The output of an interview is typically an **interview report**, which contains the original interview transcription (assuming that the interview was taped) and a collection of user quotes along with a summary of the main points found.

4.1.2 Focus group

In a focus group, about six to nine users are brought together to discuss new concepts and identify issues. Each group is run by a moderator who is responsible for maintaining the focus of the group. Session is intended to feel informal, although the moderator keeps the conversation on track and sometimes introduces new topics of discussion. (Nielsen 1993)

This technique is commonly used in the beginning of the product development **to see how people react to ideas** (Greenbaum 1998). The session is typically recorded in some way, preferably to video.

Maguire presents practical guidelines for focus groups (Maguire 1997):

1. Decide on the objectives of the meeting and the participants required to take part in it.
2. When contacting participants explain clearly the meeting format and what topics are to be discussed. Get everyone's agreement beforehand on the planned recording formats.
3. Produce a timetable for the session and run a pilot session to make sure it holds. Prepare the necessary background information sheets for the participants to fill.
4. During the session the discussion leader should be active in formulating the themes and summing up the results at the end of each topic. The opinions of individuals and the consensus of the group should be separated and recorded.

The main **good thing** of focus groups is that it brings up users' spontaneous reactions and ideas through the interaction of the participants (Nielsen 1993). Users can comment on each other's ideas and if there are disagreements they have to explain their viewpoints.

The free-floating conversation can also be a major **downside** if the moderator is not careful. Some people are shyer than others, and it's the moderator's job to get everyone's opinion heard (Nielsen 1993). Few individuals can easily dominate the entire session. It is also common that people try to find a common understanding because it's socially more acceptable than arguing on details. If interviewed separately the users would have stronger opinions than they admit to have when they are in a focus group.

Typically the focus group method can be time consuming, because usually more than just one group has to be held. Finding group members and arranging everyone to the same place at the same time can be challenging. On the other hand they are usually faster to conduct than site observations with the same number of people (Hackos & Redish 1998).

Because of the unstructured nature of focus groups the most typical way to document them is to write a **short report** summing up the prevailing mood in the group, illustrated with a few colorful quotes and perhaps photographs of the users' surroundings if the group was conducted in context. More structured reports can be difficult to compile due to the unorganized nature of the focus groups. (Nielsen 1993)

4.1.3 Questionnaire

Questionnaires are an interview method, in which the interviewee's answers are recorded to an answer sheet specifically prepared for the interview. They can be filled in by interviewees themselves or by an interviewing person. Questionnaires can be used as a part of some other method, for example personal interview (see subsection 4.1.1) or usability test (see subsection 4.8.4). Typically questionnaires are used to measure satisfaction to a product or to chart user background.

There are two types of questionnaires: **closed-ended** and **open-ended**. Closed-ended don't leave any room for individual comments from the respondent. They are useful if large numbers of data are required and some special questions with specified sets of answer possibilities are known. In open-ended questionnaires the respondents are able to reply in their own words. They are good for exploratory studies, for example in the beginning of product development. (Kirakowski 2000, Hackos & Redish 1998)

The **main advantage** of questionnaires is their easy administration to a large number of interviewees. This enables the use of **quantitative evaluations** on the interview data. Questionnaire data can be used to supplement other, more qualitative interview results.

The **downside** of questionnaires is that usually the interviewer isn't around to rephrase the questions if the respondent doesn't understand them. Questionnaire design requires knowledge of statistical analysis if the results are to be analyzed mathematically. In addition the design of questionnaires requires extra attention because the questions on the sheets have to cover everything the interviewer needs to know. Usually no additional questions can be asked afterwards.

Questionnaires can include three different types of questions (Kirakowski 2000):

- Factual-type questions

  These questions typically ask about public and observable information that would be tedious or inconvenient to get any other way, i.e. education or working experience.

- Opinion-type questions

  Opinion-type questions ask the respondent what they think of something. There are no right or wrong answers.

- Attitude questions

  Attitude questions focus on respondent's likes and dislikes. They are usually used in satisfaction questionnaires.

The results of questionnaires are often **analyzed mathematically** if closed-ended questions are used and the interview group is large enough. Questions of open-ended nature are analyzed the same way as other interview results. Typically all the questionnaire results are presented in an **interview report**, which summarizes the main points found. Graphical representation is helpful if the data permits it.

4.1.4 Conclusions on interview methods

All the interview methods presented in the preceding subsections provide information on the user, only the scopes change. If a large amount of quantitative data is needed, to gather user preferences on various interface techniques for example, a survey using questionnaires is the best choice. If more qualitative data is needed, for example cases of previous use of a certain product, a personal interview or a focus group is more appropriate. Usually interviews complement observations, task analysis or usability evaluations.

It is always important to remember that the users do not always say the same thing as they actually do. **People have a tendency to mince** their use preferences or opinions to please the interviewer or other people in the situation. Especially if asked of difficult situations the interviewees may belittle the problems they have had. The interviewer's job is to interpret which statements are actually important and useful.

Interviewees also tend to **talk more about issues that interest them** even though they are not important in the task at hand (Jeffries 1997). The interviewer has the responsibility to keep things in proportion to get realistic interview results.

People are also poor in generalizing their behavior. Despite this fact people still tend to generalize their working habits (Beyer & Holzblatt 1998). Usually when gathering information on the use context or user background it's better to ask if the user can give examples of actual cases which have happened in real life than ask them to give a general description. Interviews conducted in real context are usually more fruitful because the environment helps the interviewee to remember things better. Real environment also gives the interviewees an opportunity to elaborate their answers by actually showing the interviewer the task discussed.

4.2 Observation

Observational methods involve an investigator viewing users as they work and taking notes on activity that takes place (Maguire 1997). They differ from interviews in the sense that the information is not gathered solely by asking questions but also by watching users actually perform tasks. Observational methods are especially useful when studying situations, which are cognitively demanding enough that informants are likely to forget important subtasks if merely interviewed (Jeffries 1997). Observational methods also give a better picture of the context the user is working in.

In this section two basic observation methods are presented: observation and contextual inquiry. The latter is a mixture of interview and observation, while the first one is more purely a basic observation method.

4.2.1 Observation

Observation means watching the users without interfering with their activities. It can be **direct or indirect** through video camera or other surveillance equipment. Direct observation is usually the better choice, because the observer can clarify the user actions he didn't understand. Indirect observation is better only if the presence of an observer is totally impossible or would severely hinder or alter the user's actions.

Maguire suggests the following **observation preparation and analyzing process** (Maguire 1997):

1. Establish objectives and information requirements. Decide what information is needed and what is to be reported of the observation.
2. Gain contacts and especially their co-operation. Establish times, places and people who will be observed.
3. Decide on the recording technique. The most typical choices are hand-written notes, audio, or audio and video records. The more complete the record the longer it takes to analyze.
4. Analyze, summarize and report in relation to the objectives set out at the start.

The main **good thing** in comparison to interviews (see section 4.1) is that the researcher is able to see what the user actually does. The data gathered is based on empirical findings instead of what the users say.

Problems in observation often relate to the presence of the observer. The phenomenon in which persons being observed change their behavior due to the presence of the observer is called the

Hawthorne effect (Preece 1994, Faulkner 2000). The observed persons may try to please the observer or do that unintentionally. The more accustomed the users are to the observing personnel, the less they generally change their behavior.

The report of this method depends on the process stage and the data gathered. Sometimes a written report of the main findings is enough, sometimes a more detailed description of the users and their tasks and context is required. The report can be illustrated with pictures of users' surroundings and workflow charts to make the user activities and context more understandable.

4.2.2 Contextual inquiry

Contextual inquiry was developed as a part of larger contextual design (Beyer & Holtzblatt 1998) but can be used on its own. It is based on ethnographical studies, which are more informal than the researcher-controlled observations and interviews. The aim is to **study people's everyday life** to see how they use technology and to understand how they act in normal working situations.

Contextual inquiry is a **combination of interview and observation**, although it differs from both of them in a sense that in contextual inquiry the researcher does not control the situation in any way. Usually the researcher tries to get away from the traditional interviewer-interviewee – situation into more natural master-apprentice type of **participative study**. The researcher observes the person's actions and if he has any questions, the person explains why he did something or why things went the way they went.

The two main uses of contextual inquiry are **context and user studies** very early in the product development and **prototype validation**, in which the product prototype is observed in real use environment.

The kinds of things that are studied through contextual inquiry include (Beyer & Holtzblatt 1998):

- Structure and language used in the work
- Individual and group actions and intentions
- The culture affecting the work
- Explicit and implicit aspects of the work

Hackos and Redish give some basic tips for conducting contextual inquiry in their book "User and Task Analysis for Interface Design" (Hackos & Redish 1998):

- Plan. Understand the issues and objectives for the visits.
- Select users to represent the diversity of the group.
- Treat the user as a partner.
- Watch, listen to, and talk with users, usually one at a time, about their work as they work in their own environment.
- Make the conversation concrete. Talk about what the user is doing or just did.
- Take your cues from the user. Share your emerging understanding with the user to make sure you are interpreting what you see and hear correctly.

Typically the contextual inquiry sessions last longer than normal observations and interviews. Getting enough information and interpreting it reliably is a **slow process**. Therefore the contextual inquiry on a specific site can last for several days. This can be a problem, if the product development time is short.

The **main benefit** of contextual inquiry is that it gathers information not only of the users and their tasks, but also their habits, language and working culture. This information is often difficult to find in interviews or controlled observation situations.

The reporting of contextual inquiry results can be challenging. Usually affinity diagrams are created to present the users' working culture and social connections. The task and context information can be presented in the same kind of a report that results from an observation session.

4.3 Probes

A probe is a name for all the methods, which study the users and their use of a product and **don't require interviews or an observer present in the actual use situation**. They are often somewhat "automated" when looked from the researcher's point of view, requiring only the creation of the initial setup. Probes are usually used in situations where the study would take too long to conduct, an observer can't be present or would bias the results or the data gathered is of type what is difficult to collect with observation and interview methods. Some of the probe methods can also be used in very early product concept design to provide inspirational user data.

4.3.1 Diary

Diaries are used to **collect user information from a longer period of time**. They allow data to be captured from everyday tasks without researcher intrusion (Maguire 1997, Faulkner 2000). The user can be asked to document for example a typical working day, certain incidents, the types and severity of errors encountered while doing specific tasks or the usage of a newly acquired product.

The length of the diary keeping period depends on the information needs of the research. If the study centers on the use of a single product that is not used very often, the diary may have to be kept for weeks. If general information on the user's working day or environment is needed, the study can last for a couple of days or a week.

Diaries can vary from open-ended, where the informants write in their own words, to highly structured tick-box forms, where the respondents give multiple choice yes/no answers. The required materials vary from paper and pencil techniques to videotape diaries and online forms. (Maguire 1997)

Maguire presents **guidelines for diary keeping** technique (Maguire 1997):

1. Decide on whether the diaries are to be free for allowing the persons to express themselves freely, or structured with fixed response formats, which will be easier to analyze.
2. If a structured method is used a careful selection of questions and response categories must be produced.
3. Decide how often the respondents should complete the diary e.g. hourly, daily, weekly. This is dictated by the nature of the data needed. Alternatively the respondent may complete the diary after a particular event has occurred.
4. Produce copies of the diary and clear instructions for completing them.
5. Provide a means (e.g. a telephone number) whereby the respondent can check on the diary keeping procedure.

The main **advantage** of diary keeping is that no observer or interviewer is required. The data can be gathered from a long period of time, and therefore can sometimes represent the user's life better than the quicker observation and interview methods.

The **downside** of diary keeping is that the information gathered is only the things the informant wants to reveal to the researchers. Enough information is not gathered, if the questions aren't specific enough or do not cover everything of interest. If the periods between the information recording are too long, some of the probably important pieces of information might be altered or forgotten.

It is usually useful to **go through the diary entries with the informant** after the diary-keeping period is over. By doing this the researchers can clarify any markings that remain unclear and make sure that they understand the events described in the diary the same way as the informant meant. The actual reporting of the findings can be done in form of a report, which can include scenarios, user profile illustrations or user task descriptions depending on the subject under research. If the diaries are not long, they can be included wholly as appendixes to the report.

4.3.2 Use logging

In use logging a computer or other electrical device collects the input it has received for analysis. Usually the information extracted from the data is the **frequency of various operations** of interest (Nielsen 1993). By charting the use of different functionality it's possible to see which features are the most used and should be therefore be concentrated on. It's also possible to see frequencies of error states and the less popular parts of the product from the statistics gathered.

Typically use-logging software can be divided into **time-stamped keypress logging** and **interaction logging**. In time-stamped keypress logging every single command is recorded with the exact time of the event. Interaction logging is otherwise the same, but is recorded and played back in real time thus enabling the researchers to see the interaction just as it happened. These two use logging methods can be combined with other recording techniques such as video taping and voice recording to gather more versatile data. (Preece 1994)

Use logging **only tells what the users did, not why** they did that. This is why use logging should sometimes be combined with post-use interviews based on the statistics generated. (Nielsen 1993)

The most important thing to remember in logging user's activities is that the user always has to be informed that the logging is taking place. On the other hand the knowledge of use logging can introduce a **bias** to the study: when the users know that they are being monitored they may change their behavior. This is the same issue as with observations (see subsection 4.2.1). (Faulkner 2000)

Another **difficulty** of use logging is the very large amount of detailed information. The analysis of all the data gathered can be very slow and it is often difficult to find the relevant bits of information. A good solution to speed up the analysis is to use computers to find out the interesting data. Another important issue in dealing with the huge amounts of data available is deciding beforehand what is important to include in the logs and what's not. (Faulkner 2000)

Use logs are **best documented in a form of a table**. The form of the table depends on the data needs, but usually the table shows different functionalities and their use frequencies. The table can be sorted in different ways to point out various areas of interest.

4.4 Task analysis

Hackos and Redish define task analysis in their book "User and Task Analysis for Interface Design" as "understanding the work users do and how they do it" (Hackos & Redish 1998). By understanding the user's working habits and product use it's possible to design products that support user's goal achievement and mental models better.

In task analysis the user's **goals**, **tasks** and **activities** are studied (Preece 1994). Users of a product have goals, which they try to fulfill by choosing tasks to do with the product. Each task is built of subtasks and activities. This structure researched in task analysis can be seen in figure 13. Task analysis tries to describe and explain these three levels of human behavior in different product use contexts. It is a current-status analysis, which tries to find ways to improve on the present situation.

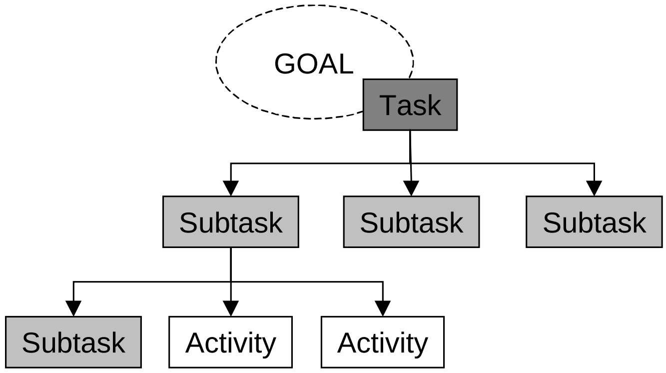

Figure 13: Tasks, subtasks and activities in task analysis

Hackos and Redish argue that the task analysis is best conducted in top-down fashion, so **user goals are addressed first** (Hackos & Redish 1998). This can be done by a number of observational, interview or probe methods. Goals can be identified on many levels of detail. It's important to find the goals on the right granularity – not too specific but not too general. The granularity is decided on a case-by-case basis.

After the user's goals are understood and the tasks related to them are decided it's time for actual task research. There are many types of task analysis depending on the focus of the study (Hackos & Redish 1998):

- **Workflow analysis:** how the work gets done when several people are involved.
- **Job analysis:** what an individual does throughout the day or week or month.
- **Combining workflow analysis and job analysis:** how workflow analysis interacts with job analysis.
- **Task lists and task inventories:** what tasks are performed by all the people who might be using the product.
- **Process analysis, task sequences:** the order in which to do tasks.
- **Task hierarchies:** how a large task is made up of subtasks.
- **Procedural analysis:** what steps and decisions users take to accomplish a task or a part of a task.

Workflow analysis aims to the understanding of how a particular process is accomplished if several people are involved. It shows who does what in each step of the process. The aim is to find any redundancies and unnecessary steps in the current process and to understand who is involved in what and what everyone's goals are in the process. If a task analysis is done by looking at just one part of the workflow process there is a risk that the product is incompatible with the rest of the process. Tasks, which require reorganization by assigning the work differently are easier to modify after a workflow analysis. (Hackos & Redish 1998)

Job analysis aims to understand a single person's work during a day, week or a month. By job analysis a picture of person's tasks over a longer period of time is gained. In comparison to the workflow analysis the job analysis goes deep into one person's work, while workflow analysis is a shallower look into how the work moves across people. A job analysis is best conducted with observational methods, which enable the researcher to study the person in her natural environment. If observation is not possible, probes are to be considered. Interesting factors besides what tasks the user does and how the tasks are accomplished are (Hackos & Redish 1998):

- Frequency: how often do these people do each task?
- Criticality: how important is each task to their job?
- Time to complete: how time consuming is each task?
- Difficulty: how much of a problem is accomplishing this task?
- Division of responsibility: do all the people in that job do this task? Do different people with the same job title do different tasks?

Combining workflow analysis and job analysis means that in practice both workflow and job analysis are needed in the final task analysis. Typically the workflow analysis is done first, and when the persons involved in the work are clear their jobs are studied in more detail by job analysis. (Hackos & Redish 1998)

Task lists and inventories are created by studying what user tasks found in job and workflow analyses concern the developed product's functionality. The lists tell the designer what the users have to be able to accomplish with the product, but not how the tasks are done. The user's task list should drive the decisions on the product's functionality. While generating a task list it's best to start by listing the main tasks. Later when planning the design the tasks are broken into smaller units. The same factors as in job analysis are important in creation of task lists as well. (Hackos & Redish 1998)

Task sequences tell in which order the actions or subtasks in a task are taken. Normally the users do things in different order and take steps, which are not logically necessary. While studying task sequences it's important to find out if the tasks are always done in the same order and why. If different users do the same task differently it's useful to find out how important flexibility is to the system. It's also important to notice if users always perform a task in a same way. (Hackos & Redish 1998)

The two remaining task analysis types are the most common in literature and most down-to-earth. **Task hierarchies** are tree structures (see figure 13) or flow charts consisting of tasks, their subtasks and activities. They are created by dividing the job at hand to tasks and then dividing the tasks into smaller subtasks and activities. The problems associated with hierarchical task decomposition concern the level of detail used in the analysis. The granularity of the decomposition has to be decided on case-by-case basis. The most important thing is consistency – every task should be decomposed to the same base level. (Hackos & Redish 1998)

Finally, the **procedural analysis** goes deepest to the structure of an individual task. It describes the decisions and steps the user has to take while performing a specific task. Procedural analysis differs from the other task analysis types by taking the current user interface into account while describing the task procedure. The analysis shows *how* users complete the task under inspection. It can be used to show the idealized way of doing the task with the current equipment, or the observed real task completion. (Hackos & Redish 1998)

All the task analysis types use basically the same base methods: **probes, interviews and observations** (Jeffries 1997). Especially observational methods are very important, since the actual work can differ from what informants tell in an interview (see subsection 4.1.4). Probes are useful in job analysis if user information from a longer period is required.

The interview structure by Nielsen et al. presented in subsection 4.1.1 can be used as a guideline in conducting task analysis of a single task. Faulkner also presents a useful task analysis procedure, which concerns mostly task sequence, task hierarchy and procedural analysis (Faulkner 2000). The procedure can be seen in Appendix A.

Preece argues that there lies a **danger** in concentrating too much on analysis of the current situation. There is a possibility that the designers become too acquainted with the present solution that they can no longer see other possibilities and are more reluctant to change (Preece 1994). A task analysis can also be time-consuming and slow to conduct.

Task analysis documentation is usually a **task analysis report**. It should include short descriptions of relevant users, their goals concerning the system designed, current task lists, task decomposition into task hierarchies and procedural analysis of the current ways of completing the tasks. At least the latter two are best presented in a form of a chart.

4.5 Guidelines

Jakob Nielsen describes guidelines as ”Guidelines list principles for user interface design, which should be followed in the product development project” (Nielsen 1993). In other words **guidelines mean all the documentation which gives advice for user interface design**. Guidelines differ from user interface standards by offering higher level advice on interface design while standards often dictate how an interface should appear to the user (Nielsen 1993). Guidelines aim to increase good design practices as well as product user interface consistency both within the company and with other manufacturers' products. They must be interpreted on case-by-case basis to fit the current design situation.

As stated in subsection 3.2.2, guidelines can be divided into **general**, **category specific and product specific**. General guidelines are typically collected in the user interface community. Some category specific guidelines can also be found from research literature, but more commonly from company documentation and previous projects. Product-specific guidelines can be formed by competitor analysis or during the product development or testing phases. (Nielsen 1993)

Preece divides guidelines into **design principles** and **design rules** (Preece 1994). Principles are more general and offer high-level advice. An example could be Nielsen's usability heuristics (see subsection 4.8). Design rules are instructions that can be obeyed with minimal interpretation by the designer.

Typically guidelines are used in either as **advice during the design** of a product or as a **checklist during the user interface evaluation** (see subsection 4.8). Usually the same set of guidelines can be used in both situations.

The main **advantage** of guidelines is that they are often flexible and can be adapted to multiple situations. This can also be seen as a disadvantage: the adaptation requires expertise and proficiency in HCI (Hix & Hartson 1992).

4.6 Task communication tools

Task communication tools are methods used to communicate the user tasks to people outside the interface design team and to clarify them inside the team. The term “task communication tool” developed during the writing of this thesis to describe the tools used in telling other people what the designer has in her mind.

Task communication tools can be used to present the user interview or observation results, or as parts of usability evaluations to assess the task flow suggestions the designers have created.

Task communication tools elaborate the user tasks by placing them into actual, real life context or describe them in a structured and detailed way. The way of representing the tasks depends on the audience and the phase of design process.

4.6.1 Scenarios

Scenarios are stories created to **describe the user tasks and the context of use**. They are made very **concrete** so that the situation is made as easy to emphasize with as possible. Their purpose is often to **provoke conversation** on the activities the user has to engage in while doing the task described.

Jakob Nielsen describes a scenario to be a description of (Nielsen 1993):

- An individual *user*

- using a specific set of computer *facilities*
- to achieve a specific *outcome*
- under specified *circumstances*
- over a certain *time interval*

John M. Carroll describes scenarios as follows: “The scenario identifies the person as having certain motivations toward the system, describes the actions taken and some reasons why these actions were taken, and characterizes the results in terms of the user’s motivations and expectations.” (Carroll 1997)

Typical uses of scenarios include usability tests, where users’ tasks are given to them in the form of scenarios, and different types of interviews in which the scenarios can be used as a basis for conversation. They do not necessarily have to be in written form – other typical forms include storyboards, cartoons, series of photographs and even small plays. The level of detail can also vary. In the beginning of product development scenarios are typically more vague than the scenarios used in usability tests or other interface reviews.

The **advantage** of use scenarios in comparison to only using the product’s technical specifications as a basis for conversation is that they are more easily comprehended and commented. They make the use of a product concrete and less abstract and show the action from the user’s point of view. In usability tests this makes the user feel more natural while doing the tasks given.

On the other hand a scenario **can only present a fairly small portion of system functionality**, and not in very great detail. Therefore they are not very good in describing system specifications or other technical details. Use scenarios are best used in early product development to explore ideas or later when communicating design solutions outside the design team.

4.6.2 Use cases

Use cases are in a sense **generalized scenarios** describing user tasks put into specific and more structured format. They are a part of Unified Modeling Language, UML, which extends the whole software production lifecycle. In UML the use cases serve as the basis for computer systems design.

Use cases describe how a system interacts with users and other systems. It has two parts: the **use case diagram** (see figure 14) and the **use case** in textual form. The use case diagram shows the primary actors on the left side of the diagram and the secondary, supporting actors on the right side. Each scenario is represented as an oval. The scenarios are arranged from left to right in order of their typicality. Only the common cases are represented in the diagram, exceptions are handled by other diagrams and the textual description. The arrows show, which scenarios are included in each other.

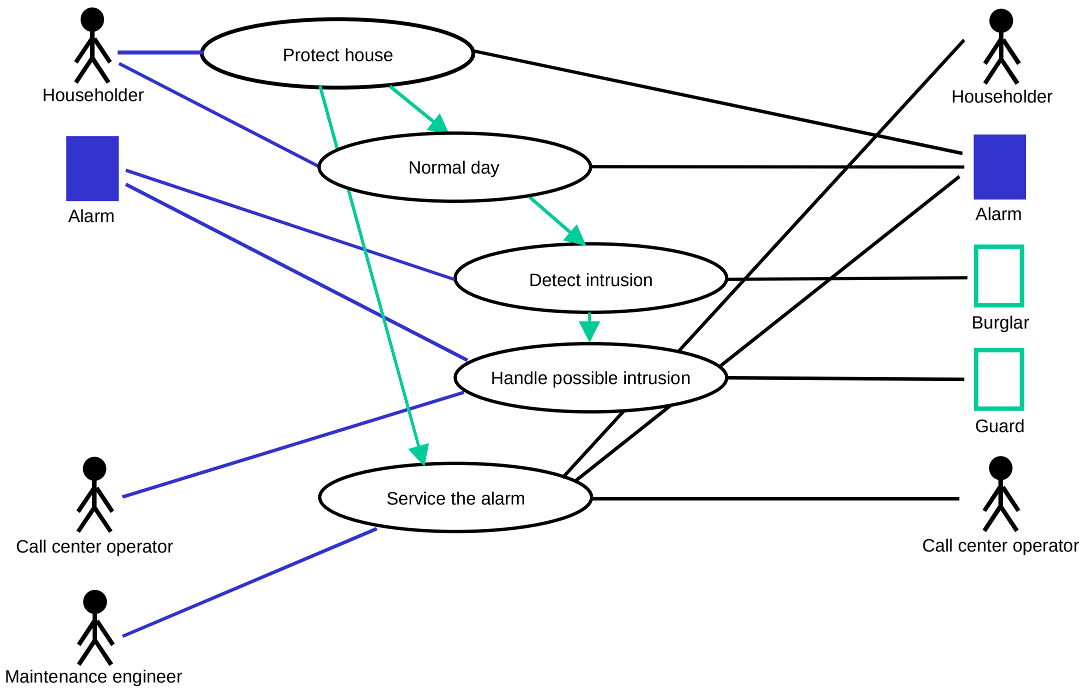

Figure 14: An example of a use case diagram (Alexander 2001)

The textual descriptions explain each use case in more detail. The **Cockburn format** of representing use cases Alexander suggests in his article includes (Alexander 2001):

- The primary scenario - what is normally done, task flow
- Alternative paths to complete the scenario
- Exceptions to normal routines
- Constraints
- Trigger – what causes the scenario to happen
- Preconditions – what conditions are required for the trigger to work
- Minimal guarantees – what can be said for sure of the activity in the scenario
- Stakeholders and interests
- Success guarantees – what things combined indicate the success in the scenario

Ivar Jacobson et al. suggest the following way of generating use cases (Jacobson et al. 1994):

1. Define the actors.
2. Pick one of the actors.
3. Define what the actor wants to do with the system. Each task will be a use case.
4. Define a “normal” way of doing the task for each use case.
5. Describe the basic way of doing the task in detail.
6. Add the alternative ways of doing the task.
7. Compare the use case to other use cases. Combine the activities by using “extends” and “uses” –notation.
8. Repeat 2-7 for each actor.

Use cases are a good basis for beginning the software design. They are more clearly specified than scenarios. Some programming tools, which use UML can create some of the program structure based on the use cases.

The main **drawback** of use cases is that they often focus too much on the software system and user activities. This often leaves too little attention for user context and characteristics. While using use cases it's easy to make up general use cases and forget to study the real users. Another problem is the question of granularity - it is not clearly defined how high or low level descriptions the use cases should be. (Muller et al. 1997)

4.7 Prototyping

While scenarios and use cases can be serve as tools for communicating user tasks, prototypes can be seen as user interface communication tools. They can be used to demonstrate design ideas either within the design group, to the upper management or to the users. Prototypes can be used in usability evaluations (see subsection 4.8) and sometimes in contextual inquiry (see section 4.2.2).

Houde and Hill point out that the most important aspect of a prototype is the purpose it's built for (Houde & Hill 1997). They have constructed a triangular model of different uses of prototypes, which can be seen in figure 15 below. Before any prototype is built, its purpose should be clear.

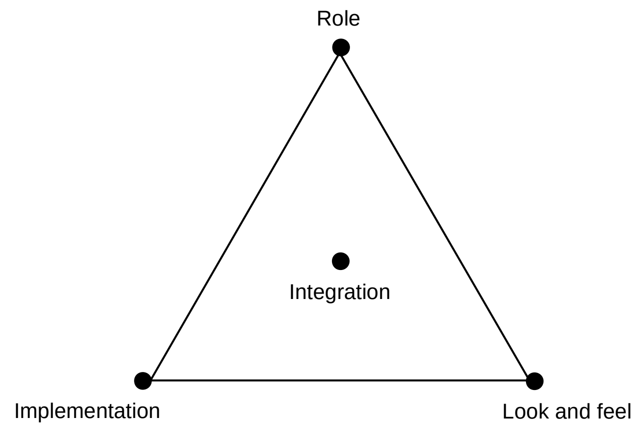

Figure 15: A model of what prototypes prototype (Houde & Hill 1997)

Role prototypes are those, which are built primarily to investigate questions of what a product could do for a user. They describe the functionality a user might benefit from. Role prototypes can sometimes be close to scenarios or storyboards. **Look and feel prototypes** are built to simulate what the product would be like to look at and interact with. They focus on giving the right experience of the product designed. **Implementation prototypes** concentrate on technical questions on how a future product can be made to work. **Integration prototypes** are built the present the whole user experience of the product. They are used to verify that the design is complete and coherent. (Houde & Hill 1997)

Usually prototypes are divided to **high and low fidelity** depending on how close they are to the final product. Low fidelity prototypes usually model one or few of the product's features and do not necessarily run on a computer system or look like the final product. High-fidelity prototypes are usually implemented with computers and resemble the final system in most of their aspects. Jakob Nielsen presents yet another division of prototypes by dividing them into **horizontal and vertical** prototypes (Nielsen 1993). Their descriptions can be found in section 3.2.2 under the discussion of prototyping phase.

The most common types of prototyping are non-functional mock-ups, paper prototypes and functional prototypes. **Non-functional mock-ups** are created to study and communicate the physical dimensions, weight and ergonomics of the product, so they are typically look and feel prototypes. They can be of either high or low fidelity.

Paper prototypes are low-fidelity prototypes that can be used even in the very early product development. Their functionality is based on hand drawn or printed sheets of paper, which are presented to the prototype users according to the their choices of action. The advantages of paper prototypes are (Hackos & Redish 1998):

- They cost little to produce.
- They are fast and easy to create and change.
- They lend themselves to easy creation of alternatives.
- They require only tools everyone knows how to use.
- They work well to show "proof of concept" and to explore metaphors.
- They allow everyone on the team to participate in creating the prototype.
- They may encourage more suggestions because they seem more changeable.

The disadvantages of paper prototypes are (Hackos & Redish 1998):

- They usually only show some of the final functionality.
- What is sketched may not be possible in the final technology.
- Eventually they will be thrown away.
- They require a human facilitator to mimic what the computer will do.
- The paper versions may lack "face validity" to users, they may not be taken seriously enough.

Functional prototypes are usually high-fidelity prototypes that are created with computers. They are used in later product development, when the basic user interface structure and layout is already tested with lower fidelity prototypes. Their advantages are (Hackos & Redish 1998):

- Users can work with them directly.
- They often cover more tasks or functions than low-fidelity prototypes.
- They look and feel more like the final product.
- If done in a tool that feed directly into code, they show what is feasible in the final product.
- They can be used by marketing and sales demonstrations of the product.

Their disadvantages are (Hackos & Redish 1998):

- They are more expensive to build.
- They are more time-consuming to build.
- They require knowledge of a prototyping tool.
- They may raise unrealistic customer expectations of how soon they can have the product.

4.8 Usability evaluations

This section addresses the usability evaluation methods. They are commonly divided into two types: **usability inspections** and **usability tests** (see figure 16). Usability inspection means that usability professionals or other knowledgeable personnel test the prototype whereas usability tests are conducted with the help of the actual users.

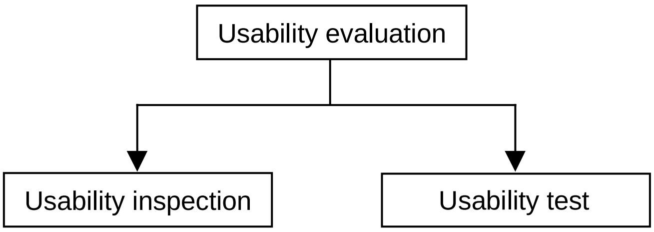

Figure 16: Division of usability evaluation into inspections and tests

Usability evaluations should be used through the entire product development process to ensure the right design choices from as early on as possible.

4.8.1 Usability inspections in general

Usually usability experts perform the usability inspections. The inspections are usually fast to conduct and they produce fairly good results, depending on the evaluator's expertise. Usability inspections can be done to very low-level prototypes, even sketches of the user interface.

Even though the usability inspection methods are used, the usability of the product should always be assured with tests with actual users. Usability tests are discussed in more detail in subsection 4.8.4.

The most common types of usability inspections are **heuristic evaluations** and **cognitive walkthroughs**, which are described in the following subsections.

4.8.2 Heuristic evaluation

In heuristic evaluations the product or system is checked against a specified set of interface design guidelines or usability heuristics. A usability expert usually chooses the heuristics and does the evaluation. The heuristics can be general or case-specific. The most common set of heuristic rules is Jakob Nielsen's ten usability heuristics (Nielsen 1993):

1. **Simple and natural dialogue**

   The user interface should be simplified as much as possible. The interface structure should also match the users' task in as natural a way as possible to minimize the users navigation efforts.

2. **Speak the users' language**

   The interface terminology should be based on users' own language. System oriented and other unfamiliar terms, symbols, metaphors and ways to present information should be avoided.

3. **Minimize user memory load**

   Interfaces should be based on recognition rather than recall. An interface should be designed in a way that it doesn't require remembering difficult rules or commands.

4. **Consistency**

   The information and commands should be presented always the same way to facilitate recognition. Consistency includes layout, functionality, tasks and other similar interfaces.

5. **Feedback**

   The system should continuously inform the user what it is doing and how it is interpreting the user input. Good feedback includes short response times and is in proportion to the importance of the action being done.

6. **Clearly marked exits**

The system should offer an easy and clearly visible way out of as many situations as possible. An exit can be for example an undo-option or a cancel button.

7. **Shortcuts**

   The system should give an advanced user an opportunity to perform frequent operations especially fast by using shortcuts. Shortcuts include for example hyperlinks, shortcut keys, default values and bookmarks.

8. **Good error messages**

   Good error messages are written in clear language, precise, constructive and polite. System should also provide good means for error recovery.

9. **Prevent errors**

   The number of situations a user can give false input to the system should be minimized. Especially modes are often confusing and should be avoided.

10. **Help and documentation**

    Provide good task-related search capabilities and in case of online help context sensitiveness. Keep the documentation simple enough to be easily understood.

Ben Schneiderman presents his own eight golden rules of interface design in his book “Designing the User Interface” (Schneiderman 1998). Their substance is virtually the same as Nielsen’s, only some minor differences can be found.

As can be seen from the list of short descriptions of the heuristics above, heuristic evaluations often **rely heavily on experts’ own judgement**. With just one person evaluating it’s not likely that all the usability problems are found. Because of this Nielsen suggests that at least three independent evaluators should be used. With three evaluators approximately 65% of the usability problems will be found (Nielsen 1993).

The main **benefit** of this method is that it is cheaper and less time consuming than performing actual user tests. Nielsen classifies heuristic evaluation to be a “discount usability method” (Nielsen 1993), because of its speed a relatively good performance in finding most of the bigger usability problems.

Usually the evaluations are done first individually. After that all the results are combined and the problems prioritized together. Each problem is described and the related heuristics are written down. The result of heuristic evaluation is an **evaluation report**, which includes a problem description, heuristics violated and a severity rating for each problem. It is usually best viewed in table format with pictures of the user interface problem areas.

4.8.3 Cognitive walkthrough

Cognitive walkthrough is an analysis method that focuses on ease of learning by exploration (Riihiaho 2000, Polson et al. 1992). It is a form of a use simulation, in which **typical user tasks are studied by determining a correct action sequence and asking if first time users would actually follow it**. The analysis considers both user characteristics (for example background knowledge) and user interface to find usability problems. Typically the findings consist of mismatches between users and the designers understanding of the task, poor presentation of cues or lack of feedback. (Lewis & Wharton 1997)

The **main benefit** of cognitive walkthrough is that only a rough specification of the interface is required: user characteristics and the context of the task play a bigger role in considering the users’ mental processes (Riihiaho 2000).

Generally the cognitive walkthrough can be divided into three phases: preparation, analysis and interpretation of results. In **preparation phase** user background and knowledge as well as most representative tasks and their context are studied. Then the action sequences to complete the tasks are recorded and user interface description or prototype is acquired. (Lewis & Wharton 1997)

During the **analysis phase** the usability experts comment on sequences of actions that user have to execute to accomplish certain tasks. If problem with an action is found it is recorded but the sequence continues as if nothing had happened. (Riihiaho 2000)

In the analysis session the evaluator goes through a set of four questions in each step of activity: (Lewis & Wharton 1997, Riihiaho 2000)

1. **Will the user try to achieve the right effect?**

   Does the user divide the task into similar actions as the designer has assumed?

2. **Will the user notice that the correct action is available?**

   Is the user able to perceive the controls required or otherwise know what to do?

3. **Will the user associate the correct action with the desired effect?**

   Are the labels, icons and terminology clear to the user?

4. **If the correct action is performed, will the user see that progress is being made?**

   Is the feedback of the action sufficient?

Polson et al. have created forms to support cognitive walkthroughs (Polson et al. 1992). The forms can be seen in Appendix B. They offer more detailed questions to find problems related to establishing goals, choosing and executing the action and system feedback.

The **downside** of cognitive walkthroughs is that they can't be used to test a whole system with lots of functionality. The evaluation concentrates only on the most important user tasks. Cognitive walkthrough is a narrow method also in a sense that it concentrates on learnability alone. On the other hand it can be one of the most important usability aspects.

A result of a cognitive walkthrough is a list of all the steps of a task with the four questions above commented and assumptions about users' needed knowledge, possible mistakes and design change suggestions commented (Riihiaho 2000). The forms in Appendix B also serve as a basis for reporting the results as they give very specific questions to answer. Typically the main results of cognitive walkthrough are discussed in a **report**, accompanied with the detailed walkthrough results (see Appendix B) as appendixes.

4.8.4 Usability test

Usability evaluations **involving actual end users** are referred to as usability tests. The participating users do test tasks with the product prototype while the testers observe their progress and record any problems found. Usability tests are usually conducted with one user at a time, although paired tests are also possible.

A usability test normally includes instructor-given tasks for the users to accomplish. The participants are instructed to **think aloud** during the test to get the information on why they do the activities they do. After the tests the usability problems the user encountered are diagnosed and change proposals are recommended.

Usability tests are often very successful in finding the most relevant usability problems. Jakob Nielsen writes about usability tests: "User testing with real users is the most fundamental usability method and is in some sense irreplaceable, since it provides direct information about how people use computers and what their exact problems are with the concrete interface being tested" (Nielsen 1993). The main **downside** of usability testing is the amount of work and time needed.

A typical and effective way of conducting usability tests is a ten-step process (Hansen 1991):

1. Get the background information about usability evaluation

2. Make a test plan
3. Design the test
4. Arrange a test environment and equipment
5. Conduct a pilot test
6. Recruit participants
7. Set up the test room
8. Conduct the test
9. Compile and analyze the test results
10. Recommend changes

The purpose of the **test plan** is to get the management and other people involved, and to organize and clarify the goals of the test (Hansen 1991). It should include the purpose and objectives of the test, user profiles, used methods, user tasks and scenarios used, test environment and equipment, the role of the administrator, evaluation measures (i.e. the data to be collected) and a report content plan (Rubin 1994). The purpose of the test can be either a **formative evaluation**, in which usability problems are sought, or a **summative evaluation**, in which the interface performance is measured against preset usability goals or requirements (Nielsen 1993).

The core of planning a usability test is the creation of test tasks according to the goals of the test and typical user tasks. The test tasks are resented to the user in the form of **scenarios** (see subsection 4.6.1). In the scenarios only the present state things and the goals are given. If a formative usability test is planned the scenarios usually represent the most typical user tasks, while in summative evaluation the scenarios are written to test the user interface against the usability goals specified in the test plan. Typically a usability test is a mixture of both the evaluation types.

Usability tests can be conducted in usability laboratories or in the field. The test context should be as realistic as possible, because in unnatural conditions some usability problems related to the context of use can remain unnoticed thus biasing the evaluation results. It's best to videotape the entire test to ensure that every relevant detail of the test is analyzed. Other backup recording equipment should also be considered.

Before the actual usability tests a **pilot test** should be conducted. The goals of the pilot test are to test the equipment and the test tasks, and to get an estimation of the duration of each task and phase of testing (Riihiaho 2000). In the pilot test the whole test is done with a single user to make sure everything works as planned. The pilot user doesn't have to belong to the user group the product is designed for. To have time to make necessary changes the pilot test should take place at least two days before the actual tests (Dumas & Redish 1993).

Nielsen suggests that the most efficient number of test users is 5 (Nielsen 2000). This is because after five usability tests only about 15 percent of the usability problems remain undiscovered. The problems remaining are usually minor, and it would require as many as 15 usability tests to find them all, which is usually too costly and time consuming. The amount of usability problems found versus the number of test users is illustrated in figure 17.

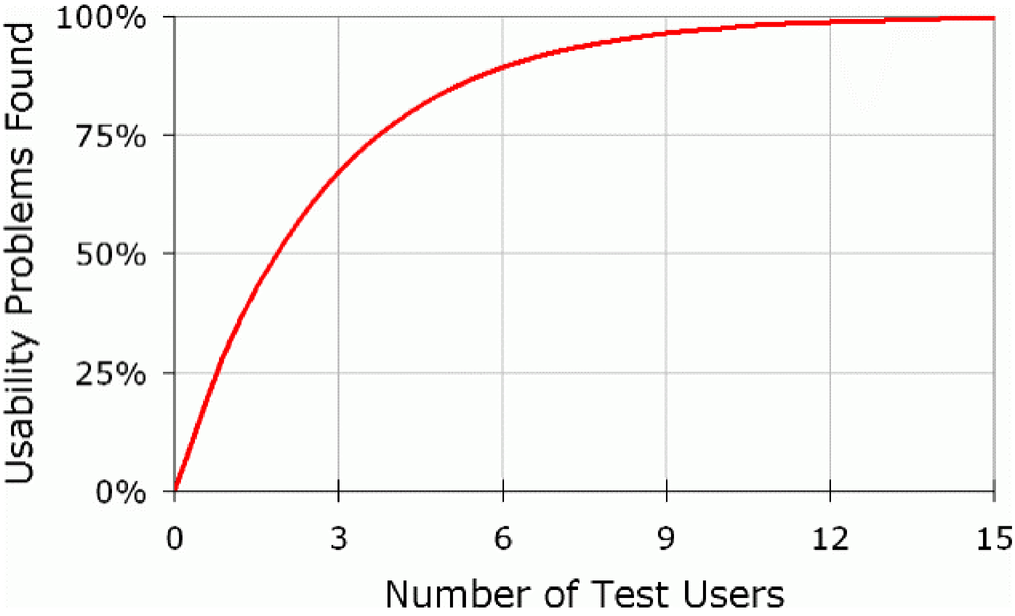

Figure 17: Amount of usability problems found with different numbers of users (Nielsen 2000)

Jakob Nielsen describes a usability test to have four phases: preparation, introduction, the test itself and debriefing (Nielsen 1993). In **preparation phase** the experimenters should check that the space reserved for testing is ready and that all the required test materials are available. During the **introduction phase** the experimenter welcomes the test user and gives an explanation of the test situation. Typical things to mention in the introduction are (Nielsen 1993):

- The purpose of the evaluation is to test the product, not the user
- The experimenter hasn't designed the product (if that is the case)
- The test data is used to improve the design
- The test and the product prototype are confidential
- The test is voluntary and can be stopped at any time
- An explanation of any recording equipment present
- User has a permission to ask questions, but the experimenter will answer some them only after the test
- Usability test specific instructions, such as explanation of thinking aloud or working as fast as possible

The **actual test** is conducted by giving user the scenarios one by one, preferably in both written and oral form. The users do what the scenario wants them to do and state when they think the task is finished. This is continued until all the scenarios are gone through. During the test the experimenter usually refrains from interacting with the users and tries not to help them in any way. The user should be helped only when he is stuck and getting unhappy with the situation (Nielsen 1993). The amount of assistance should be minimized to only getting the user unstuck. Observers and other personnel present the test should not interfere with the test at all.

After the test the user is debriefed in a form of a free conversation. During the discussion the user is asked about events during the test that the experimenter and the observers did not understand. The user is also free to comment anything on the interface and come up with design improvements. Usually some form of questionnaire (see subsection 4.1.3) is used to get feedback from the test and the interface.

It is important to realize that usability tests are conducted with real people. Ethical guidance for usability tests (Nielsen 1993) is provided in Appendix C.

The outcome of this method is a **usability test report**, which usually includes (Dumas & Redish 1999):

- **Executive summary**, which covers the product tested, goals and the major findings as well as the business case for fixing the findings.
- **Description of the test**, which covers the product tested, test dates and schedules and who did the tests. Descriptions of participants, tasks and methods used as well as the goals of the tests are presented.
- **Summary of the results**, which describes the main findings of the tests. The data from post-test questionnaires as well as the findings in the study are summarized in few pages of tables.
- **Findings, explanations and recommendations**, which form the bulk of the report. Explanations to findings and supporting data are presented as well as recommendations for corrections.
- **Appendixes**, which include the scenarios, questionnaires and data from the questionnaires.

Another, more detailed usability test report example can be found from ISO 13407 standard (ISO 1999).

4.8.5 Comparison of usability inspections and usability tests

In addition to the fact that the evaluators differ, the difference between usability inspections and tests is that they produce different types of results. Testing with users gives understanding on real users' task and understanding related problems in contrast to the more general usability related issues found in the evaluations made by experts. This doesn't mean that usability inspections are less valuable than usability tests, they are meant for different uses. Usability inspections are faster and easier to conduct in comparison to the sometimes time consuming user tests. *Both evaluation methods should be used in parallel to achieve the best results.*

5 The current UCD process and methods

This chapter describes both the research done to understand the usability engineering activities and the current process model at Datex-Ohmeda and the description of the current activities. The new process model based on the theory part and the current state described here can be found in chapter 6.

The first section is about the current state research. It describes what was done to collect the data presented in the rest of this chapter. After the research section the usability related issues are discussed in a general introduction, and after that the current process model is presented and commented. Finally Datex-Ohmeda usability engineering methods and maturity assessments done so far are discussed.

5.1 Research on the current UCD activities

The research on the current usability engineering activities had two phases: gathering the required information and analyzing the data. In the following these two phases are introduced.

5.1.1 Gathering data on the current situation

The information gathering phase was the most important, because all the following analyses and some parts of the new process model were based on it. The idea was to find out as much as possible on the current practices as well as the ideal way of doing things.

The gathering phase consisted of two parts, research on current usability methods and UCD process model.

Usability methods

The study started with a collection of material concerning usability methods from all the Datex-Ohmeda sites. The **usability practitioners from all company sites were asked to list all the usability engineering methods that they had used** in their recent projects. Päivi Roiha, the global usability manager of Datex-Ohmeda, did the inquiry. In addition the Datex-Ohmeda sites delivered material on the methods they had listed, mainly study reports. The collection of reports was not thorough, but enough information was collected to ensure the understanding of what is done at the moment.

Method source material was also gathered from the Datex-Ohmeda **usability methods database**. Basically all the methods mentioned in the inquiry were also described in the methods database. It offers mainly theoretical and brief descriptions of the methods, and doesn't help much in understanding the actual usability activities taking place at Datex-Ohmeda.

The third way of gaining knowledge on usability methods were **interviews** of company's usability personnel. The interviews were used mainly as secondary tools to clarify the thing left unclear from the material given. The interviews were often concentrated on one topic at the time, and were of very informal nature. Although they were first intended to be only the clarifying method, they proved to be a good source of information on practical issues.

Usability engineering process

The current process model was first researched by studying the **usability engineering process database**. It introduces the phases of the user-centered design process in Datex-Ohmeda by providing a diagram of the company's UCD process and describing them shortly. After the independent study period a company's usability professional explained the process model and the usual practices in its implementation in an **introductory interview session**. A usability engineering process training slide show for project managers was also introduced in the interview. The unclear parts discovered later were also clarified by **short interviews** or inquiries among the usability professionals.

The current user-centered design process model includes references to product review sessions, which linked the usability engineering process activities to the other product development efforts. The reviews and Datex-Ohmeda product development process were included in the study, because the reviews were linked to process phases dictated by FDA's design controls. The reviews and their explanations were researched by reading the Datex-Ohmeda **product development process database**.

5.1.2 Analyzing the data on the current situation

The analysis phase overlapped partly with some of the data gathering described in the previous section and new UCD process development, because the process model development process itself was iterative. This phenomenon can be seen in the process descriptions in the following.

Usability methods

As stated in section 1.1, the **aim was in clarifying the current use of the methods**, not in inventing new techniques. Thus the analyzing process started by looking at the usability engineering methods currently in use. In the first phase the methods material consisted of the results of the inquiry: a one sheet of paper listing all the usability engineering methods used in different company sites, and the documentation of the methods if the site had sent any.

The **items of the methods list were first arranged** to find groups of similar techniques. By reviewing the descriptions of the similar-looking methods they were combined into larger units. In practice this was done by cutting the sheet of paper into strips that contained one method each, and combining them to post-it notes to groups of similar methods. The post-it notes were then labeled to match the contents of methods put to them. For example a post-it note labeled "Interviews" contained following strips:

- Questionnaires (Finland)
- Interview clinicians and managers (Sweden)
- Casual interviews-questionnaires (Sweden)
- Field (user) interviews (U.S.)
- Interviews (Finland)

By this first step, the number of different methods was reduced to nine groups, with about two or three "sub-methods", which were combined from the strips on the post-it note. For example the "Interviews" group contained two items: "Questionnaires" and "Personal interviews". Later on after talking to usability team members "Focus group" was added under the "Interviews" – group. Usability meta-methods, for example "Usability goals" and "Usability engineering plan", which were usually inputs or outputs of usability engineering methods, were discarded from the methods study at this point.

The next step was the study of the methods documentation and the user interface database and conducting a **literature study**. During this phase the methods were somewhat rearranged while some new groups of methods arrived and some disappeared. For example in the participatory design -method group was considered to be an always-ongoing practice rather than a single method.

Some of the methods under participatory design, use scenarios for example, were moved to a new group called "Task communication tools" to better describe them. Some new methods, for example use cases, mentioned in the interviews were also added.

"Competitor evaluation" and "Feedback analysis" were considered at this point not to be strictly usability methods, although they were so far treated as such. No clear descriptions of them were found from the literature from the usability point of view. They were still included in the study as important activities of the usability personnel, but not described with the other methods in chapter 4.

The literature study completed the methods analysis. After this phase the methods were integrated to the process model, and the combination was considered as a whole after that. The full list of currently used methods at Datex-Ohmeda can be seen in section 5.4, and the final methods recommended in chapter 6.

Usability engineering process

The process model analysis was much more straightforward than the methods study. After studying the Datex-Ohmeda Usability engineering process database and hearing the presentation it was quickly clear that the process model itself was a quite straightforward application of ISO 13407 (see Table 1 in section 5.3).

The biggest unfamiliar aspects were the connections to other product development processes through review sessions. The reviews were the results of applying the FDA design controls, and therefore they needed to be researched to meet the regulatory requirements. **In this way the scope of the work had to be redefined** to include also the necessary connections with the rest of the development process (see section 1.1 for the original scope of the work). These reviews were only studied to understand their purpose and effect to the UCD process.

As said in section 1.1, the objective of the research was on finding things to be improved in the current process model. The things to improve were identified after the interviews of the usability professionals. Some of the comments came as late as when the first prototype of the process model was introduced (see subsection 6.1.1), some were brought forward in interviews and conversations with the company's usability personnel before any process model creation work was done.

The results of the usability engineering process analysis can be found in section 5.6, after the following description of the current usability activities at Datex-Ohmeda.

5.2 Usability at Datex-Ohmeda

Usability engineering has a long tradition in Datex-Ohmeda. Company-wide usability efforts started in the late 1980's, and since then usability has become a standard part of every product development process. Nowadays the company has a **defined usability engineering process** and **databases** for usability methods, user and environment profiles and usability study reports. Usually the **product development times are fairly long**, typically from several months to years, which leaves time for usability activities.

Every Datex-Ohmeda project has at least one defined **usability specialist** who is in responsible for all the usability work done during the project. The usability professional acquires help from the other project team for usability testing and other purposes, which require more than one person. **The user interface created by one usability professional is always reviewed by at least two others** to ensure that the design is consistent and usable. For information on design reviews in Datex-Ohmeda see subsection 5.3.5.

The usability professionals of Datex-Ohmeda also **participate in the standardization** of medical device development related usability procedures. The company is involved in the creation of the upcoming IEC 60601-1-6 standard (IEC 2002), and requires its UCD process model to conform to it even though the standard isn't finalized yet. The company has also been represented in the developing committee of AAMI HE74:2001 standard. The IEC and AAMI UCD standards are briefly introduced in subsection 3.2.4.

The user and context studies done don't need to be tied to product development. The usability specialists of Datex-Ohmeda may visit hospitals and observe health care personnel even though there is no current project on for the type of environment they are studying. The data gathered is stored to environment and user databases for later reference.

Usability work in Datex-Ohmeda is characterized by a large number of **clinical specialists**, nurses, and **medical advisors**, physicians, which advice the product development team on medical issues. Usually all the material going to the users is created with or at least checked by a medical field professional to ensure that the facts are right. For example usability test scenarios and interviews are checked by the clinical specialists or medical advisors.

The usability group of Datex-Ohmeda is divided into three countries: Finland, Sweden and the United States. Different schools of opinion can be seen, and levels of detail and customs in usability studies vary. The methods are not used in a similar ways or situations. The facts can't be checked from the usability engineering methods database because it is so vague and not very practical.

Sometimes the **usability experts are not along the design team from the beginning** of the development process. This creates problems when combined with another typical Datex-Ohmeda product development feature: **long project research phase**. A project is often started by a group of designers and is continued as a project study until all the preparations for the actual design activities have been made. In the point when the project is officially started in the regulatory sense, the background studies should be done and the design is nearly complete. If the usability knowledgeable people aren't able to join the design team early enough, some of the design decisions may already have been made without consulting them.

5.3 The usability engineering process

The usability engineering process in Datex-Ohmeda contains seven phases:

1. Write usability engineering plan
2. Research on the user, environment, tasks and system
3. Set usability goals
4. Design the user interface
5. Review the user interface specification
6. Evaluate the user interface
7. Specify the user interface

The process model is method-independent and is **based in ISO 13407** described in chapter 3.2.1. The comparison of usability process model phases between Datex-Ohmeda and ISO 13407 can be seen in Table 1 below. The usability engineering plan has been mentioned in the ISO 13407 pre-activity "Identify need for human centered design", although it isn't an actual phase in the ISO model. The other Datex-Ohmeda phases correlate with ISO model in a straightforward way, except the 5th and 6th phases, which are both derived from the "Evaluate designs against requirements" –activity in ISO 13407. The 7th phase, "Specify the final user interface", isn't clearly a part of any activity but might be considered to be an extension of the 3rd ISO activity, "Produce design solutions".

Table 1: A structural comparison between Datex-Ohmeda and ISO 13407 process models

Datex-Ohmeda usability engineering process phase	**ISO 13407 activity**
1. Write usability engineering plan	(Identify need for human-centered design)
2. Research on the user, environment, tasks and system	1. Understand and specify the context of use
3. Set usability goals	2. Specify the user and organizational

	requirements
4. Design the user interface	3. Produce design solutions
5. Review the user interface specification	4. Evaluate designs against requirements
6. Evaluate the user interface	4. Evaluate designs against requirements
7. Specify the final user interface	

The usability engineering process is connected to the phases of Datex-Ohmeda overall product development process the way shown in figure 18. The first step in the overall product development is a **project study**. Its purpose is to determine the necessary background and feasibility information for the launch of the project. It serves as the **design input** for the project (see the discussion on design controls, subsection 3.2.4). After the project study the project is either started or dismissed in **design input review**. As a part of project study the project's usability activities are planned, users and their tasks and context are studied and the usability goals are recorded. The first three usability engineering phases are revisited during the later product development when necessary.

The three next usability engineering phases connect to the design, design verification and design validation phases of overall product development. In **design verification review** the design is compared with requirements and goals set for the product in design input review. In **design output completion review** the results of design validation are checked and approved. Design validation means that the product is tested for satisfaction and acceptance in real or real-like circumstances.

In practice most of the usability work is done during the project study. By the time the project study is over and the project has started, the hardware and software design should be done as quickly as possible. The engineers need the **user interface specification** from the usability expert to do their work, and therefore the user interface and its documentation should be developed as far as possible in the project study phase.

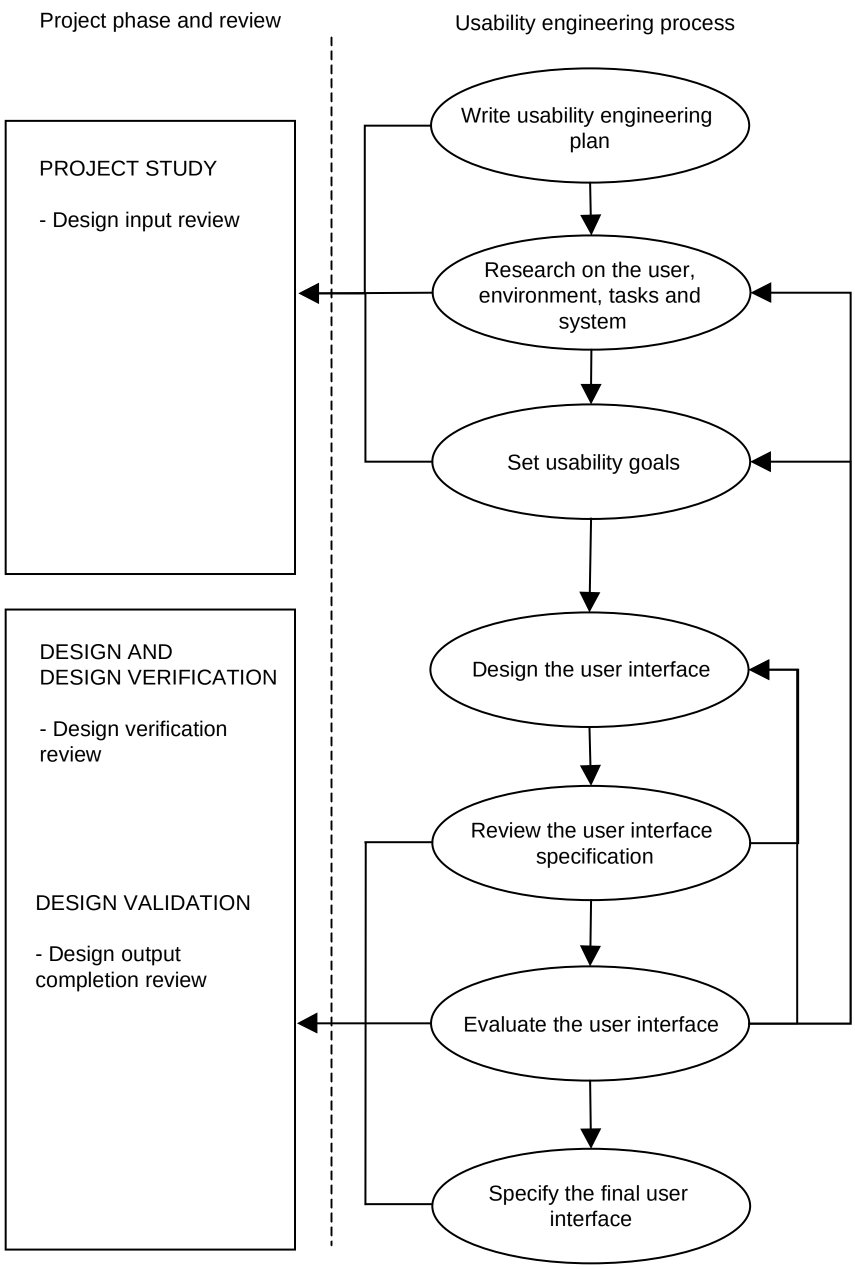

Figure 18: The current usability engineering process model at Datex-Ohmeda

Ideally the design the user interface, review the user interface specification and evaluate the user interface –phases are cycled in a manner shown in figure 19. The model is based on a discussion with Virpi Nummijoki, the patient monitoring usability team leader at Helsinki site. First, a design solution is made. It is then written in a specification form, which is checked in a review session. After that the design is tested with users, and it is altered according to the feedback from the users. In practice this is not often possible because of time and personnel resource problems. The review and evaluation efforts are often combined to bigger units.

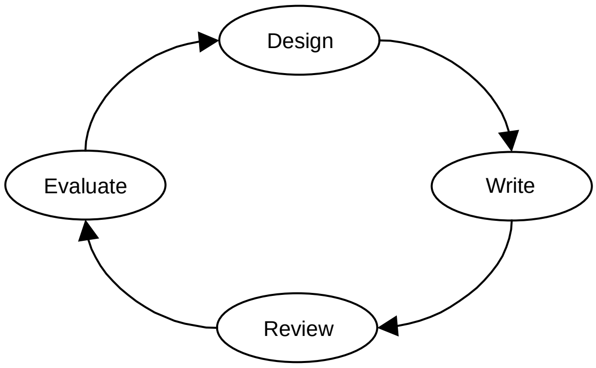

Figure 19: The ideal design cycle

The amount of usability activities done **depends on the size of the project**. Some of the smaller patient monitor accessory development or hardware component or upgrade projects do not need thorough usability engineering activities. On the other hand some important projects can have many iterations of usability testing in addition to detailed user observations and context studies.

One clear difficulty with the current usability engineering process is that it is **not very thoroughly documented**. Some of the process phase descriptions are virtually non-existent. This leaves lots of room to maneuver for the designer, and the product development activity quality depends greatly on the competence of the usability practitioner.

In the following the phases in Datex-Ohmeda usability engineering process are described.

5.3.1 Write usability engineering plan

A usability engineering plan is a **mandatory part** of all Datex-Ohmeda projects. It basically specifies what is currently known and what is to be done concerning usability during the product development project. A typical usability engineering plan discusses the following topics:

- Who is involved in usability work and the project in general
- Other projects which relate to this one
- Usability analyses and studies plan, including for example user, task and context studies as well as competitor analysis
- User interface design goals and evaluation
- List of usability documentation to be generated during the project

The contents of the usability engineering plan has influences both from ISO 13407 and Nielsen's usability engineering lifecycle. The basic model with responsible people, appropriate methods, documentation and time scales is taken from ISO documentation (ISO 1999) described in subsection 3.2.1. The feedback- and competitor analysis plans relate to Nielsen's usability engineering lifecycle (Nielsen 1993) presented in subsection 3.2.2.

The usability plan is reviewed and **approved** after the product research phase. After that the usability engineering plan usually changes somewhat during the design process according to situation at hand.

5.3.2 User, environment, task and system research

In user, environment, task and system analysis the context of use is studied. Usually user profiles and some of the environment information can be found directly from the corresponding **databases**. Task information is included in the user profiles. The profiles in the databases list the most common tasks of the hospital staff, but do not describe them in great detail. Most of the task knowledge rests on the usability practitioner's own experience and knowledge acquired in the research conducted in the past or during the project.

Although research is often connected directly to some feature of design or a project, some research may be done in a more ad-hoc way. Usability practitioners visit hospitals and observe or interview the hospital personnel during their visits to events such as conferences. The results are recorded in **travel reports** and internal databases.

The outcomes of this phase are the user and environment profiles with scenarios and other material from the user task observations and interviews. If user and environment studies are conducted, the databases are updated to match the most recent information. This way they are always as up to date as possible.

This phase is derived from ISO 13407 description (ISO 1999) described in subsection 3.2.1.

5.3.3 Usability goals

Usability goals mean the same thing as user requirements in ISO 13407 (ISO 1999). They are compiled from the project focus and the information gathered in the user, environment, task and system research phase. **Usability goals are used mainly in usability tests** to ensure that the user interface design meets the preset objectives. Because of this all the usability goals have to be measurable in the tests.

Each usability goal is composed of:

1. An argument or a short activity description (e.g. “I was able to see whether the monitor was connected to network or not” or “The time to notice an alarm”)
2. The preferred answer or way of action (e.g. “agree / strongly agree” or “under 5 seconds”)
3. A number or percentage of usability testers to answer or act the preferred way (e.g. “75%”)
4. The part of usability testers who are included in the measurement (e.g. “all” or “only the nurses who have over 5 years of experience with Datex-Ohmeda monitoring”)

Ideally the usability goals should be decided before the user interface design to guide the design focus to the right direction. In practice the goals are not always clear at the time the design starts. Sometimes they are thoroughly thought of only just before the usability tests. This may lead the designers to concentrate on less relevant usability issues in their design.

This phase has a lot in common with setting the usability goals –activity of Nielsen’s usability engineering lifecycle (Nielsen 1993) described in section 3.2.2. The goals are described with the appropriate metrics and minimum levels of acceptance. The ISO 13407 model (ISO 1999) described in subsection 3.2.1 also mentions the measurability.

The goals are documented in their own document. It states clearly the goals and their accepted levels of performance. The usability goals are used as the basis for the documentation of the usability tests.

5.3.4 User interface design

User interface design is the most vague phase in Datex-Ohmeda usability engineering process. The process documentation does not give any information on how the design should be structured or carried out. The design phase is documented in a way that a designer with no experience in Datex-Ohmeda user interface development could not do her job on her own.

The Datex-Ohmeda **User Interface Handbook** (UIH) is a database, which describes the use of the basic user interface components. It provides the low-level building blocks for user interface design, such as what the alarms sound like and how the menus and controls function.

Usability heuristics by Nielsen (see subsection 4.8.2) are also used as guidelines for design. Datex-Ohmeda usability engineering process description stresses consistency to be the main usability aspect. Other important aspects are safety, simplicity and error tolerance.

The result of user interface design is a **user interface specification**. The specification begins to form during the design, and is finalized after reviews and usability tests. The side products of user interface design are different types of prototypes and sketches created during the design process.

5.3.5 User interface specification review

At some point the user interface under construction is assessed in two review sessions, which can be repeated if necessary. The sessions are consistency review and usability review. Consistency and usability reviews can both be held as soon as there is something to assess. The reviews are iterative and can be redone if the interface changes notably.

Consistency review

In consistency review the user interface specification is measured against the User Interface Handbook. There are at least two reviewers, who are usually usability professionals and not involved in the project's user interface design. The reviewers do the check first on their own and share their findings in a common meeting with the interface designer.

Usability review

In practice the usability review means a heuristic evaluation. The interface is checked against design guidelines to check how well it conforms to the design rules followed in the company. The reviewers are chosen the same way as in consistency reviews: at least two usability professionals not involved with the interface design.

5.3.6 User interface evaluation

User interface evaluation is normally done by **usability tests**. In virtually every project the user interface is tested with at least one test. The evaluations are begun as early as possible. The participants are sometimes the Datex-Ohmeda's own clinicians, but mainly they are acquired from appropriate hospitals. The Datex-Ohmeda clinicians are usually used to participate in the usability test of the systems that require very high level of expertise or the expertise level of the user doesn't matter.

Usability evaluations are documented in a usability evaluation report. They usually begin with the main findings, followed by task-by-task descriptions of the test conducted and measurements of the usability goals.

5.3.7 Specify the final user interface

The result of interface design is the **user interface specification**, as stated in subsection 5.3.4. It is the formal document that the software, mechanical and hardware engineers require to design their parts of the system and to implement the user interface. The specification describes exactly what each screen should look like and how the controls function.

In this phase the user interface specification is written to its final form and delivered to project management to be approved. Changes to user interface specification are still possible until the launch of the product, but they have to go though the management to be approved.

5.4 Usability engineering methods

In Datex-Ohmeda the usability engineering method palette is designed to be flexible and largely decidable by the usability specialists. The only obligatory practices stated by the Usability engineering process are **usability reviews** which in practice mean **heuristic and guideline evaluations**. There is no mapping between the use of usability methods and the UCD process model. The Usability engineering process database only suggests that in user research observational studies are to be preferred and tasks should be documented as scenarios. The same document considers usability testing to be the most preferred tool for evaluation of usability.

The **free use of usability methods** is partly responsible to the current situation where usability methods have evolved to be only regionally coherent. Slightly different techniques are used at different sites, and one concept or method can have different meanings. This has led to a situation where the quality of all the usability activities can't be guaranteed. The **methods are not clearly defined** and they are sometimes used in an arbitrary way.

Differences in usability practices are easiest to see from the documentation of the usability engineering methods use. Although the usability practitioners are able derive enough information for themselves from the methods they used, it's also essential to write a good and comprehensible report. This is not always the case, and the information gathered from the field stays sometimes just in the head of a single usability practitioner. For example the usability test reports vary considerably both in length and detail.

The studies done at Datex-Ohmeda (see section 5.1) identified the methods and their groups seen in Table 2. The groups were thought up during the study, while the names of the methods are in the precisely same format that the sites reported them. The sites used in the table are Helsinki, Stockholm, Madison and Louisville, from which the last two are located in the U.S.

Table 2: The current usability methods used at Datex-Ohmeda

Method group	Method name and site
Interview	• Questionnaires (Helsinki) • Interviews (Helsinki) • Casual interviews/questionnaires to users (Louisville) • Field (user) interviews (Madison)
Observation	• Observations (Helsinki, Louisville, Madison) • Contextual inquires (Helsinki, Madison) • Wholistic/anthropology studies “discovery” (Madison)
Task analysis	• Task analysis (Helsinki, Madison)
Probe	• Diary (Helsinki) • Key logs (Helsinki) • Probe (Helsinki)
Competitor evaluation	• Competitors evaluations (Louisville) • Competitor comparison (Madison)
Feedback analysis	• Accident reports (Louisville, Helsinki) • Accident reports, customer feedback (Madison)
Guidelines	• User Interface Handbook (Madison, Louisville) • UI design guidelines (Helsinki) • Eng. UI plans (Madison)
Prototyping	• Mockups (Helsinki) • Computer based prototypes (Madison) • SW prototyping (Helsinki) • Paper prototyping (Madison, Helsinki) • Prototypes; wood, pictures (paper), sterolyth (Louisville) • Simulator testing (Madison)

	• Simulations (Helsinki)
Task communication tools	• Use scenarios (Helsinki) • Use cases (Helsinki) • Continuos communication with clinical specialists during development (Stockholm)
Usability testing	• Manual studies for comprehension navigation (Madison) • Usability testing (Helsinki, Stockholm, Madison, Louisville)
Usability inspection	• GUI evaluation (Louisville) • Consistency reviews (Louisville, Helsinki) • Consistency + spec reviews (Madison) • Usability prestudy with clinical specialists (Stockholm) • Heuristic evaluations (Helsinki) • Cognitive walkthrough (Madison)

As can be seen in Table 2, most of the methods inside a method group are similar, but they are named slightly differently. The differences continue in the execution of the different practices. For example the activities in **usability testing** can vary from testing with five users for two hours each in the company's usability laboratory to testing with sixty users for five minutes each at a trade fair.

Some of the methods are understood plainly wrong. The **cognitive walkthrough** method seems to be seen as a free-form evaluation with no apparent structure in either the method or the report written as the result. These kinds of differences can affect the efforts of making the usability effort coherent in a company-wide scale.

Few of the methods presented have some special features in Datex-Ohmeda, or in medical device manufacturing industry in general. When conducting **observations** in hospital it's sometimes impossible to get in the middle of action. Usually surgeries and trauma activities are watched from distance, and the observations are complemented with interviews of the corresponding people. This is naturally because of patient safety. The combination of observations and interviews is even more common than in other fields of design. Sometimes both the methods can include various **artifacts** as the starting of a study or a conversation. They can be either collected from the hospital environment or created as early prototypes at Datex-Ohmeda.

Competitor analysis is typically quite difficult to arrange with traditional methods. The hospital systems are often large and purchasable only directly from the manufacturer. Thus, acquiring a patient monitor or an anesthesia machine from a competing company is a challenging job. Another possibilities to get information of competitor's equipment are visiting hospitals using them or study them in trade shows.

The company has done **diary** studies by giving nurses a booklet in which to record any erroneous situations with patient monitors and the measures taken to correct them. **Key logs** mean the same as use logging described in subsection 4.3.2. The plain "**probe**" –method mentioned refers to a currently ongoing study that tries to find out things about nurses' work by giving them a set of things (the probe) to encourage them to describe their work. The probe includes for example a disposable camera and a small diary.

The company usability personnel do also different types of **literature studies**. Typically they can be **feedback analysis** or **accident report** studies from the official FDA or company's own databases**.** The studies are done to find out design constraints and things to improve from the previous designs. Literature research is usually a standard part of the user and context studies (see the Usability engineering plan example in subsection 5.3.1) and therefore done in some degree in every product development project.

The **simulations** mentioned in Table 2 are usually synonyms for high-fidelity look-and-feel or implementation prototyping (see section 4.7). In addition the company has made attempts to simulate entire patient-care environments and study the usefulness of their equipment in a more real-like surroundings. In these tests the focus of study was in learning about the entire context, not just the single monitor or anesthesia machine.

The methods in Table 2 that were not discussed in the text above are used in a way that they more or less correspond to the formal descriptions in chapter 4 and do not require any additional clarification.

5.5 Usability maturity assessments

Datex-Ohmeda has used usability maturity assessments in two studies between 2000 and 2001 in an attempt to find the best ways to monitor and improve usability efforts. Both the studies were made using the same technique called "Software Usability Management Maturity Grid". The grid is based on Philip Crosby's quality management maturity assessment grid (Crosby 1985). The only thing changed from the original grid are the categories assessed, otherwise it has remained the same.

During the previous usability maturity assessments three study questionnaires were given to one person from each site or business unit participating in the study. Each questionnaire inquired on two to four aspects of usability, which had to be rated from one (the lowest) to five. Each rating had a description of what it meant in practice, and the participant just had to choose the description closest to the current situation in his or her business unit.

The main problem with the usability maturity assessment technique described above is that **everyone evaluates their own site**. This leads to a situation, where more self-critical evaluators get poorer marks than the more self-confident ones while doing the same things the same way. There are also **differences in the perception of quality** in usability work. The questionnaires offer room to maneuver and interpret differently, and the ratings given in each category don't have to be reasoned in any way. It seemed that Finnish evaluators tended to be harsher to themselves than the others.

The assessment was also very general by nature. The three sheets used in the study are labeled "Management Understanding and Awareness", "Usability organization Status" and "Usability Principles Applied in Development". The assessment did not cover any actual working habits or the quality of the usability engineering methods used, it just inspected if the general usability principles were followed and the common knowledge on usability among the management.

5.6 Conclusions

The current state of usability at Datex-Ohmeda is fairly good. Some sites, for example Finland, seem to follow the current usability engineering process more strictly than the others, but in general every site acknowledges that usability is important and tries to support it in all possible ways.

The aim of the current state analysis conducted was to find weak spots in Datex-Ohmeda user-centered design and use of usability engineering methods. There are a few issues, which can be diagnosed as problematic:

- **The steps for User interface development -phase aren't adequately defined**.

  The methods and ways of working differ from site to site and even from person to person. The Usability engineering process does not offer any assistance on how the design should be done.

- **The terminology in methods isn't standardized**.

Different people use different terms for the same concept. This creates difficulties in communication and quality assurance of the usability work.

- **The usability engineering method database isn't functional as-is**.

  Some of the methods are presented inadequately, and there is no clear indication on when the methods should be used. The database is of no practical use in its present form.

- **Informants evaluate their own unit's efforts in usability maturity assessments**.

  The differences in evaluators' characters also bias the results. With the current evaluation methods the comparison between different sites is not possible.

- **The quality of documentation and communication varies**.

  There are no clear rules on how and what to document. Currently everyone does the documentation the way they are used to do it.

These points indicate that both the objectives of this thesis are useful in improving the current situation. The method descriptions tackle the problems with standardization of the terminology and usability engineering methods database. The new process model creation deals with the issues on the quality of documentation and user interface development phase sharpening. The usability maturity assessment problem is addressed, if the KESSU assessments are utilized in the future.

6 The new UCD process and methods

This chapter introduces the new process model developed in this thesis work. The work described in this chapter is based on the research of the current state, which is presented in chapter 5. After the results presented in this chapter a small validation study on the newest features of the process model is described in chapter 7.

A general overview of the model is presented first. Its purpose is to give an idea how the phases connect with each other and why the phases are what they are. Differences with the KESSU and current UCD process models are discussed. After the introductory section each phase is shortly described with the methods associated with it. The phases are presented by a diagram, which shows all the documents and methods relevant to the activities during the stage. Finally, the methods are presented as a whole to show the list of recommended methods.

6.1 Creation of the new process model and methods

The idea was to create the process model iteratively, as any other user-centered design project. Every time after major changes to the process model were made, the design was subjected to an evaluation group consisting of the usability professionals of the company. This was done to gather information on current work practices and feedback on the proposed process model.

6.1.1 First iteration round: combining KESSU phases and methods

After the analysis phase (see subsection 5.1.2) the methods and the method groups were studied from the process model point of view. They were **inserted to the KESSU model** phases to see how they would fit in. This was done with the post-it notes done in the analysis phase and three A4-sheets, which had labels according to the KESSU model phases. The post-it notes were then placed on the sheets of paper according to where the method group would most easily fit in. This phase is illustrated in figure 20 below.

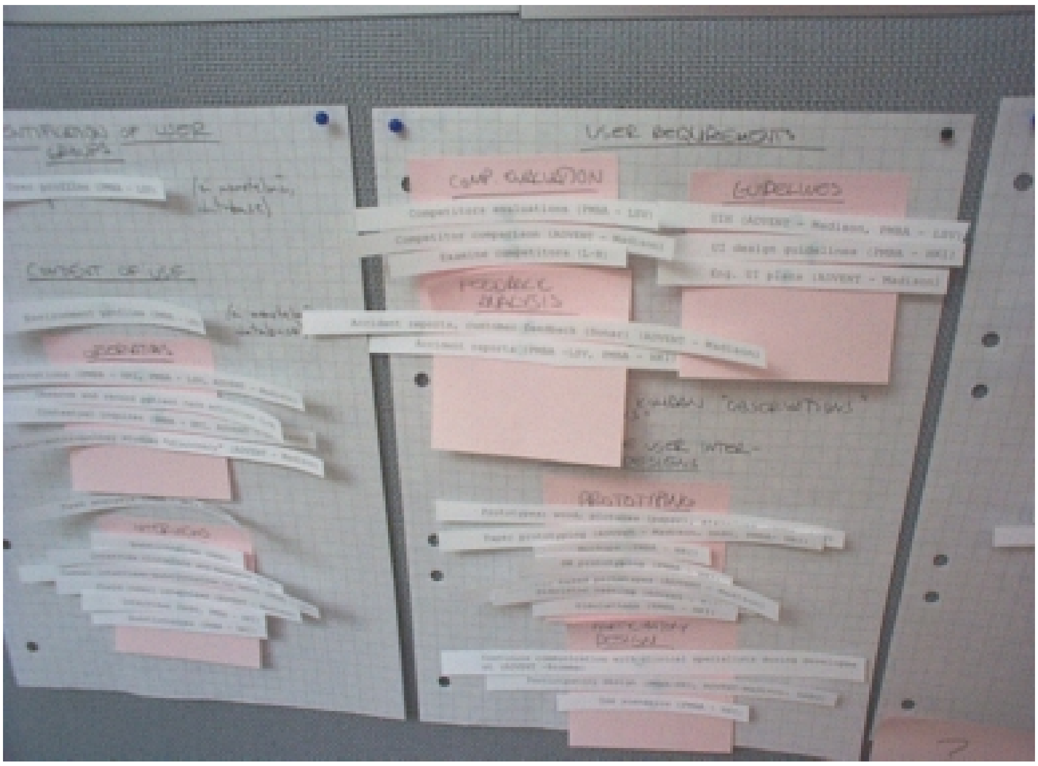

Figure 20: Usability methods inserted to the KESSU process model

After this first rudimentary study the model was converted to computerized form showing one process phase and the associated methods on one page. No overall process model was made at this point. At that time it felt more necessary to see if the phases were accepted as such and without the KESSU process model context.

The computer-drawn model was printed and **presented to the company's usability personnel**. The meeting was a formed like an informal brainstorming session, where the process model was first presented and then a free-form conversation took place. The session gave important ideas on the actual workflow of the usability specialists.

As a **result of the first validating session** a whole new phase, environment study, emerged from the context of use –phase. This was a result of a fact that in Datex-Ohmeda the product development studies start from the environment. A product is usually developed primarily to an environment, for example operating room or intensive care unit, not to a specific group of users. The users are defined and studied after the context is known.

Other notable alterations in the first meeting were the **combinations of the deliverables**. "User group definitions" and "user characteristics" were combined to a single document called "User profile", and "Context of Use, Old" and "Context of Use, New" were combined to the "Context of Use" -document. Both these changes were sensible, because the content of these combined documents remained the same and the documentation of a single phase is more comprehensible as a single document. The User profile document contains mainly characteristics of a single user group, and the definition of different user groups is done in the beginning of the usability efforts, in a document called Usability engineering plan. This practice is working fine and needed not to be changed.

The **writing of the descriptions of usability engineering methods** seen in chapter 4 begun after the validation meeting on the basis of the methods literature study described in subsection 5.1 and the validation meeting of the first combined model described here. The descriptions are meant to deliver the needed general information on the recommended usability engineering techniques. The more Datex-Ohmeda specific usability engineering methods and notes on applying the general methods described in chapter 4 are explained in section 6.11.

6.1.2 Second iteration round: the overall process model

The second iteration round took place quite quickly after the modifications required by the first validation round and the literature studies were made. By that time the **overall process model** with all the phases drawn on the same sheet in a cyclic manner had developed. It was based directly to the KESSU process model with the new Environment study -phase added. A **linear version** of the proposed process model was made to look more like the current, more linear-looking model (see figure 18 in section 5.3). The linear version felt necessary to show the differences and similarities with the current and the proposed process model. The first version of the linear model and the cyclic process model can be seen in figure 21 below.

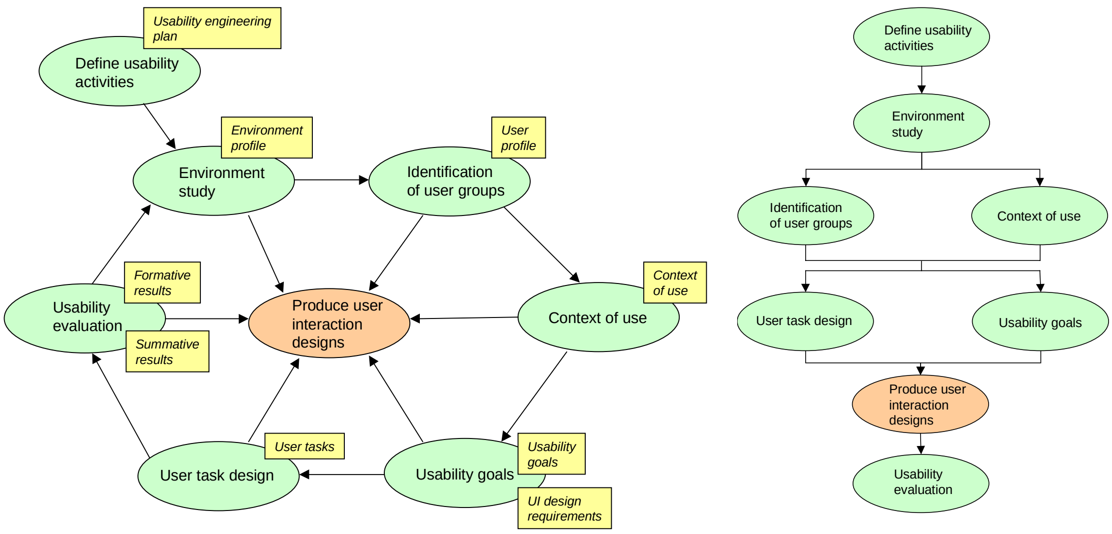

Figure 21: Cyclic and linear overall process models developed in the second iteration round

In the **second validation session** the cyclic process model (see figure 21 above) was readily accepted. It was commented to be useful and fairly accurate description of how things should be done. The placement of "Produce user interaction designs" in the center of the process was commented to be an especially good idea. No comments were made on the linear model. This was mainly because it resembled the older model, and the cyclic model's new way of representing the process was easier to comment on. Despite this, it felt still like a good idea to keep the linear model alongside the cyclic one for representing the connections to overall product development process. The connections weren't yet presented in the linear model, so this was probably a reason why it did not seem useful to the validation group at the time.

Some considerations rose during the discussion. The question of whether artifact interview should be introduced as a part of the interview –group was raised. The company's usability personnel explained that sometimes the user studies were conducted using a piece of equipment as a starting point of a conversation. After a consideration this was included as a notion to interview and observational methods in the current usability engineering methods description in section 5.3 and in section 6.4 where observational and interview methods are first mentioned in the new model.

After this phase and some minor corrections the **process model design and adaptation was complete**. The model was left to be verified in the usability team meeting, which consisted of usability professionals from all the Datex-Ohmeda product development sites.

6.1.3 Third iteration round: international methods check

The third iteration round was about **adapting the method descriptions** better to the company's product development. It took place few months after the previous iteration round.

As the new process model and the methods were so far researched in Finland, it naturally got many influences from the Finnish working culture. To get the full range of perspectives to the methods, the method descriptions were sent for evaluation to every usability professional in the company. The actual adaptation was done as an international workshop, to which all the Datex-Ohmeda usability professionals took part in after acquainting themselves with method theory descriptions.

The basis for the conversation were the method descriptions presented in chapter 4. The aim was to find out how the use of methods differs from site to site and which methods were seen as the most important ones. Originally the plan was to discuss in more detail what each site does and what methods they use, but due to time schedule problems the discussion on methodology was quite brief. Mainly it concentrated on the first items of chapter 4, which were interviews and observations.

During the discussion the usability professionals stressed that while conducting an observation or interview it was not necessary to tape everything, sometimes taking notes on paper is enough. Time management was an important topic. It was stated clearly that every method's use was considered on case-by-case basis and a general rule on when to tape and when not was hard to come up with.

Various new methods and method variants were brought up. The most notable of them were GOMS, naturalistic studies and artifact walkthroughs. These methods were not mentioned in the methods inquiry in the information gathering phase of the study because they were tried once before or were planned to be used. Because they were at this point all more or less either one person's projects or theories never tried in practice, the methods were included only as comments in this subsection to keep the final methods as clear as possible.

After the discussions and comments **the three most vital methods were chosen by voting** among the usability professionals. Everyone in the meeting had three votes to cast to the three most important methods of their choice. The result can be seen in Table 3 below. The aim of the vote was to direct the future work by prioritizing the methods

Table 3: The results of the methods vote

Method	Number of votes
Usability test	7
Contextual Inquiry Scenarios	6
Personal interview	3
Prototyping Guidelines	1
Focus group Questionnaire Observation Diary Use logging Task analysis Use cases Heuristic evaluation Cognitive walkthrough	0

Some of the methods were surprisingly unfamiliar to the usability practitioners, even though they all were given the method descriptions of chapter 4 a week before the meeting. Heuristic evaluation and task analysis were probably methods that were actually used more than what the vote results suggest.

The idea of the three-vote system was also found problematic. Many of the methods have a clear link to one another, which made it difficult to choose one method from a combination of related methods. Few examples of the method chunks are interviews and observations which can be seen as parts of task analysis, and prototypes and scenarios which are used as parts of usability testing. Because usability testing is currently the most prominent usability method, this was probably one reason why scenarios got so many votes. **Clearly better results would have been achieved if the preferences and the vote results would have been just discussed in the meeting**. Unfortunately there was no time for that.

Anyhow the results seen in Table 3 could be used as the basis for the method adaptation as they were originally intended to. The three most useful methods, **contextual inquiry, scenarios and usability testing**, were chosen to be the first methods to have company adapted descriptions. The basis of the descriptions will be from chapter 4, but some additional clarifications, extra tips and adaptation notes will be added as well as more detailed description of the deliverable from the method. The finalized descriptions are not presented in this thesis, but some considerations on the use of methods can be found from section 6.11. This is because the aim of this thesis was just to clarify the meaning of the current practices, not to describe them in great detail (see section 1.1).

The usability professionals had surprisingly few things to comment on, so the theoretical descriptions in chapter 4 were left unmodified. No new sources or unclear descriptions were recorded. The method adaptation notes in section 6.11 were created after the meeting from the participator's comments and the things learnt in previous interviews and conversations.

Before the meeting the linear model mentioned in the previous section was also reformed to show the connections to the other product development processes. As stated before, there was eventually no time to check it in the meeting. The final version of the linear model can be seen in figure 22 in section 6.2. Its main function is to show the new model's connections to other product development.

6.2 General overview of the process model

As can be seen from the figure 22, the process model resembles clearly the KESSU UCD process model (see figure 11 in subsection 3.2.3). It is cyclic, and centers on "Produce user interaction designs" –phase. All the other design phases feed the central phase with new information and ideas. Most of these phases are the same as in KESSU model. The boxes indicate the documentation that is produced in each phase.

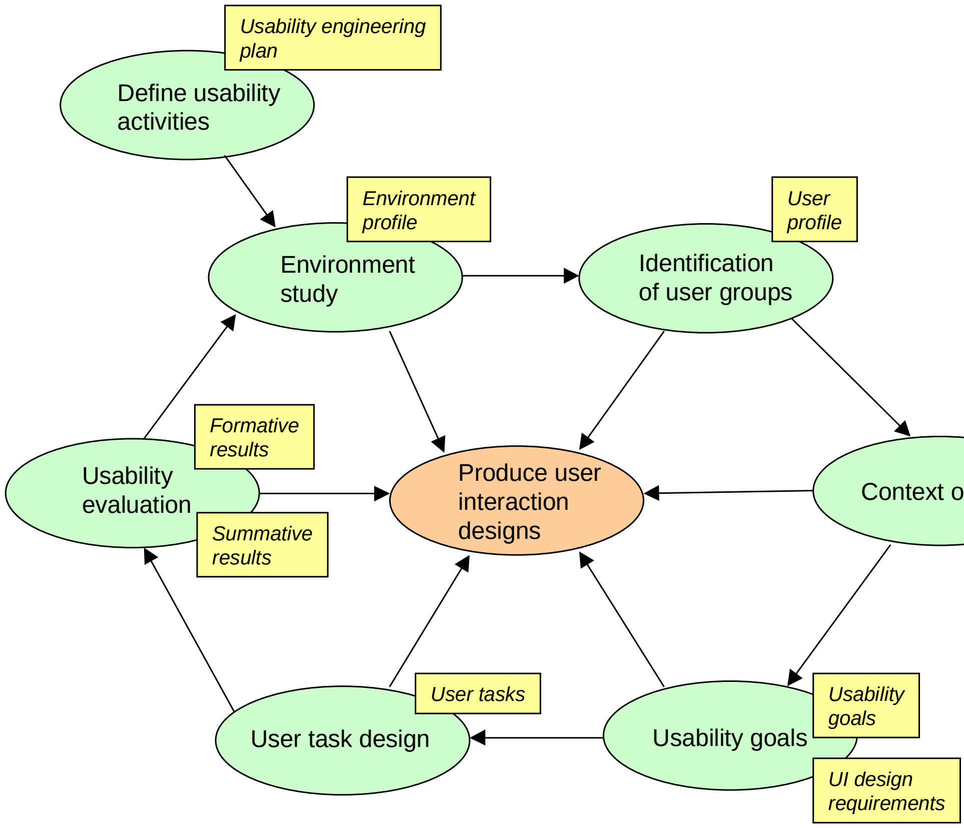

Figure 22: The new user-centered design process model

The design cycle starts after the Usability engineering plan is written. This is not mentioned in Jokela's KESSU model, but is clearly an important phase. Because the usability engineering plan was already a part of Datex-Ohmeda usability activities, it was not sensible to drop this first and sensible stage from the new process model. The second stage, environment study, also differs from the KESSU point of view. As stated in subsection 6.1.1 this stage was added because the products of Datex-Ohmeda are often designed to a certain environment, not so specifically to a certain group of people.

The rest of the phases are more or less the same as in KESSU process model. Most of the changes are made to the documentation. In KESSU model many of the phases had more than one deliverable to define them. To clarify the phases, some of the documents are merged into one, which has happened in "Identification of user groups" and "Context of use" –phases. The reasons for these changes were the same: the document assigned for each stage covers the both old documents.

Table 4 presents the matches and differences between the current process model and the new process model. Its purpose is to show how the new process model relates to its KESSU source process model and the current usability engineering process. The current process model can be seen in section 5.3 and KESSU process model in subsection 3.2.3.

Table 4: How the new process model phases relate to current and KESSU process model

Current process model	New process model	KESSU process model
1. Write usability engineering plan	**1. Define usability activities**	
2. Research on the user, environment, tasks and system	**2. Environment study**	2. Context of use (of user group N)

2. Research on the user, environment, tasks and system	**3. Identification of user groups**	1. Identification of user groups
2. Research on the user, environment, tasks and system	**4. Context of use**	2. Context of use (of user group N)
3. Set usability goals	**5. Usability goals**	3. User requirements
	6. User task design	4. User task design
4. Design the user interface 7. Specify the final user interface	**7. Produce user interaction designs**	5. Produce user interaction designs
5. Review the user interface specification 6. Evaluate the user interface	**8. Usability evaluation**	6. Usability evaluation

As can be seen from table 4, there are many modifications to the current usability engineering process. First of all, the big “Research on the user, environment, tasks and system” –phase is split into more manageable “Environment study”, “Identification of user groups” and “Context of use”. A totally new activity, user task design, is introduced to give structure to the interface design. The “Produce interaction designs” –phase now includes both the prototype design and the specification writing. Finally, all the evaluations are combined into a single phase, “Usability evaluation”.

The connections to other product development processes are difficult to visualize in the cyclic model. Basically the idea is to do as much user research and design work as possible before the design input review, which starts the official product development process (see section 5.3). This is illustrated in figure 23 below. As can be seen from the arrows connecting UCD process with other processes, the main bulk of the usability work should be done during the project study. In any case all the usability activities can’t stop after the project study. This is represented by the dashed arrows from the design and evaluate –blocks.

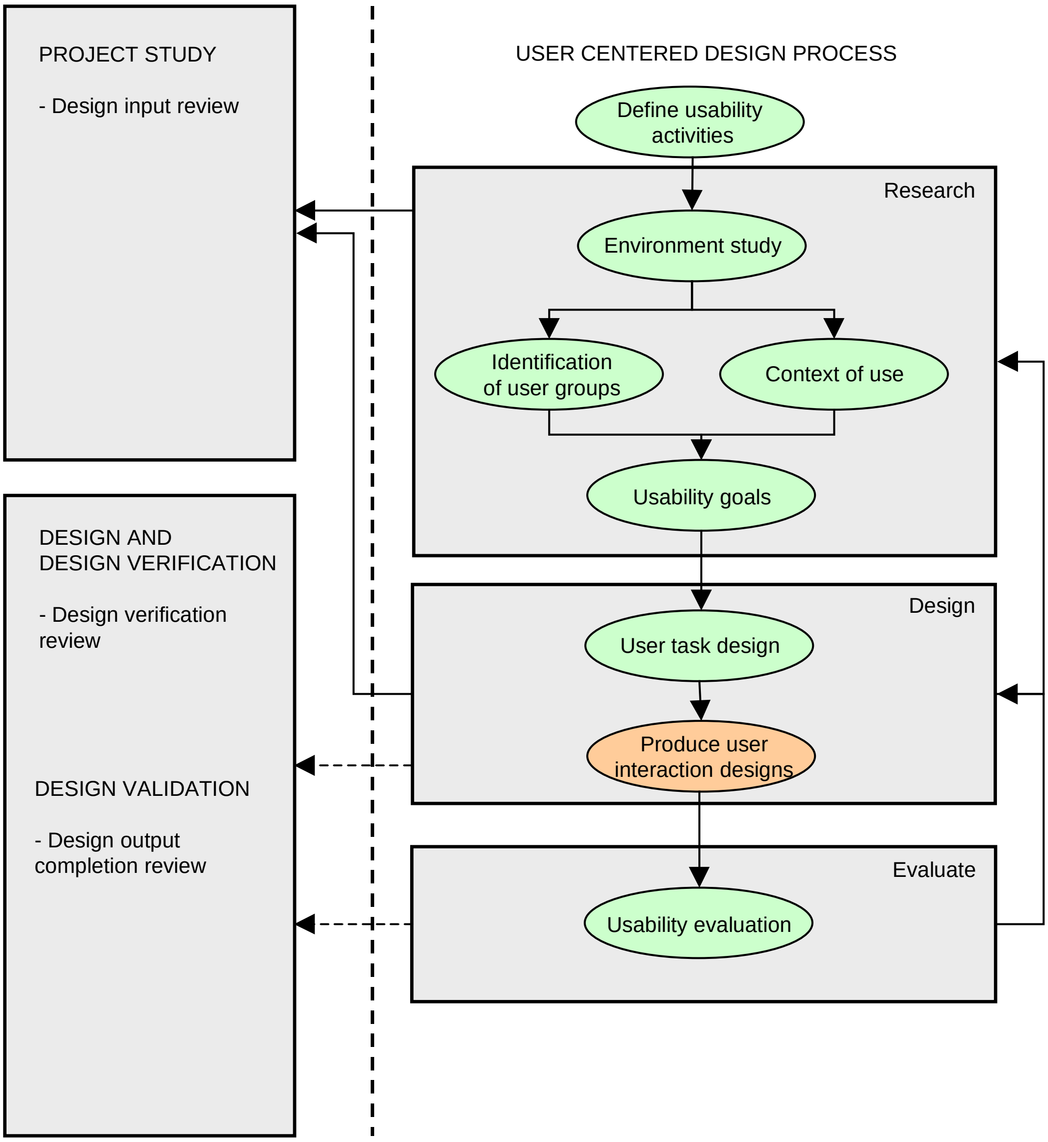

Figure 23: The new UCD process model connections to other product development activities

In the following sections each of the new process model phases is gone through in more detail. The descriptions concentrate on the aspects that differentiate the model from KESSU UCD process model described in subsection 3.2.3.

6.3 Define usability activities

The **purpose** of the Design usability activities –phase is to plan and document the activities taking place during the upcoming product development project. It is always done before any other usability activity takes place. The deliverable from this phase is the **Usability engineering plan**, which states clearly (see subsection 5.3.1):

- Who is involved in usability work and the project in general
- Important other projects, which are needed for co-operation
- Usability analyses and studies plan:
  - Environment
  - User
  - Tasks and functions
  - Accident reports

- Competitor's products
- Feedback databases
- Relevant literature resources
- Predefined usability goals
- User interface design – key issues and use of guidelines
- User interface evaluation plan
- User interface review plan
- Schedule of activities
- List of usability documentation to be generated during the project

The Usability engineering plan is approved and enforced by the project manager. Usability engineering plan can later be changed if the situation calls for it, but any change must have a valid reason.

6.4 Environment study

The **purpose** of the environment study is to understand the physical and social surroundings related to the product currently designed. This is important, because the environment is usually known in the beginning of the development project, and study also reveals the relevant personnel to be studied in the Identification of user groups -phase.

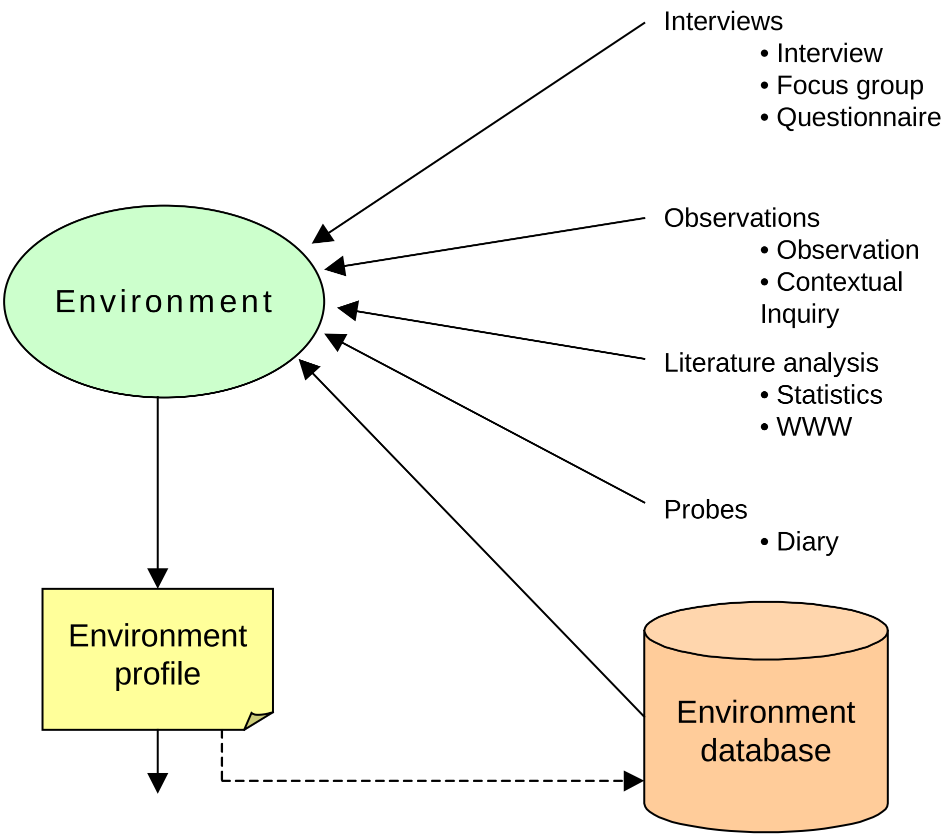

Figure 24: The Environment study –phase

The company's **environment database** is studied first. If appropriate information is already in the database, there is little need for additional research. If the environment is not documented in the database or the information entry date suggests the data might be out of date, a more thorough research needs to be done.

The most recommendable way of doing environment study is the use of various **observational methods** in a real hospital environment. Interviews and probes with artifacts collected from the site visits can be used as supplementary methods for clarifying the issues left unclear or gathering information from longer periods of time. Different **literature sources** can be used as a source of background information. The recommended usability engineering methods can be seen in figure 24.

The documentation of this phase is an **environment description**. It presents the environment in a level of detail that is relevant to the design efforts. Typical things to describe are unit function, purpose and layout, patients and their flow inside the unit, personnel, ergonomic issues, treatment notes and typical equipment present. Pictures and video material are recommended as appendixes to the textual description. If new research is done during the environment study, the results have to be inserted into the environment database to enable later utilization of the same data. All the usability studies should also be inserted in the Usability studies database.

6.5 Identification of user groups

The **purpose** of this phase is to identify who the users of the medical device are. Their relevant characteristics, for example education, language skills, knowledge of equipment in the unit, responsibilities, a list of typical tasks and stress factors, are documented in a **user profile document**. The document can contain one or more of these descriptions, depending on how many types of personnel use the device.

The ways of conducting the user research are the same as in the Environment study -phase. The first thing to do is to check the **user profile database**. If the information isn't adequate, some form of **observational study** is recommended. It is useful to combine the observational method with some form of interview to ensure the validity of the findings. Literature analysis and probes can be used to complement the study as seen in previous section. The User profile- and Usability studies databases are updated accordingly if any new studies are made.

The Identification of user groups –phase is illustrated in figure 25.

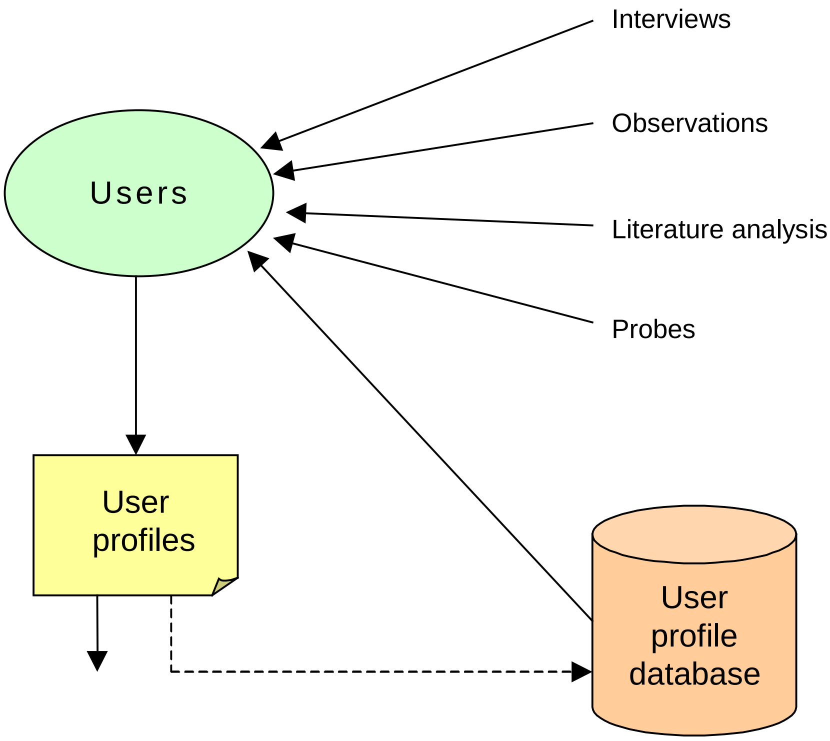

Figure 25: The Identification of user groups -phase

6.6 Context of use

The **purpose** of Context of use –phase is to deepen and combine the research done in the Environment study and Identification of user groups. In practice this means identifying the user accomplishments with the current and the future systems, the environmental factors concerning the use of the current and the future devices and the tasks that the user does with the current system along with the non-functional attributes (see subsection 3.2.3) affecting them. Important sources of information are the User and Environment profiles created earlier, but they are refined into more accurate and relevant level. The Context of use –phase is illustrated in figure 26 below.

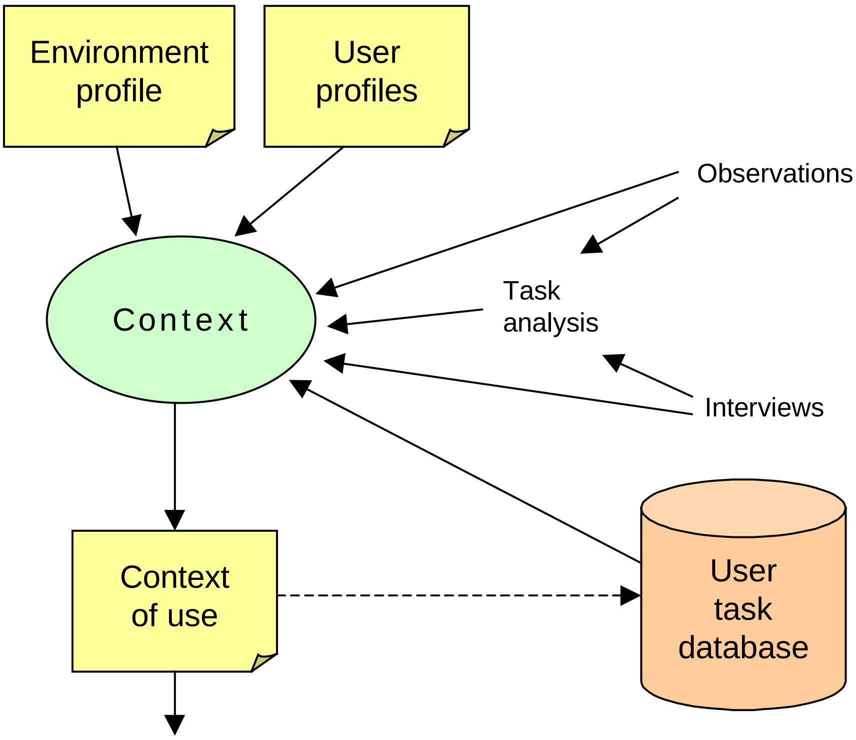

Figure 26: The Context of use –phase

An important part of defining and documenting the context of use is **task analysis**. By it the users' tasks are decomposed into knowledge of the users' actions and the motivators behind them. This can require more observations and interviews, if the user tasks are not yet fully understood. The same methods can be used to find out the non-functional attributes related to the tasks. The reports of context studies are stored to Usability studies –database.

The outcome of this stage is a **Context of use –description** that defines the current user tasks, their attributes and the environmental factors affecting the current and future task completion in a comprehensible and clear way.

As an addition to the current databases of Datex-Ohmeda a **User task database** would be a useful tool. It should function the same way as User profile- and Environment –databases.

6.7 Usability goals

The **purpose** of the Usability goals –phase is to set measurable goals for user interface usability and constraints and guidelines for the design. Usually the goals can be derived from business goals and the information gathered in the previous phases.

Some information on how the goals can be found by **examining competitors' products** when possible. In addition the **feedback** databases and in-house test databases should be checked to ensure that all the difficulties with the previous design have been taken into account. Company

guidelines affect directly the user interface design process. The most important guideline to use throughout the whole design process is the **User Interface Handbook (UIH)**, but also other company standards, for example localization standards can affect the design and should be checked.

The outcomes of this stage are the design constraints documented as **UI design requirements** and the **usability goals**, which should be documented in a measurable way. The current way of documenting usability goals should be maintained (see subsection 5.3.3). The Usability goals –phase is presented in figure 27.

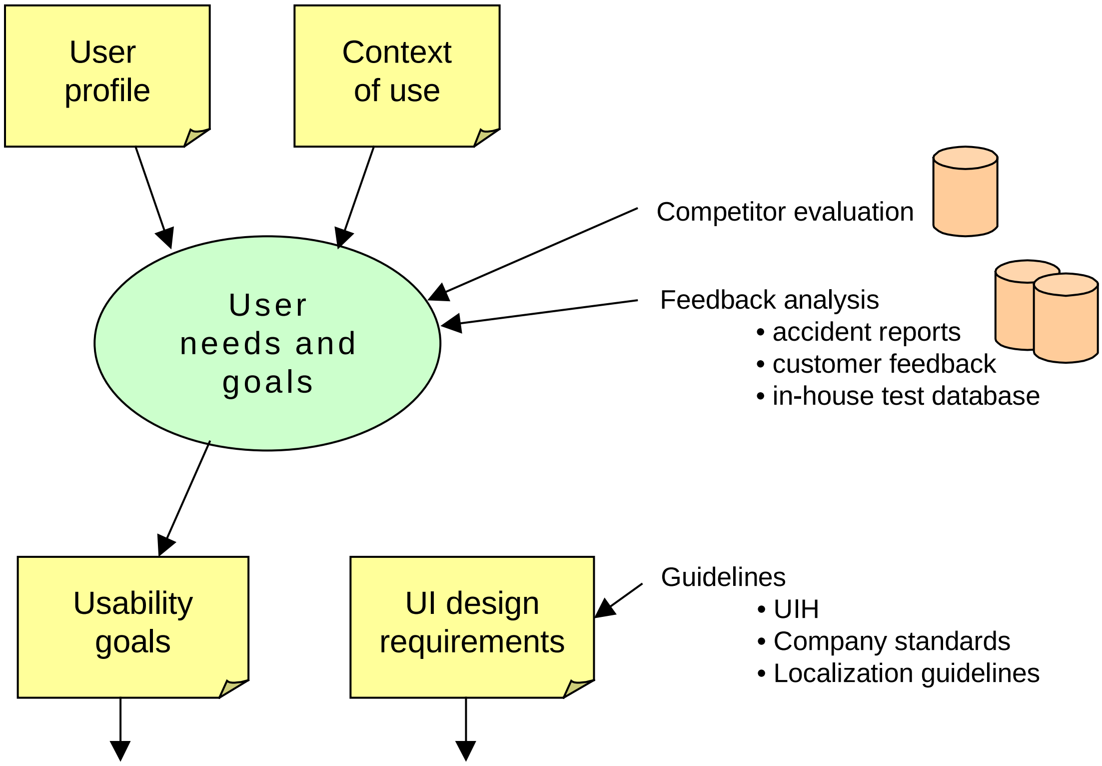

Figure 27: The Usability goals -phase

6.8 User task design

The **purpose** of the User task design phase is to design how the users would carry out their tasks with the new medical device. The user actions the device will support are decided at this point. The User task design –phase is presented in figure 28 below.

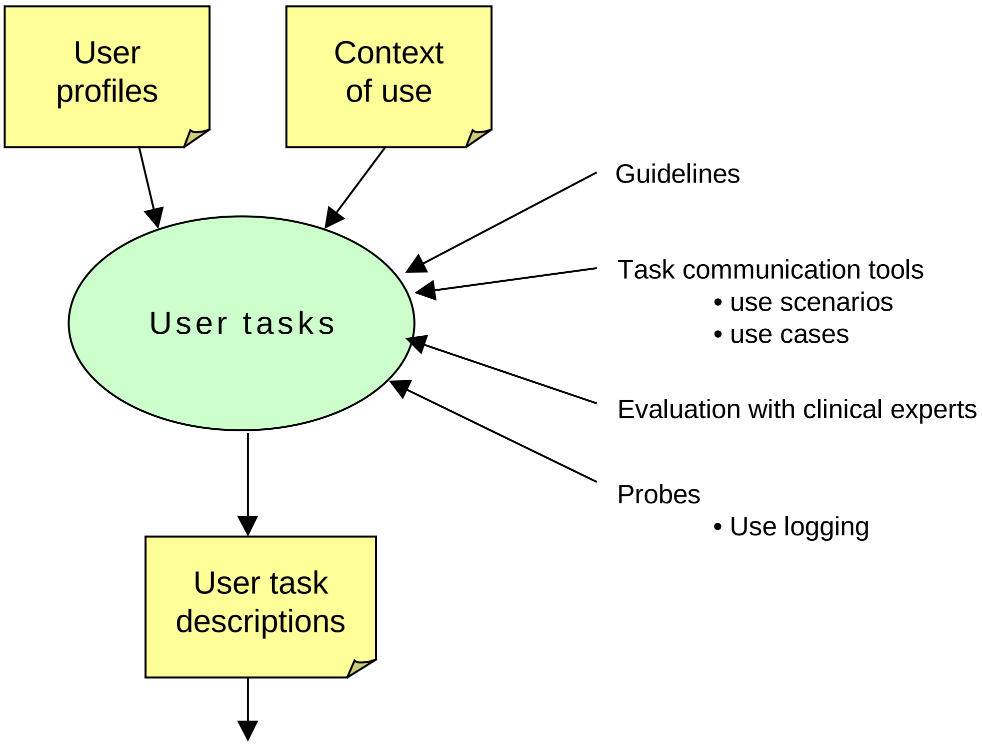

Figure 28: The User task design -phase

The recommended ways of documenting the user tasks with the future system are **the task communication tools**. The scenarios or use cases should always be done in **co-operation with the clinical experts** of the company to ensure their accuracy and validity to represent the task. Relevant company **guidelines** and industry standards should be checked to ensure the task design's compliance to them.

The **outcomes** of the User task design phase are the **scenarios or use cases** written of each typical task the user does with the device. Especial focus should be placed on designing those tasks which have usability goals placed on them. It is recommendable to use pictures and other clarifying material in addition to the task communication tools.

6.9 Produce user interaction designs

The **purpose** of this phase is to design the actual interface the user interacts with. It is the central activity in the user-centered design cycle, and produces the concrete results of the user interface design efforts. User training and documentation should also be considered at this point.

User interface solutions are explored with **prototypes**. In the beginning the prototypes can be hand-sketched drawings and scenarios, and as the design elaborates the prototypes move towards high-end functional prototypes. Mock-ups can be used to study and demonstrate the physical dimensions of the device. The Produce user interaction designs –phase is illustrated in figure 29.

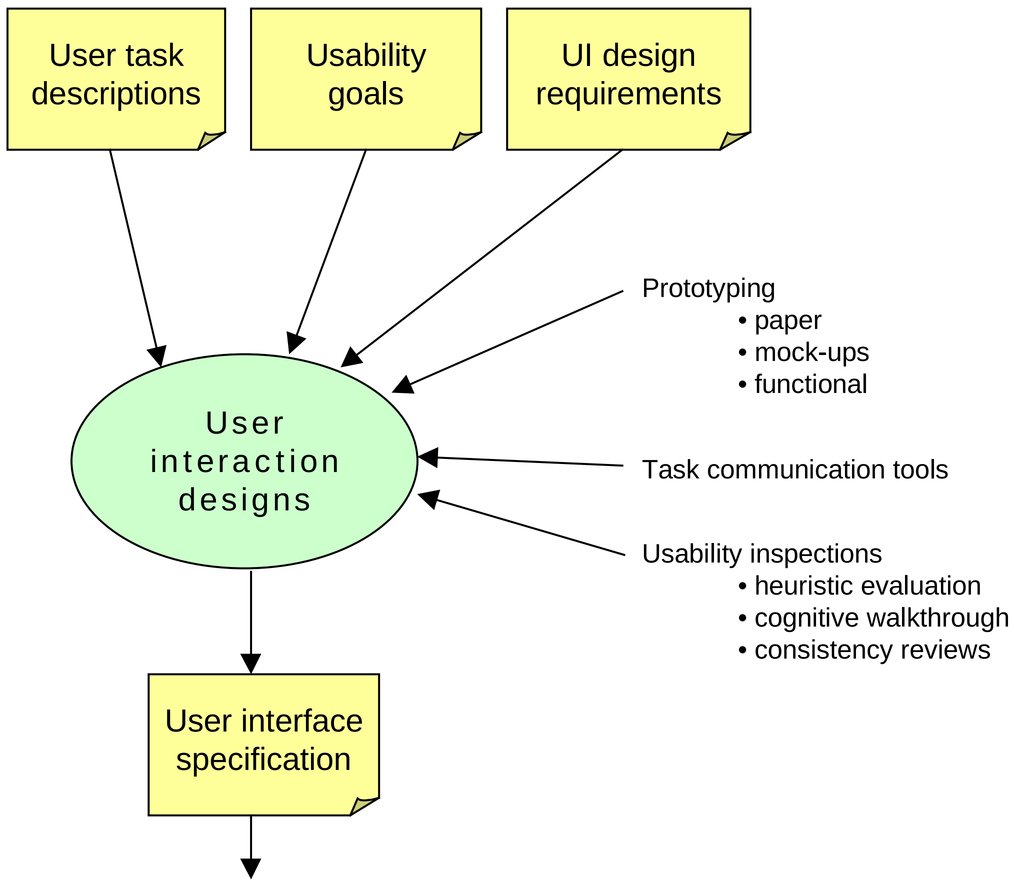

Figure 29: The Produce user interaction designs -phase

The user interaction designs that are uncertain in some way should be tested with actual user using **task communication tools** or inspected with **usability inspection methods**. These activities should be kept light and focused at this point. They should be used only to clarify specific design issues, not to study the whole interface.

The user interface is documented to **User interface specification**. The User interface specification acts as an unambiguous blueprint for the other design team on how the user interface of the device is constructed.

6.10 Usability evaluation

The **purpose** of Usability evaluation is to check the product against the usability goals. Usability evaluations can also be arranged to check user opinions, to gain knowledge on design variables that are not yet fully understood by interface designers and to find usability problems in the current design.

The User interface specification is checked against company User Interface Handbook. This check is called **consistency review**, and it is conducted when the specification reaches a state in which all the necessary information is written down. The check should be conducted with at least two other members of the usability team.

Another review is the **usability review**, which is based on heuristic evaluation. It is conducted on an interface prototype by at least two usability team members not involved with the design. Other smaller checks can be done with **clinical experts** during the design. The consultation of clinical experts is needed especially when the interface is evaluated with **cognitive walkthroughs**, because the knowledge base of medical care professionals is often hard to simulate by usability specialists.

Every project should test if the usability goals set to it are met by arranging a **usability test**. Usability are also used to validate the design decisions on real users. The Usability evaluation phase is presented in figure 30 below.

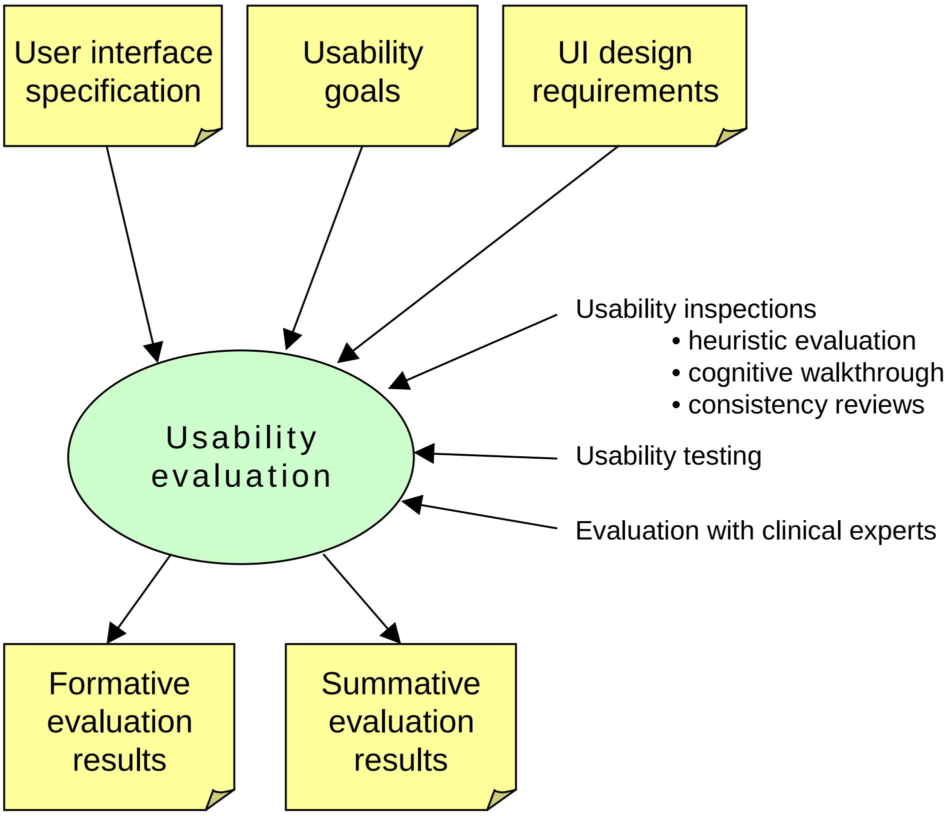

Figure 30: The Usability evaluation -phase

The **outcomes** of this phase are formative and summative evaluation results. Formative results include the qualitative feedback from the users and the evaluators, whereas the summative results present the test results against the usability goals set earlier. The usability evaluation reports are stored in the Usability studies database.

6.11 Usability engineering methods

This section discusses the new usability engineering methods at Datex-Ohmeda in general. The descriptions of the usability engineering methods discussed here can be found from chapter 4. The idea of this section is to give a rudimentary idea on priority of the methods. In other words, the methods are considered in a sense that which is the most useful in certain situations.

6.11.1 Methods of user and context study

If the **product is being designed to a completely new environment**, a good way to begin the environment and user studies is to use of some type of a **probe**. A diary can be a fair start, accompanied with some other material to encourage the users to document their life. The advantage of probes over observational methods is that they are often less obtrusive and can gather data from a longer periods of time.

Inside the **interview group**, the personal interview should be used as the main method for information gathering. Questionnaires should be used only in conjunction with the personal interviews or if the interviews can’t be done in person, or for some reason a large quantity of interviewees is required. Focus groups are time consuming and should usually be used only for prototype or idea acceptance evaluation purposes.

In the **observational methods** the contextual inquiry is the best choice for almost every situation. Only if conversation hinders the performance of the observed person or compromises patient safety, the basic observation should be chosen.

When **choosing between interviews and observational methods**, the observational ones are always the first choice. The interviews can be included in the observations to form more free-formed combinations, but they should be used in a complimentary role. If observations can't be arranged for some reason, the interviews are a less resource consuming choice.

6.11.2 Task analysis and communication

Task analysis is highly recommendable, especially if the new product is developed to a context that hasn't previously been studied. Tasks should be studied both from a single caretakers point of view and from the whole care process point of view to understand the patient's flow through the care process. Clinical specialists and medical advisors can be used as a resource in studying the tasks.

Scenarios are the primary way to document the user tasks with the device under development. They should be used before the user interface is designed to guide the design efforts to the right direction.

6.11.3 Prototyping and evaluation

Prototyping should be started as early as possible, because especially with new ideas it's difficult to ask people's opinions on something that does not exist. The evaluations should start the same time as the prototyping – all the conversations on the early prototypes can be seen as usability evaluations of a sort.

Every product should have at least one thorough **usability test**, preferably at least two to see if the changes made after the first iteration were to the right direction. When writing usability test reports equal attention should be based on describing the positive and negative things so when fixing the problems the good things are not changed.

In the review sessions (see section 6.10) the preferred method is **heuristic evaluation**. The main tasks defined in the User task design –phase should also be checked with a **cognitive walkthrough** to see if they are understandable and logical for the user. This should be done with the assistance of clinical experts or actual users.

6.12 Conclusions

When looking at the objectives set in section 1.1 it can be concluded that the process model creation was a success. The current usability engineering methods are described in chapter 4, and they will be added to Usability methods –database of the company along with the implementation notes in section 6.11.

The main problematic aspects of the current usability engineering practices were studied (see section 5.6) and addressed in the new process model and methods in the following way.

- **The tools for user interface development phase aren't adequately defined**.

  A new process phase, User task design, addresses the conceptual design of the interface. The user's most important tasks are designed to be as easy as possible before the user interface is actually realized. The tools for actual interface design activities are still somewhat undefined.

- **The terminology in methods isn't standardized**.

The new definitions of the usability engineering methods are describes in chapter 4 and section 6.11.

- **The usability engineering method database isn't functional as-is**.

  Usability engineering methods database is redesigned to support the new UCD process model, which includes the methods. The links between the process phases will therefore be stronger and the methods database more useful. The combination of the methods database with the UCD process database is also under consideration. The future use of the Usability methods database remains to be seen.

- **Informants evaluate their own unit's efforts in usability maturity assessments**.

  The company will probably implement the KESSU usability maturity evaluation, which uses a single impartial evaluator. This makes the results comparable and more useful.

- **The quality of documentation and communication varies**.

  The quality of communication is enhanced by the descriptions of the deliverables of each usability engineering method. In addition each of the product development phases now requires a deliverable to be created.

  The solution to this problem area is not complete, as the documentation templates and the phase deliverables are not described in detail. Due to the big variability in product development projects giving specific documentation and communication suggestions is difficult.

The new process model described in this chapter satisfies the requirements from FDA presented in subsection 3.2.4. The process has a **plan**, Usability engineering plan, which is followed throughout the process. **User research** is conducted. **User requirements** are specified in a measurable way (see section 6.7) and the review sessions are kept the same as in the current model (see section 6.10). **Usability testing** is arranged and every stage of design has a concrete **deliverable**, which is included in the project documentation.

As stated in section 1.1 while discussing the scope of the work, it was originally meant that the product development process models of other professions shouldn't have been considered. Soon when the study on the current process model began it was noted that at least the review sessions were important to the UCD process model because they linked the usability efforts to the FDA design control structure, which regulates the usability work in medical field. Therefore the **process reviews were essential to be included** to show that the new model takes the regulations into account.

In the beginning of the study it was planned that every usability method should be documented in this chapter as they would be used at Datex-Ohmeda. During the study it became clear that **the full method descriptions would take up too much space**. The objective of clarifying the meaning of each method was already accomplished by describing the theories (see chapter 4) and by writing the practical notes in section 6.11.

There are still **things to improve in the new process model**. The Produce user interaction designs –phase doesn't take manual writing or packaging design into account, which are presented in KESSU model (see subsection 3.2.3). Also, the product development doesn't end when the product is released or the final user interface specification is written. Activities such as customer feedback collection and product support are left unattended in this study. They should be addressed in the company before the process model is taken into use.

7 Validation of the research results

The evaluation of the UCD process model introduced in chapter 6 was difficult due to the fact that every product development project lasts for at least several months. Therefore the whole model couldn't be tested in the limits of this thesis work. The biggest new feature introduced by the new model is the **User task design –phase**, which had to be tested somehow. This was convenient, because one of the Datex-Ohmeda projects was in just the right stage for task design.

In the following section the evaluation process is introduced for the task design phase.

7.1 The User task design -phase

The Task design phase was done for a portable and personal Datex-Ohmeda patient monitor. The project was in a phase that there was some idea on the potential user group, but no clear understanding on how or what the users would use the product to. These issues were addressed by a user study done by interviews and observations. The product had already a working early prototype, which was about to be usability tested.

The methods used in the user task design were **scenarios** and **evaluation with clinical experts** (see figure 28 in section 6.8). One of the interviewed physicians was a full-time Datex-Ohmeda employee, who also had a history of product design. Interviews were used as a task information gathering method. In this sense the User task design –phase was somewhat mixed with Context of Use –phase, which concerns research on the typical tasks of the user.

The interviews consisted of series of conversations with doctors and nurses. They were conducted within Datex-Ohmeda premises. Each interviewee was asked to come up with situations where he would see the concept of personal and portable monitor to be most useful. The respondents were also shown the prototype design to provoke ideas and comments.

After the user studies the actual task design began. The **aim of the task design phase was to create scenarios for the most typical cases** of the usage of the patient monitor. Usually the scenarios were based on a real story or situation described by one of the interviewees. The idea was that the scenarios would be written for every possible user group of the product. In the first phase the target user group would only be one of them, but by doing the interviews and scenarios with all the user groups the future development of the product would be easier. The design team would then already have a good idea on what the other possible users want with the product.

In practice the user task design worked very well. The scenarios not only described the most typical situations so that the design could focus on the most important tasks, but they also served as a basis for usability test scenarios. During the usability test arranged later, the scenarios were found to be good. All the participants agreed that the scenarios were good examples of situations they would probably use the device in. In a way the usability tests served as validation round for the written scenarios as well.

In summary it can be said that this new phase **clearly benefits user interface design**. It gives a clear understanding on what is important and what is not. It also helps in designing the user interface to fit the use context better because of the scenarios that describe the situations where the users would do the things they do with the interface.

7.2 Other process phases

As the other new UCD process stages were existing practices at Datex-Ohmeda they were not validated during this research. The practicalities within each phase were mostly just documented more thoroughly and therefore there would have been little point in checking the other, more "familiar" phases of the user-centered design model.

8 Discussion

As stated in section 6.12 the new process model development process was mostly a success. Both main objectives (see figure 1) set in the beginning for the process model creation were met: a new model, which fixed some important issues on Datex-Ohmeda usability activities was created and the methods were identified and documented in a more standardized way. The **problems** with the process model creation process were mostly related to inadequate documentation and lack of proper long-term planning, as described below.

As a whole the activities while creating the new process model **should have been documented better**, especially in the beginning. While writing this thesis it was somewhat difficult to determine what details of the process model had changed at what point and why. A **design rationale** would have been a useful tool, and is recommended to anyone doing process model development work. Luckily, enough material was written down to get a rudimentary view of what was done, when and why. Supposedly some details were still lost due to inadequate documentation. The lack of documentation was probably due to the fact that the structure of the work wasn't yet entirely thought through when the interviews and inquiries were made. It was not clear on what level of detail the documentation should have been made.

In addition to the inadequate documentation a **better research plan should have been created** in the beginning. Now the study was conducted at some points in an ad-hoc way, thinking mainly the questions coming to mind at the moment. On the other hand the context of the study was new to the researcher. Not everything was clear in the beginning, and many new things to focus on were revealed during the research. This made it impossible to design the whole study beforehand in a precise way.

The **international influence** to the process model and the methods was very small, because the usability professionals' meeting discussed in the previous subsection wasn't as helpful as predicted. Mainly this was due to the scheduling problems. The adaptation with the required international influence will be done in year 2003. The resistance to the change the new process poses may be a challenge, since virtually the whole process was developed quite far without comments from other Datex-Ohmeda sites.

On summary it can be said that the **scope of this thesis was a bit too ambitious**. A more suitable subject for a master's thesis would have been either methods documentation or a new process model creation, not both. Now the methods study had to be restricted to just clarifying the concepts instead of building finalized and more useful descriptions. On the other hand this two sided subject allowed the exploration of the combining process, which was probably the most interesting thing in this work.

The improvement work begun with this thesis will be continued at Datex-Ohmeda by first improving the Usability Engineering Methods –database. The first step should be to write accurate and thorough documentation on the most important methods, which were chosen in the Usability team meeting (see subsection 6.1.3). The documentation should include both theoretical and practical considerations. At some point the new process model will be implemented, but before the implementation it should be gone through with the other sites of Datex-Ohmeda.

Lots of questions for future research still remain. How should the actual implementation of the new model be done? How the future usability maturity assessments should be organized? These are among the questions that are to be answered before this process model is fully functional at Datex-Ohmeda.

9 References

Alexander, I. (2001), Visualizing requirements in UML. http://www.telelogic.com/resources/show_article.cfm?id=2018, referenced 1.8.2002.

ANSI/AAMI (2001), HE74:2001 Human factors design process for medical devices. AAMI.

Beyer, H. & Holtzblatt, K. (1998), Contextual Design – Defining Customer-Centered Systems. Morgan Kaufmann. ISBN: 1-55860-411-1.

Burlington, D. B. (1995), Human Factors and the FDA's Goals: Improved Medical Device Design. In Human Factors in Medical Devices: Design, Regulation and Patient Safety. AAMI / FDA Conference Report. AAMI. ISBN: 1-57020-057-2.

Carroll, J. M. (1997) Scenario-Based Design. In Helander, M. et al. (eds.) Handbook of Human-Computer Interaction, 2nd edition. Elsevier Science. ISBN: 0-444-81876-6.

Constantine, L. & Lockwood, L. (1999), Software for Use – a Practical Guide to Models and Methods of Usage-Centered Design. ACM Press. ISBN: 0-201-92478-1.

Crosby, P.B. (1985), Laatu on ilmaista. Laatuteema Oy. ISBN 951-99737-9.

Dumas, J. S. & Redish, J. C. (1999), A Practical Guide to Usability Testing – Revised Edition. Intellect. ISBN: 1-84150-020-8.

Faulkner, X. (2000), Usability Engineering. Macmillan Press Ltd. ISBN: 0-333-77321-7.

FDA (1997), Design Control Guidance for Medical Device Manufacturers. http://www.fda.gov/cdrh/comp/designgd.pdf, referenced 30.5.2002.

FDA (2002), 21 CFR 820.30 Quality Systems Regulations – Subpart C: Design Controls. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=820.30. Referenced 11.7.2002.

Greenbaum, T. L. (1998), Focus Groups: A Help or a Waste of Time? http://www.groupsplus.com/pages/pmt0797.htm, referenced 26.11.2002.

Gross, T. P. (1995), Human Factors and Postmarket Surveillance at FDA. In Human Factors in Medical Devices: Design, Regulation and Patient Safety. AAMI / FDA Conference Report. AAMI. ISBN: 1-57020-057-2.

Hackos, J. T. & Redish J. C (1998), User and Task Analysis for Interface Design. John Wiley & Sons, Inc. ISBN: 0-471-17831-4.

Hansen, M. (1991), Ten steps to usability testing. In Proceedings of the conference on 1991 ACM ninth annual international conference on systems documentation.

Hix, D. & Hartson, H. (1993), Developing User Interfaces: Ensuring Usability Through Product and Process. Wiley. ISBN: 0-471-57813-4.

Houde S. & Hill C. (1997), What do Prototypes Prototype? In Helander, M. et al. (eds.) Handbook of Human-Computer Interaction, 2nd edition. Elsevier Science. ISBN: 0-444-81876-6.

Hyman, W. A. (1994), Error in the Use of Medical Equipment. In Bogner, M. S. (ed.) Human Error in Medicine. Lawrence Erlbaum Associates. ISBN: 0-8058-1386-1.

IEC (2002), 60601 62A/CD2 Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability.

ISO (1998), 9241 Ergonomic requirements for office work with visual display terminals (VDT's) – part 11: Guidance on usability.

ISO (1999), 13407 Human-Centered Design Processes for Interactive Systems.

ISO (2000), 18529 Ergonomics – Ergonomics of human-system interaction – Human-centered lifecycle process descriptions.

Jacobson, I. et al. (1992), Object-Oriented Software Engineering: A Use Case Driven Approach. Addison-Wesley. ISBN: 0-201-54435-0.

Jeffries, R. (1997), The Role of Task Analysis in the Design of Software. In Helander, M. et al. (eds.) Handbook of Human-Computer Interaction, 2nd edition. Elsevier Science. ISBN: 0-444-81876-6.

Jokela, T. (2001), Assessment of user-centered design processes as a basis for improvement action – an experimental study in industrial settings. Doctoral thesis, University of Oulu. http://herkules.oulu.fi/isbn9514265513/isbn9514265513.pdf, referenced 10.6.2002.

Jokela, T. (2002), A Method-Independent Process Model of User-Centered Design. IFIP 17th World Computer Conference 2002 - TC 13 Stream on Usability: Gaining a Competitive Edge, Montreal, Kluwer Academic Publishers.

Kirakowski, J. (2000), Questionnaires in Usability Engineering – A List of Frequently Asked Questions (3rd Ed.). http://www.ucc.ie/hfrg/resources/qfaq1.html. Referenced 2.7.2002

Lewis, C. & Wharton, C. (1997), Cognitive Walkthroughs. In Helander, M. et al. (eds.) Handbook of Human-Computer Interaction, 2nd edition. Elsevier Science. ISBN: 0-444-81876-6.

Maguire, M. (1997), RESPECT User Requirements Framework Handbook, version 2.2. Preliminary version. EC Telematics Applications Programme.

Mayhew, D. (1999), The Usability Engineering Lifecycle – a Practitioner's Handbook for User Interface Design. Morgan Kaufman. ISBN: 1-55860-561-4.

Muller, M. J. et al. (1997), Participatory practices in the Software Lifecycle. In Helander, M. et al. (eds.) Handbook of Human-Computer Interaction, 2nd edition. Elsevier Science. ISBN: 0-444-81876-6.

Nielsen, J. et al. (1986), Integrated Software Usage in Professional Work Environment: Evidence from Questionnaires and Interviews. In Mantei, M. & Orbeton J. (eds.) Conference proceedings of CHI ´86.

Nielsen, J. (1993), Usability Engineering. Academic Press Inc. ISBN: 1-12-518406-9.

Nielsen, J. (2000), Test with 5 Users. Alertbox column, March 19th 2000. http://www.useit.com/alertbox/20000319.html, referenced 27.6.2002.

Nielsen, J. (2001), The Usability Lifecycle. http://www-106.ibm.com/developerworks/library/it-nielsen3/, referenced 5.6.2002.

Polson, P. G. et al. (1992) Cognitive walkthroughs: a method for theory-based evaluation on user interfaces. International Journal of Man-Machine Studies, 5 / 36.

Preece, J. (1994), Human-Computer Interaction. Addison-Wesley. ISBN: 0-201-62769-9.

Riihiaho, S. (2000), Experiences with Usability Evaluation Methods. Licentiate's thesis, Helsinki University of Technology. http://www.soberit.hut.fi/~sri/Riihiaho_thesis.pdf, referenced 2.8.2002.

Rubin, J. (1994) Handbook of Usability Testing: How to Plan, Design and Conduct Effective Tests. John Wiley & Sons Inc. ISBN: 0-471-59403-2.

Sawyer, D. (1996), Do It By Design - An Introduction to Human Factors in Medical Devices. http://www.fda.gov/cdrh/humfac/doit.html, referenced 29.5.2002.

Schneiderman, B. (1998), Designing the User Interface - Strategies for Effective Human-Computer Interaction, 3rd edition. Addison Wesley Longman Inc. ISBN: 0-201-69497-2.

Senders, J. W. (1994), Medical Devices, Medical Errors, and Medical Accidents. In Bogner, M. S. (ed.) Human Error in Medicine. Lawrence Erlbaum Associates. ISBN: 0-8058-1386-1.

Sommerville, I. (1989), Software Engineering, 3rd edition. Addison-Wesley. ISBN: 0-201-17568-1.

Appendix A: a guideline for task analysis

Xristine Faulkner's guideline for task analysis (Faulkner 2000):

Define the inputs of the task:

- **What information is needed?** What information the task performer needs to complete the task?
- **What are the characteristics of the information sources?** Is the information reliable? Is it in the right form?
- **What is the availability of information?** Is the information affected by outside sources or restricted in some way?
- **What possible errors might occur?**
- **Who or what initiates the task?** What has happened before to initiate this task?

Define the outputs:

- **What are the performance criteria?** What is the range of possible outcomes? Which of them are acceptable?
- **What happens to the output?** Is the output passed to some other task or process?
- **How does the task performer get feedback about task performance?** How the feedback is currently gathered?

Define the possible task transformations:

- **What is the nature of the decision making?** What decisions the task performer has to make?
- **What strategies exist for decision making?** How the user makes the decisions she makes?
- **What skills are needed?**
- **What interruptions are likely to occur and when?** Which interruptions could cause errors?

Define the task composition:

- **How often the task is done and when?**
- **Does the task depend on any other task?** Do the other tasks effect this one in any way?
- **What is the normal/abnormal workload?** How does the user cope with an abnormal workload?
- What control does the task performer have over workload? Can the user schedule her own work?

Appendix B: forms for cognitive walkthroughs

Cognitive Walkthrough Start-up Sheet

Interface ____

Task ____

Evaluator(s) ____ **Date** __________

Task Description: Describe the task from the point of view of the first-time user. Include any special assumptions about the state of the system assumed when the user begins work.

Action Sequence: Make a numbered list of the atomic actions that the user should perform to accomplish the task.

Anticipated Users: Briefly describe the class of users who will use this system. Note what experience they are expected to have with systems similar to this one, or with earlier versions of the system.

User's Initial Goals: List the goals the user is *likely to form* when starting the task. If there are other likely goal structures list them, and estimate for each which percentage of users are likely to have them.

1. Cognitive Walkthrough For A Step

Task ____ **Action #** __________

Goal structure for this step

Correct goals. What are the appropriate goals for this point in the interaction? Describe as for initial goals.

Mismatch with likely goals. What percentage of users will not have these goals, based on the analysis at the end of the previous step? Check each goal in this structure against your analysis at the end of the previous step. Based on that analysis, will all users have the goal at this point, or may some users have dropped it or failed from it? Also check the analysis at the end of the previous step to see if there are unwanted goals, not appropriate for this step, that will be formed or retained by some users. (% 0 25 50 75 100)

2. Choosing and executing the action

Correct action at this step ____

Availability. Is it obvious that the **correct** action is a possible choice here? If not, what percentage of users might miss it? (% 0 25 50 75 100)

Label. What label or description is associated with the **correct** action?

Link of label to action. If there is a label or description associated with the **correct** action, is it obvious, and is it clearly linked with this action? If not, what percentage of users might have trouble? (% 0 25 50 75 100)

Link of label to goal. If there is a label or description associated with the **correct** action, is it obviously connected with one of the current goals for this step? How? If not, what percentage of the users might have trouble? Assume all the users have appropriate goals listed in Section 1. (% 0 25 50 75 100)

No label. If there is no label associated with the **correct** action, how will users relate this action to a current goal? What percentage might have trouble doing so? (% 0 25 50 75 100)

Wrong choices. Are there other actions that might seem appropriate to some current goal? If so, what are they, and what percentage of users might choose one of these? (% 0 25 50 75 100)

Time-out. If there is a time-out in the interface at this step does it allow for the user to select the appropriate action? How many users might have trouble? (% 0 25 50 75 100)

Hard to do. Is there anything physically tricky about executing the action? If so, what percentage of users will have trouble? (% 0 25 50 75 100)

3. Modification of goal structure

Assume that the correct action is taken. What is the system's response?

Quit or backup. Will the users see that they have made progress towards some current goal? What will indicate this to them? What percentage of users will not see progress and try to quit or backup? (% 0 25 50 75 100)

Accomplished goals. List all current goals that have been accomplished. Is it obvious from the system response that each has been accomplished? If not, indicate for each how many users will not realize it is complete.

Incomplete goals that look complete. Are there any current goals that have not been accomplished, but might appear to have been based on the system response? What might indicate this? List any such goals and the percentage of users will think they have actually been accomplished.

"And-then" structures. Is there an "and-then" structure, and does one of its subgoals appear to be complete? If the subgoal is similar to the supergoal, estimate how many users may prematurely terminate the "and-then" structure.

New goals in response to prompts. Does the system response contain a prompt or cue that suggests any new goal or goals? If so, describe the goals. If the prompt is unclear, indicate the percentage of users who will not form these goals.

Other new goals. Are there any other new goals that users will form given their current goals, the state of the interface and their background knowledge? Why? If so, describe the goals, and indicate how many users will form them. NOTE that these goals may or mat not be inappropriate, so forming them may be bad or good.

Appendix C: ethical considerations on usability testing

Jakob Nielsen's ethical considerations on user testing:

Before the test:

- Have everything ready before the user shows up.
- Emphasize that it is the system that is being tested, not the user.
- Acknowledge that the software is new and untested, and may have problems.
- Let users know that they can stop at any time.
- Explain any recording, keystroke logging, or other monitoring that is used.
- Tell the user that the test results will be kept completely confidential.
- Make sure that you have answered all the user's questions before proceeding.

During the test:

- Try to give the user an early success experience.
- Hand out the test tasks one at a time.
- Keep a relaxed atmosphere in the test room, serve coffee and/or have breaks.
- Avoid disruptions: Close the door and post a sign on it. Disable telephone.
- Never indicate in any way that the user is making mistakes or is too slow.
- Minimize the number of observers in the test.
- Do not allow user's management to observe the test.
- If necessary, have the experimenter stop the test if it becomes too unpleasant.

After the test:

- End by stating that the user has helped you find areas of improvement.
- Never report results in such a way that individual users can be identified.
- Only show videotapes outside the usability group with the user's permission.