Chapter 10
Using New Model-Based Techniques for the User Interface Design of Medical Devices and Systems

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ABSTRACT

Studies concerning critical incidents with technical equipment in the medical/clinical context have found out, that in most of the cases non-ergonomic and non-reliable user interfaces provoke use deficiencies and therefore hazards for the patient and the attending physician. Based on these studies, the authors assume that adequate and powerful tools for the systematic design of error-tolerant and ergonomic Human-Machine-Interfaces for medical devices are missing. In this context, the Chair of Medical Engineering (mediTEC) has developed the new software-based tool mAIXuse in order to overcome these difficulties and to support designers as well as risk assessors. Based on two classical formal-analytical approaches, mAIXuse provides a high-performance modelling structure with integrated temporal relations in order to visualise and analyse the detailed use process, even with complex user interfaces. The approach can be used from the very early developmental stages up to the final validation process. Results of a comparative study with the new mAIXuse tool and a conventional process-FMEA (Failure Mode and Effect Analysis) show, that the new approach clearly outperforms the FMEA technique.

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INTRODUCTION

The major objective of the rapidly evolving technological progress and automation in the field of medical devices and systems is an enhancement of the efficiency and effectiveness of diagnostic, therapeutic procedures. This is partially associated with fundamental changes of the Human-Machine-Interaction characteristics. To ensure safe and reliable user interfaces not only ergonomic but also error-tolerant interface design has to be taken into consideration by the design engineer. In this context, a new software-based tool *mAIXuse* for formal-analytical usability evaluation and use-oriented risk analysis of medical devices and systems has been developed at the Chair of Medical Engineering and will be presented in this chapter. The in depth analysis of human error in the clinical context of use are of major importance particularly for the introduction of new technical equipment into the medical work system. State of the art methods and tools in usability engineering and risk analysis still have some problems and bottlenecks related to a systematic a-priori as well as a-posteriori review and analysis of human induced risks in risk sensitive work processes. As the complexity and speed of development of medical devices is increasing (more than 50% of medical products typically are less than 2 years on the market) and as the incidents of human error in medicine increases, more sophisticated tools for human error risk analysis seems to be mandatory.

The main focus of this chapter is on the development and evaluation of the *mAIXuse* approach for model-based usability evaluation and use-oriented risk analysis.

BACKGROUND

The overall risk for manufacturers of risk-sensitive products (e.g. in aeronautics, nuclear engineering, medical technology and pharmaceuticals) has increased in recent years. Expensive products can only be lucrative if they are distributed to a large number of customers worldwide. This increases not only the cumulative potential damage, but also the potential consequences. Especially in the medical field of diagnostic and therapeutic systems undetected remaining failures or residual risks, which occur in the development process, often cannot be tolerated. Bringing defective and erroneous products to the market means a high potential of severe consequences for the manufacturers. Apart from ethical considerations, related costs can endanger the livelihood of enterprises. It ranges from warranty and goodwill costs to product recalls as well as liability for consequential damages.

The medical branch is, similar to almost all manufacturing industries, under a high cost and time pressure, which is characterised by globalisation and dynamic markets, innovation and shorter product life cycles. The increase of the complexity of products and production processes is another factor determining the situation of the risk (Doubt, 2000). The necessity to respond to the risks, is also reflected by the fact that the introduction of systematic risk management processes including the early application of an usability engineering process in accordance with established national and international standards (EN ISO 14971, IEC 62366, MDD (Medical Device Directive), FDA (Food and Drug Administration)) are obligatory for medical device manufacturers.

The risk management process can be seen as a "systematic application of management principles, procedures and practices to identify, analyse, treat and monitor understanding of risks, allowing organisations to minimise losses and maximise opportunities" (Hoffmann, 1985). However, these goals are often missed in practice (Hansis, 2002). There are about 40.000 malpractice complaints and the evidence of more than 12.000 malpractice events per year in Germany (Kindler, 2003). More than 2.000 cases of this so-called "medical malpractice" can be traced to medical and surgical causes, leading in the end to the death of the