Usability and ergonomics in medical equipment

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In the area of healthcare, the use of technical equipment is increasing every year. The extensive use of technology puts large demands on the operators' capabilities to handle the equipment in a proper way. If the interaction between the human and the machine fails, it can lead to consequences for the patients. To avoid these problems, it is important to design medical equipment with high usability and ergonomic features. This can be performed by using a use centred product development process, involving human factors engineering methods, and ergonomic requirements, goals and guidelines. Especially the involvement of actual users in the design process is crucial

Medical technology, usability, ergonomic features, use centred design

1 Introduction

In the area of healthcare, the use of technical equipment is increasing every year. The extensive use of technology puts large demands on the operators' capabilities to handle the equipment in a proper way. If the interaction between the human and the machine fails, it can lead to consequences for the patients (Crowley and Kaye, 2002). Three main effects of insufficient handling can be distinguished:

- The user makes a mistake that results in injury to the patient – a use error,
- The users become stressed and anxious, diminishing their capacity for giving the patients care,
- The user can not use the technology and therefore the treatment does not benefit the patients

To avoid this, it is important to design medical equipment with a high usability and good ergonomic features, so the device is adapted to the human, the task and the environment. This can be performed by using a use centred product development process, involving human factors engineering methods, and requirements, goals and guidelines. To be able to do this, the first and foremost is the involvement of actual users in the product development.

2 Objectives

This paper describes experience from working with ergonomics and usability for medical equipment in product development projects. The paper emphasis three main parts and present practical advice for: (1) Use requirements, (2) Involvement of users, and (3) Use of human factors engineering methods the product development process.

3 Usability and physical ergonomics

The aim for the area of Human Factors Engineering is "*The application of knowledge about human behaviour, abilities, limitations and other characteristics to the design of tools, machines, equipment, devices, systems, tasks, jobs, and environments to achieve productive, safe, comfortable, and effective human use."(Chapanis, 1985).* Two central parts in the definition are usability and physical ergonomics. Physical ergonomic features are often well known but usability features may need an explanation.

Usefulness is a measure of how well a technical system can achieve a desired goal. Usefulness can then be divided into two aspects; utility and usability (Nielsen, 1993). Utility depends on whether the functionality of the technical system can perform what is required, while usability depends on how well the user can use that functionality. In medical equipment the utility becomes then the medical function of the equipment, such as how well a blood-pressure gauge measures blood pressure, or how well a scalpel cuts. Usability becomes how well the medical personnel can use the equipment's medical functionality, such as whether a nurse can understand what the blood-pressure gauge displays or whether the scalpel fits in a surgeon's hand.

The main thing is that both high usability and good physical ergonomics is not an inherent characteristic of a product or technical system. They are derived from the interplay between the human, the machine, the task and the environment.

4 The need for user involvement

To achieve high usability and good physical ergonomics the involvement of users are essential. Users' influence in the evaluation of prototypes can never be neglected. As test subjects in empirical evaluations, the users' expertise or previous experience influences their final decision making in performance. Real test users' interpretation, behaviour and handling of a device or user interface can never be estimated in advance. User profiles, including age, sex, expertise, number of years in profession, culture, training, education level, risk taking etc., are essential to define for each specific user study. The number of test subjects to involve in a specific evaluation is also dependent of the expected outcome of the study. If the results should be used for statistical analysis the number of test subjects in a group should be at least 12. If the results only should be used for identifying possible usability problems, the number could be decreased to 6.

5 The need for use of requirements, goals and guidelines

To support the engineering work in the product development process, there is a need for a standard, which shows the good enough level for usability and physical ergonomics. Such a standard should contain three types of components:

1. Goals - Measurable quality goals for usability and physical ergonomics
2. Requirements - Verifiable requirements from usability and physical ergonomics
3. Usability Guidelines - Help and support in the design work

5.1 Goals

The goals describe measurable attributes that needs to be fulfilled to achieve a "good enough" usability and physical ergonomics (IEC, 2004). The goals can bee both objective and subjective.

5.1.1 Examples of Usability goals

Objective	Subjective
80% of the operators shall successfully be able to calibrate the device within 5 minutes of first try.	Two thirds of the operators shall prefer the next generation of machine to the existing device
After reading the quick reference guide, 90 % of the operators shall be able to configure the display correctly to show two lead traces on the first try.	On average, 80% of the operators shall rate the monitor display as 5 or better on a scale of 1=very hard to read, to 7 = very easy to read.
If users have performed dressing of the dialysis machine once, the second time there shall not be any remaining use errors.	After performing dressing of the dialysis machine for the second time, no user should feel insecure about his/her executed actions.

5.1.2 Examples of Physical Ergonomic goals

Objective	Subjective
For a 5-percentile woman, only 0,5 % of the tasks should be performed above shoulder level.	Two thirds of the operators shall prefer the next generation of dialysis machine to the existing device upon dressing an single needle treatment,
For a 95-percentile male, the hips shall not be bent more then 60 degrees when dressing the device.	On average, 80% of the operators shall rate the physical workload as 5 or better on a scale of 1=very heavy workload, to 7 = very light workload.
For a 50-perceptil user, no actions shall be graded higher then 7 in the REBA analysis,	On average, 90 % of the operators shall rate perceived discomfort lower then 3 on a scale of 1=no discomfort, to 7 = very high discomfort.

5.2 Requirements

The requirements describe what the medical equipment shall or should fulfil to ensure sufficient quality in usability and physical ergonomics.

5.2.1 Examples of usability requirements:

- In maximum 6 different colures should be used in the graphical user interface.
- All connectors to disposables should be coded and keyed.
- The text on the display should be readable from a distance of 2 meters for normal eyesight.

5.2.2 Examples of physical ergonomic requirements:

- There should not be any manual handling actions below knee height.
- The display should be possible to tilt from 60 – 90 degrees from floor level.
- The grip force needed to open the clips should be less then 3 N.

5.3 Guidelines

As help to reach the goal and the requirements guidelines are used. The guidelines are created from theory, previous experience and analysis of user and use.

5.3.1 Example of usability guidelines

- Make potentially dangerous actions difficult or impossible to perform.
- Minimize activities requiring passive or repetitive actions.
- Continually update operators on the current process state.
- Minimize the semantic distance between interface displays and mental models.

5.3.2 Example of ergonomic guidelines

- Avoid all twisting and bending of the back.
- Keep variation in total body posture; avoid static loads.
- Avoid forward inclination of the head and trunk, which can be the case when machine buttons and controls are placed to low.
- No backwards bending of the neck should be needed to view displays

6 The need for methods

In the work with usability and physical ergonomics there exist a large number of methods to be used. Two groups of methods often used are data collection methods and evaluation methods.

6.1 Data collection methods

In product development, it is necessary to gather information from the user and the use. Important methods are, for example, those of gathering information from users, such as interviews, observations and surveys.

6.2 Evaluation methods

This group of methods aims to evaluate the design of a product or a technical system. In the area of physical ergonomics there exist methods for posture analysis, e.g. Rapid Upper Limb Assessment (McAtamney and Corlett, 1993), Rapid Entire Body Assessment (Hignett and McAtamney, 2000) and Predictive Ergonomic Error Analysis (PEEA) (Bligård and Osvalder, 2006).

The methods evaluating usability can be divided into two sub-groups: empirical and analytical/theoretical methods. The empirical evaluation involves studies of users who interact with the user interface, for example in usability tests (Nielsen, 1993). In analytical evaluations, it is not the “genuine” interaction between artefact and user that is studied – the evaluation is made by one or more analysts with the help of a theoretical method. Thus no real users need to collaborate in the analytical evaluation. Nonetheless, it is a great advantage if some or all analysts have experience of use. Examples of analytical methods are Heuristic Evaluation (Zhang et al., 2003), Enhanced Cognitive Walkthrough (Bligård and Osvalder, 2006) and Predictive Use Error Analysis (Bligård, 2007).

7 Discussion and concussion

To involve work with ergonomics and usability in the product development process for medical technology is very important today. Medical companies have started to market their products not only with high functionality and a lot of technical features, but also as being effective, safe and easy to use. Work related problems are also important to prevent, both physical stress of the muscular skeletal system due to bad working postures, as well as overload of information leading to mental stress. By offering a product with high usability and ergonomic features, a company can compete with new qualities and design features that are up to date and just in time for the future.

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