Development and Evaluation of a Knowledge-Based Method for the Treatment of Use-Oriented and Technical Risks Using the Example of Medical Devices

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Abstract. Rapidly evolving technological progress in the field of medical devices not only leads to a potential enhancement of therapeutic results but also to a change of the Human-Machine-Interaction characteristics, causing deficiencies in the use process and bringing along high potential for hazardous human-induced failures. This implicates higher risks for patients, medical professionals and third parties. In order to support the usability engineering and risk management process of medical devices, a new methodology for risk control has been developed and evaluated. The aim is to implement appropriate counteractions in the risk control process, reducing errors in the Human-Machine-Interaction process as well as system-inherent technological risks. Accessing information from the method's knowledge base enables the operator to detect the most suitable countermeasures for the respective problem. 41 approved generic countermeasure principles have been indexed as a resulting combination of root causes and failures that might appear during Human-Machine-Interaction or manufacturing and developmental process. The method has been tested in comparison to conventional approaches. Evaluation of the matrix and reassessment of the risk priority numbers by a blind expert demonstrated a substantial benefit of the new *mAIXcontrol* method.

Keywords: Human Error Taxonomy, Usability Engineering, Human-Machine-Interaction, Risk Control, Human Factors in Risk Management, System Safety, Theory of Inventive Problem Solving (TRIZ), Healthcare/Medical Systems.

1 Introduction

In the field of medical devices, strict regulatory standards exist, defining the development process for medical devices, supporting good manufacturing practices and giving advice for user-centered human device interfaces [8][9]. One important standard is the DIN EN ISO 14971 (Medical devices - Application of risk management to medical devices) which divides the risk management process into four stages: risk identification, risk evaluation, risk control and market observation [10]. In contrast to risk identification or risk evaluation, at present no methodological approach for the generation and selection of countermeasures within risk control process exists.

A. Marcus (Ed.): DUXU/HCII 2013, Part II, LNCS 8013, pp. 452–461, 2013.

Brainstorming – being the most common state-of-the-art method - is a rather simple and unsystematic approach. Moreover, as a quality criterion of a countermeasure, only the recommendation to distinguish between inherent, protective and descriptive security measures makes it possible to compare safety measures on the basis of a common value system [10]. This makes it difficult for developers and risk managers to find, choose, implement and also justify effective and efficient risk control measures when designing a product or setting the alignment for a manufacturing process.

2 State of the Art

2.1 Usability Engineering and Risk Management

Scientific studies in the medical context show that in most of the cases use-oriented or human-induced errors [1] are the cause for critical events concerning the introduction and application of medical devices [2]. Therefore it is indispensable that risk management guidelines are supported by usability specifications (especially for risk sensitive systems as medical devices) such as DIN EN 62366 (Medical devices - Application of usability engineering to medical devices) [8] or DIN EN ISO 60601-1-6 (Medical electrical equipment - General requirements for basic safety and essential performance – collateral standard: usability) [11] and DIN EN ISO 9241-110 (Ergonomics of human-system interaction: Dialogue Principles) [12]. Whereas general advice for the design of human-machine-interfaces or the composition of environmental working conditions is easily accessible in standards and guidelines, comprehensive methods for the risk control process (especially with a focus on human-induced errors), that offer advice in dependency of the specific problem or context, are rare.

In recent years we implemented and evaluated the risk analysis method mAIXuse for risk analysis of human-machine-systems very successfully (Walter Masing Award 2010 of the German Society for Quality - DGQ (http://www.walter-masing-preis.de/wmp/walter-masing-preis.htm) [18, 19]). On this basis, we developed the concept of *mAIXcontrol*, a risk control tool that fills the methodology-gap within the (use-oriented and technical) risk control process. The methodology harks back to a knowledge-base of so far 14 risk analyses from industry and research and can gradually be fed with further data in the future. The method allows a systematic treatment and control of a particular risk as a function of previously identified weaknesses of the product or use process.

2.2 Theory of Inventive Problem Solving

The new method has been developed on the basis of the contradiction matrix of Genrikh S. Altshuller's TRIZ (Theory of Inventive Problem Solving), which is particularly known in innovation management and mechanical construction design [7]. TRIZ includes a practical methodology, a knowledge base for generating new ideas and solutions for technological contradictions. The problem solving process (shown in 1) has been adapted to the needs of usability engineering and risk management in medical context, mapping typical use deficiencies with interfaces and their potential solutions amongst others, but the general modus operandi of the matrix stays the same. The necessary steps to successfully apply the method to a specific problem are:

1. The specific problem has to be abstracted.
2. The matrix proposes one or several abstract solution approaches, which serve as a thought-provoking impulse.
3. The proposed approach needs to be adapted to the specific case by developers' efforts.

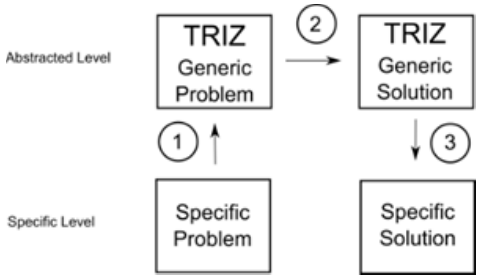

Fig. 1. Schematic Illustration of the Problem Solving Process, Applying TRIZ

In particular the steps one (induction) and three (deduction) require the developer's creative contribution, whereas step two is provided by the matrix.

3 A New Approach for Risk Treatment: mAIXcontrol

The new *mAIXcontrol* methodology accesses experts' knowledge from a database of different risk analyses and maps suitable context-individual countermeasures as a function of failures and failure-causes. On a superordinated level, it structures causes and failures by terms of their error taxonomy. For applying the methodology to a specific problem, the operator has to check the failures and causalities within the axes and has to find the respective failure-causality combination. In consequence the method proposes one or several of the 41 abstract principles of risk control. An excerpt of the new matrix can be seen in Figure 2.

3.1 A Knowledge-Based Matrix for Human Risk Control

In order to detect the most suitable countermeasures, the method has to assess the risk (combination of failure and cause) as precisely as possible on the one hand, proposing a case-tailored approach for the individual case and stay user-friendly on the other hand, avoiding a disaggregation into a catalogue of numerous individual cases. To solve this trade-off, different approaches have been analyzed regarding to their road capability. The approach implicating that principles of risk control can be mapped as a function of causes and failures turned out to be the most reasonable. Other approaches, e.g. combining different (root) causes with each other, different failures, or displaying the principles of risk control in dependency on a combination of cause and effect, have been dismissed after a detailed analysis of alternatives. Essential for the final design is the awareness that any harm originates from a combination of a root cause and an (undetected) failure and that this information is available in any risk analysis.

As the commutability of root cause, failure and effect (depending on the abstraction level of analysis) has been proven by several reputable researchers [5,6,1,14,15], we desisted to make a clear distinction between the three elements of the failure chain and put, root causes and failures, as coding information on the mirror-inverted axes of the matrix. In fact, during assessment of the risk analyses we discovered several cases where an incident that has been the failure for an upcoming adverse event, turned out to be the (root) cause for another consequence in a different risk analysis, showing that a distinction between (root) cause and failure is only possible in a very narrow, risk-analysis-dependent context. As we seceded from this in our comprehensive approach, the strict distinction has been dropped.

mAIXcontrol		T Insufficient Depiction/ Displaying	T Imperfect Joining	T Joining impossible
Error by Execution: Confusion Error	Confusion	[8]	[3] [8]	
	Wrong Combination			
Error by Execution	Lacking Manual Skills		[22] [27] [29]	
Error by Execution: Qualitative Error	Insufficient Execution of Work Step			[7] [27] [29]
Error by Execution: Timing Error	Execution of Work Step Too Late			
Error by Omission	Forgetfulness		[4]	

[Excerpt]

Fig. 2. Excerpt from the *mAIXcontrol* Matrix

In practical application there is a more complex failure chain at the basis of each cause-failure-effect triple than an average risk analysis is likely to show. Unfortunately, this supports a non-standardized evaluation of risks. Therefore, concerning risk evaluation of technology, manufacturing and use process, it would be meaningful to define different severity levels exclusively for personal injury like affecting health of patient, user or third party.

3.2 Taxonomy of Human Errors

Human and technical failures/causes which appear in the database have been filed and systematized based on the Human-Machine-System approach by Bogner [17]. The taxonomy of error deploys the three categories “Environment”, “Human” and “Machine”. Human errors in turn have been divided into six different categories, according to Norman’s action cycle and Rasmussen’s skill, rule and knowledge SRK-based classification [3][4]. Human errors include genotypes of errors as well as phenotypes and range from simple slips, like “unintended actions”, over basic personal skills e.g. “lacking manual skills”, up to mistakes like “misinterpretation” or “false estimation” (see Figure 3).

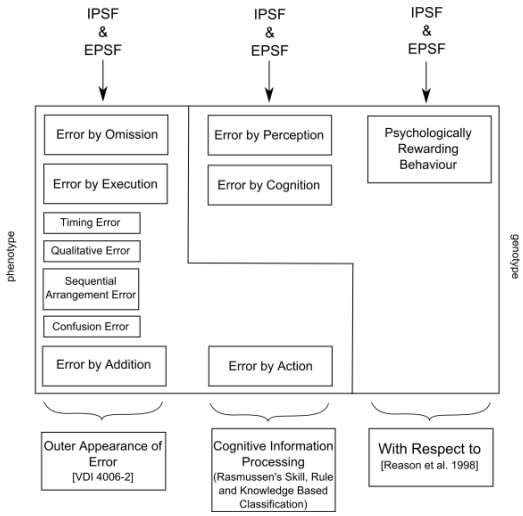

Fig. 3. Employed Categories in Human Error Taxonomy

Technical failures have accordingly been sorted into the two groups "predisposition" and "loss", dividing system faults that are inherent to the design of the product from those that emerge during the use-cycle.

3.3 Principles of Risk Control

In addition to the categorization of causes and failures, the 41 principles of risk control have also been summarized, divided into four categories "Established", "Creative", "Technical" and "Knowledge and Organization" (Figure 4).

Established			
[1] Compatibility	[5] Have Replacement in Store	[9] Exit Strategy	[13] Shift of Competence
[2] Repetition	[6] Maintenance	[10] Redundancy	[14] Wait for Reassurance
[3] Give Constraints	[7] Feedback	[11] Highlighting	[15] Display / Presentation /Illustration
[4] Simplicity	[8] Labeling	[12] Durability	

Technical			
[22] Discrete Adaption Mechanism	[26] Calibration at Beginning of Operation	[30] Thermal Behaviour	[34] Choice of Material
[23] Locking Mechanism	[27] Inseparability	[31] Avoid Lumen	[35] Anti-Adhesion
[24] Tender Velvet	[28] Enable Dismantlement	[32] Enable Free Movement	
[25] Accuracy of Fit	[29] Help for Assembly (Techn. Device)	[33] Alignment and Accessibility	

Creative		Knowledge and Organisation	
[16] Prevent	[20] Eliminate Disturbances	[36] Atention to Details in Instructions	[40] Expertise and Culture
[17] Overdo	[21] Resistency	[37] Check and Control	[41] Supply Patient with Information
[18] Divide / Seperate		[38] Standards	
[19] Reduce		[39] Anamnesis of Patient	

Fig. 4. Principles of Risk Control

4 Characteristics of Countermeasures

The counteractions generated with the aid of the method comply with the aims of usability engineering and international risk management norms, concerning risk treatment procedures: inherent safety measures, protective measures or by providing safety information. During development of the methodology, further quality characteristics of counter measures and their graduation have been identified and elaborated: degree of innovation (low-medium-high), costs/effort relation (inexpensive-reasonable-expensive), affected system components (human-environment-machine), development phase (development-manufacture-use), impact on respective components of error chain (cause-failure-effect) and degree of inherence (inherent-protective-descriptive) (Figure 5).

Subsequently, these quality characteristics have been assessed regarding the application for the review process of generated countermeasures in the course of evaluation of *mAIXcontrol*.

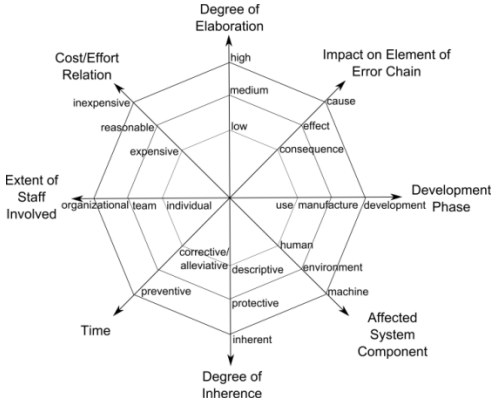

Fig. 5. Characteristics of Countermeasures

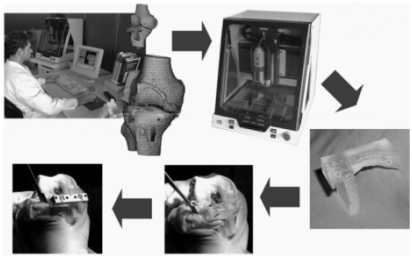

Fig. 6. Exemplary Planning, Manufacturing and Surgical Process Steps of an Individual Template for Total Knee Replacement Surgery, Finally the Simulated Intraoperative Surgical Process is Used for Evaluation of the Method

5 Evaluation

5.1 Experimental Set-Up

The method has been assessed with medical engineering students. The test population has been divided into two groups of 3 subjects, who had to deal independently from each other with the same exemplary case of total knee replacement within a flexible time frame, but a defined number of risks, which should have been minimized by

application of counter measures. Potential risks in the use-process had already been identified and assessed at an earlier stage and information has been given to the participants in an orderly documented way, using the risk analysis software CARAD [16]. The subjects had to use the new methodology and the classical approach (brainstorming) in a first and second run, with the order turned the other way around. This helped to permit detection of memory biases. Homogeneous knowledge about the particular steps of the surgery process had been assured by providing participants with detailed information on the basis of free accessible expert commentaries in the on-hand risk analysis. Finally, participants completed a questionnaire on test-level basis.

Figure 6 shows the planning, manufacturing and the intraoperative surgical process steps of an individual positioning device for individual template (custom jig) guided total knee replacement [20]. Finally, only the surgical process (using the custom jig) has been used for application of the methodology in an evaluation study. The comprehensive process includes inter alia computer-based processing of anatomical data for planning of the patient-specific template (step 1), manufacture of the custom jig (step 2), drill holing and finishing of the individual template (step 3), intraoperative positioning and fixing on the tibia bone (step 4) and fixation of cutting jig to the individual template (step 5).

5.2 Results and Interpretation

Two types of data have been generated in the framework of the tests and finally have been interpreted. Psychometric information from questionnaires as well as experimental results have been collected.

Concerning the number of measures for risk control, the *mAIXcontrol* method shows predominance compared to classical brainstorming approach, although the required time for application of the method is slightly higher than for brainstorming (see Figure 7 and 8). As can be seen in Figure 8 the total number of RPN (risk priority number) is lower after implementation of countermeasures, whenever the method is employed, although the predominance of the method is weaker in the case of group B, where brainstorming was employed after the method. Countermeasures have been reviewed by a blind expert after the tests, in order to reassess the related RPNs. As a risk is typically characterized by the probability of its occurrence (O), the probability of detection (D) and the severity (S) of its outcome, the RPN is defined by:

$$RPN = O \times D \times S \tag{1}$$

As can be seen in Figure 7, risk priority numbers after implementation of countermeasures generated with the new method, are lower than in the case when brainstorming has been employed. This does also apply to the case, when brainstorming was employed after the method. Figure 5 illustrates how group A managed to reduce the total risk priority number from 170 to 145, when working with brainstorming and twice as much (down to 120), when working with the *mAIXcontrol*. In the second run, group B achieved a total RPN of 135, when working with *mAIXcontrol* and 140, when working with brainstorming.

Evaluation by questionnaires shows a "slight advantage" of *mAIXcontrol*, compared to conventional brainstorming. Although users prefer to work with conventional brainstorming, when referring to time/benefit – ratio, higher completeness of matrix-generated results and the potential learning effect for experienced users made 83% of the polled participants state that they would prefer the method, if they were able to choose between method and brainstorming for an equivalent task. Lower risk priority numbers, demonstrate a clear predominance of the *mAIXcontrol* method. The fact that the method significantly outperforms brainstorming in case of group A can be due to memory biases from sequential conduction (*mAIXcontrol* has been applied after brainstorming). Nevertheless, it is striking that the total RPN with application of brainstorming is higher in case of group B, although group B could have been able to benefit from prior experience with the *mAIXcontrol* application.

Test Subjects: Students Medical Engineering	Test Group A		Test Group B	
	Brainstorming	mAIXcontrol	mAIXcontrol	Brainstorming
Number of generated countermeasures	54	64	55	51
Required Time [in minutes]	50	63	80	50
Sum of RPN after Counter-measures and Reassessment of Risk (Reference RPN value: 170)	145	120	135	140

Fig. 7. Results from evaluation based on risk priority numbers

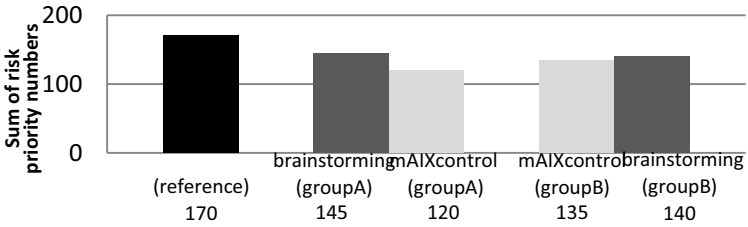

Fig. 8. Risk Priority Numbers Before and After Reassessment

6 Discussion

The first evaluation of the *mAIXcontrol* method in the framework of our feasibility study showed promising results. As observed in each of the two sessions, the use of the matrix requires a certain learning curve. The test subjects needed a learning time of more or less 15 minutes before a working routine had been adopted. This presumes a learning effect that increases time efficiency for experienced users. Best practice has been the approach of task sharing where a moderator (one subject), without any implements, is discussing each risk and potential countermeasures with the matrix-equipped team members. This proceeding enables higher communication rate and synchronicity of work, which turns out to be beneficial for performance.

Additionally, it has been observed that subjects do not always search for a defined cause-error combination on both axes, but run through complete lines of the matrix. The fact that all users have been novice users implicates a naturally higher expenditure of time. However, most participants rate the method as mainly self-explanatory, even for novice users. Additional time required with *mAIXcontrol* is compensated by qualitative advantages in total risk reduction, documentation and justification of counter measures, which in fact could be essential in the context of the official approval process of a medical device.

Acknowledgements. The *mAIXcontrol* methodology has been developed within the AiF/FQS project SysRisk which is funded by the Federal Ministry of Economics and Technology (BMWi).

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