

# The Human Factors Engineering (HFE) process, usability quality and use safety for medical equipment

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*To enable increased efficiency, effectiveness and safe handling of medical equipment, applicable frameworks are needed that support evaluation work during the product development process. A use centred design approach for medical devices has been developed, resulting in a framework consisting of three parts: (1) A Human Factors Engineering process, (2) Usability Quality and (3) Use Safety. In the framework different methods for data collection and evaluation of use errors and usability problems are proposed. To develop safe, usable and efficient products, the framework should be integrated with the overall product development process of the medical equipment.*

*Medical equipment, Human Factors Engineering, Usability, Risk, Safety*

## **1 Introduction**

In the area of healthcare, the use of technical equipment is increasing every year. This raises the need for medical equipment to be adapted to the human, the task and the environment. If the interaction between the human and the device fails, it can lead to devastating consequences for the patients (Crowley and Kaye, 2002).

The relation between the human, the task, the device and the environment needs to be attended to during the product development process. Medical equipment should be designed to (1) be effective and efficient in the use, (2) minimise the probability of use errors in the interaction, and (3) reduce the consequences if a failure does occur. This can be achieved by the designer by applying a use centred human factors engineering product development process.

To enable increased efficient, effective and safe handling of medical equipment, applicable frameworks are needed during the development process, which support the work with use centred product development.. In the research group for Human Machine Interaction, at the Division of Design at Chalmers University of Technology, research in the field of human factors engineering for medical equipment has been conducted for the last 10 years. The result from this work, together with research in the area presented in literature and existing standards, has resulted in a conclusion concerning a use centred design approach for medical devices. The framework consists of three parts:

- The Human Factors Engineering (HFE) process – *An iterative process that involves the users*
- The Usability Quality - *Making measurable requirements based on the use (human, machine, task and environment)*
- The Use Safety - *Proactive work with risk and safety related to the use*

The objective of this paper is to describe suggestions for a framework of a use centred design approach in the product development of medical equipment.

## 2 The HFE-process

The work with usability in the product development process is facilitated by the use of a structured work approach, i.e a process. The processes described in the literature have different terms and content. User centred design processes derived from software development have often emphasis on a circular process with its iterated steps, e.g. the Human-centred design activities ISO 13407 (1999). The field of classic human machine interaction also has an iterative approach, but with a more step-wise process, e.g. the Ergonomic design process ISO 11064-1 (2000). For medical equipment IEC has suggested a circular stepwise Usability Engineering Process (IEC, 2004).

The iterative design process proposed by Chalmers is a combination of the above suggested processes, with a small and a large iteration. The large iteration consists of four parts: (1) requirements and task design, (2) conceptual design, (3) detailed design, and (4) implementation (

Figure 1). In each part of the large iteration, the small iteration takes place. The small iteration consists of four steps: (1) data collection, (2) analysis, (3) synthesis, and (4) evaluation ( Figure 2). When the two iterations are put together they can be described as brickwork (Figure ).

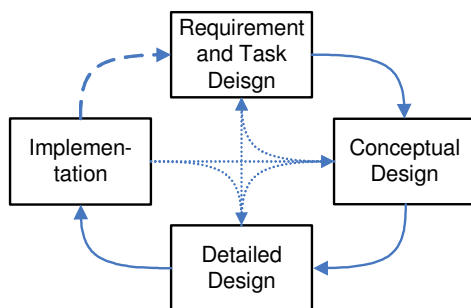


Figure 1, The Large Iteration

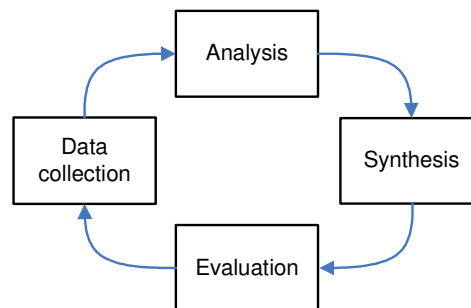


Figure 2, The Small Iteration

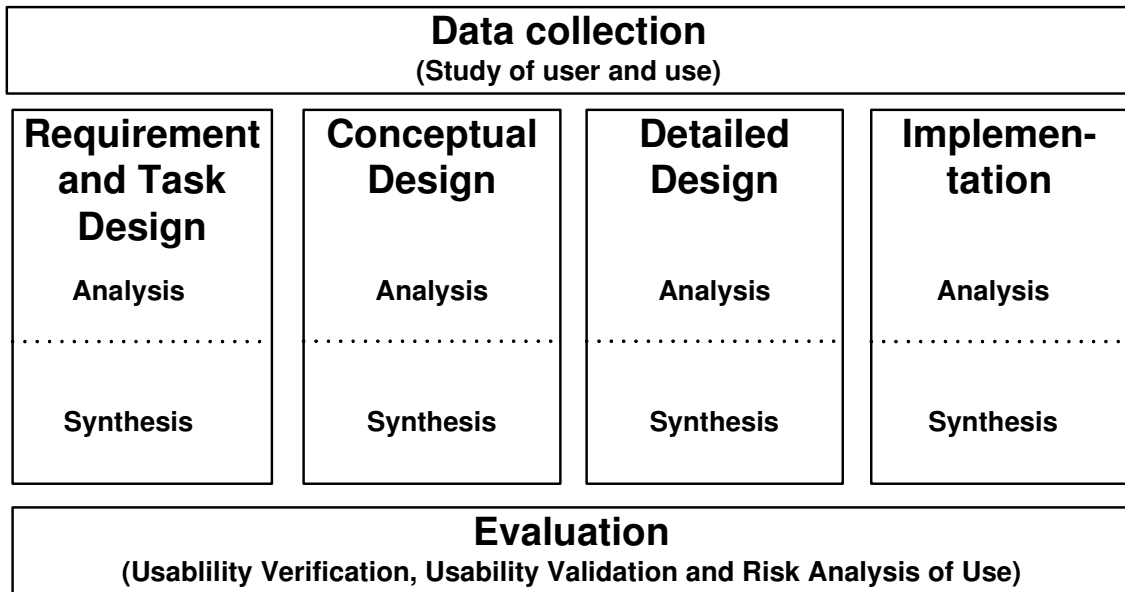


Figure 3, The Chalmers HFE-process description in brickwork

Every part of the large iteration includes data collection and analysis if the data (input from the users and use), as well as an evaluation of the synthesis (Figure 3). In the Requirement and Task Design, both the user and the use are analysed, then the synthesis results in a user profile, a task description and usability requirements, goals and guidelines. In the Conceptual Design, different types of interaction is analysed, then the synthesis results in a conceptual design of the user interface.

In the Detailed Design, the functional demands in the user interface are analysed, and the synthesis results in a detailed design specification of the user interface. In the Implementation, the fulfilment of requirements, goals and guidelines of the devise are analysed, and synthesis results in a final documentation of verification and validation. Even though the description of the process is made in different parts, much of the actual work is often made in parallel (Figure 4, ).

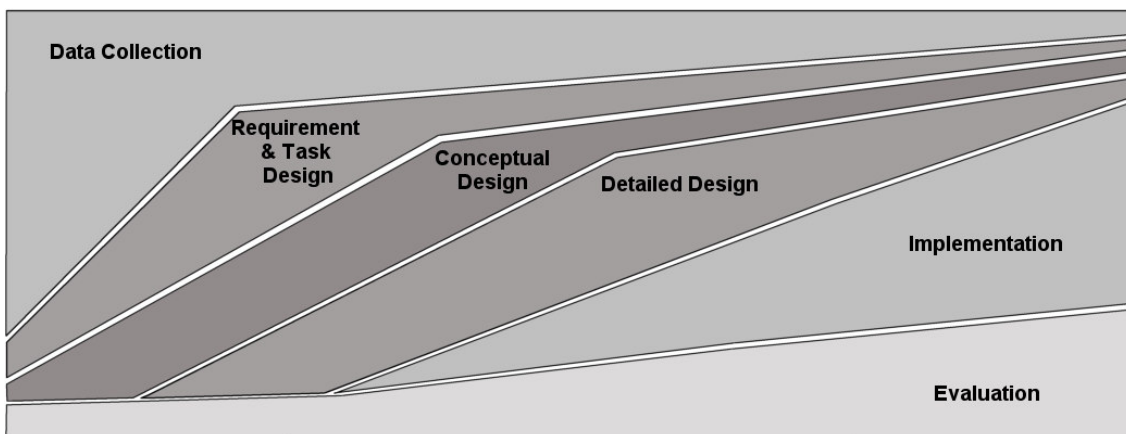


Figure 4, Distribution of the work when using the Chalmers HFE process

### **3 Usability Quality**

Quality is a term full of nuances, but the standard ISO 8042 (ISO, 1986) defines quality as the totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs. One natural part of this is the usability of the equipment. When developing devices for human use, it is of large interest to achieve adequate and proper levels of effectiveness, efficiency and satisfaction in the use, i.e. to achieve the right usability quality.

The general work with product quality (Quality Management) can be divided into three parts: Quality Planning, Quality Assurance, and Quality Control (ISO, 2000). In the work with achieving adequate and proper levels of usability (Usability Quality Management) also three different activates of quality be identified: Usability Quality Planning, Usability Quality Assurance, and Usability Quality Control.

#### *3.1 Usability Quality Planning*

The Usability Quality Planning has the aim to determine which quality standard that is relevant for the device for achieving adequate and proper levels of usability, i.e. deriving Usability Goals, Usability Requirements and Usability Guidelines. This activity is an activity of the requirement and task design part according to the HFE-processes (Figure 3). The Usability Quality Planning consists of four parts; Selection, Collection, Deciding quality standard, and Specification.

The aim with the Selection part is to establish relevant aspects of the usability quality, i.e. what scale is adequate to measure a proper level of usability on. During the Selection part, usability metrics for the usability goals, demand types for the usability guidelines, and direction for the usability guidelines are selected.

In the Collection part, information relevant to made selections on are collected. Reference values for the goals are gathered, User and use demands are gather for the requirements and relevant existing usability guidelines are gathered. Then, Deciding the quality standard is made, i.e what is the adequate and proper level of usability. This can be made by relating to other quality standards of the device and by comparison to competitive devices.

The last part of the Usability Planning is the Specification. During this part the usability goals, the usability requirements and the usability guidelines are formulated.

#### *3.2 Usability Quality Assurance*

Usability Quality Assurance has the aim to ensure that the development process of the device follows the quality standard, i.e. a formative usability evaluation. This activity is a part of the Evaluation in the conceptual design and the Detailed Design parts of the HFE-process.

#### *3.3 Usability Quality Control*

Usability Quality Control has the aim to ensure that goals and requirements are fulfilled in the developed device, i.e. that the developed device complies with the quality standards, i.e. a summative usability evaluation. This activity is a part of the Evaluation in the Implementation part of the process. The Usability Control consists of two parts;

Evaluation and Judgment. The Summative Evaluation consists of a Usability Validation which assesses the usability goals, a Usability Verification which assesses the Usability Requirements, and a Heuristic Evaluation which assesses the Usability Guidelines. The judgement investigates first if the result from the evaluation is good enough or not, and secondly what needs to be changed to get it good enough.

#### **4 Use safety**

Even if the Usability Quality Management achieves a high over all quality level, it does not automatically imply high use safety. This since over all usability focuses foremost on common and expected scenarios, and it is often the uncommon and unexpected scenarios that results in accidents. In safety critical technical systems, as medical devices, it is essential to work explicit to reduce the risk related to the use. The goal is to prevent the inherent hazards to cause harm. The use related hazards arise from use errors or hazardous use scenarios. One of the most important tasks when dealing with risk from use, is to have a comprehensive and accurate understanding of how the device will be used in reality, which also is emphasised by the FDA (Kaye and Crowley, 2000).

The work to ensure overall safety in medical equipment is made through Risk Management. According to ISO 14971 (ISO, 2000) Risk Management can be divided into three parts: Risk Analysis, Risk Evaluation, and Risk Control. FDA has stated that consideration of use-related hazards in risk management processes should include the following tasks (Kaye and Crowley, 2000):

1. Identify and describe use-related hazards through analysis of existing information
2. Apply empirical approaches using representative device users, to identify and describe hazards that do not lend themselves to identification or understanding through analytic approaches,
3. Estimate the risk of each use-related hazard scenario,
4. Develop strategies and controls to reduce the likelihood or mitigate the consequences of use-related hazard scenarios,
5. Select and implement control strategies,
6. Ensure controls are appropriate and effective in reducing risk,
7. Determine if new hazards have been introduced as a result of implementing control strategies,
8. Verify that functional and operational requirements are met, and
9. Validate safe and effective device use.

Based on this the work with use safety (Use Risk Management) can be divided in to three parts: Use Risk Analysis, Use Risk Evaluation and Use risk control.

##### *4.1 Use Risk Analysis*

The aim with Use Risk Analysis is to systematic use available information to identify use hazards and estimate the risk. The activities in the analysis are to gain knowledge of the user and the use through task analysis, observations, interviews, focus groups etc., identify anticipated and unanticipated use-related hazards through analytical and empirical methods, describe how hazardous use scenarios occur through use case and

risk analysis (e.g. Fault Tree Analysis), and estimate the risk of each use-related hazard scenario through estimation of probability and consequence.

#### *4.2 Use Risk Evaluation and Use Risk Control*

The aim with Use Risk Evaluation is to judge whether a use risk which is acceptable or if risk reduction is needed. The judgement is related to the over all risk management of the device.

The content of the Use Risk Control is to take action to reduce the likelihood or the consequences of risk through use of knowledge from the field of human factors engineering to redesign a task or product. In the Use Risk Control is also included to verify and validate the measures through analytical and empirical evaluation.

#### *4.3 Use Risk Management and the HFE-process.*

In contrast to the work with usability quality, the work with Use Safety is present in every part of the HFE-process. It is important to determine that no new hazards have been introduced as the result of the further development, and of the implemented risk control strategies. Every iteration in the HFE-process build up the use risk analysis and therefore the analysis becomes more complete during the process. It is also important to start the use risk analysis in the HFE-process. This since the result often has an influence both on the usability goal and requirement and on the whole product development process.

### **5 Concluding remarks**

The three parts of the use centred design approach; The HFE-process, Usability Quality and Use Safety, shall not be regarded as separate parts. On the contrary they are integrated, since they use the same background information and the same methods. In the same manner, the HFE-process shall be integrated with the over all product development process. The Usability Quality shall be integrated with product quality management and the Use Safety shall be integrated with other work with risk and safety of the product.

### **6 References**

- Crowley, J. J. and Kaye, R. D. (2002). "Identifying and understanding medical device use errors." Journal of Clinical Engineering **27**(3): 188-93.
- IEC (2004). IEC 60601-1-6:2004 Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability Geneva, IEC.
- ISO (1986). ISO 8042:1986 Shock and vibration measurements -- Characteristics to be specified for seismic pick-ups Geneva, International Standard Organization.
- ISO (2000). ISO 9000:2000 Quality management systems -- Fundamentals and vocabulary. Geneva, International Standard Organization.
- ISO (2000). ISO 14971:2000 Medical devices - Application of risk management to medical devices. Geneva, International Standard Organization.
- Kaye, R. and Crowley, J. (2000). Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management. Rockville, US Food and Drug Administration.