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Workflow-Orientiertes Risiko Management für ein Computerunterstütztes Nadel-Positionierungssystem

Workflow-Oriented Risk Management for a Computer-Assisted Needle Positioning System

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Purpose

The purpose of our project was to define and to perform a workflow-oriented Risk Management (RM) process to evaluate a computer-assisted needle positioning system for interventional radiology. One main objective was to identify as many risks as possible at an early project state, i.e. when starting the medical device-planning phase, during the Risk Analysis (RA) step.
We created workflows which describe the complete activity of our system and discussed them with three different groups (development, marketing, medical setting) to find hazards and risks. The requirement is to obtain a system that is free of risks.

Methods

The analyzed computer-assisted needle positioning system is currently being developed by CAS innovations and consists of 6 steps: 1. alignment of an optical tracking system (Polaris, NDI), 2. import of scanned images (direct connection of the software with the CT scanner Somatom Sensation 64, Siemens Medical Solutions, using DICOM protocol), 3. planning of a trajectory, 4. calibration of the needle, 5. navigated adjustment of the needle and 6. navigated needle feed with the possibility of initiating a control scan.
For the complete system we created three different workflows, which are specific to three independent groups. Group one consists of 13 people (developers, scientists and engineers) and the workflow for this group is based on algorithms. The second group consists of 4 people (executive manager, marketing and business administration) and their

workflow is concerned with the functional level and usability. The workflow of the last group (two radiologists and one assistant) is also concerned with the functional level and usability but additionally with the integration of the system into the medical workflow.

For every group we performed two passes of presentations of the corresponding workflow. In the first pass the group was asked to report all risks and hazards for each step in the workflow. In the second pass we repeated the procedure, including all risks and hazards found before.

Results

In both presentations, all three groups found risks and hazards based on their own workflow. Overall, most hazards and risks were found in the algorithms and software design by group one. Group two found the majority of hazards and risks for the handling and integration of the system into medical environments. Finally, the results of the last group focused on reactions of the patient during the complete procedure and possible complications with resulting risks for the patient and medical staff.

Conclusion

For a computer-assisted needle positioning system the detection of hazards and risks is one of the most sensitive fields of activity and extremely important for the RM to fulfill Medical Device Standards [1,2,3]. A standardized solution of finding risks is still under discussion. We added the presented workflow-oriented risk analysis to our RM process and were able to detect a wide spectrum of risks.

References

[1] ISO 14971:2000 - Application of risk management to medical devices.

[2] ISO 13485:2003 - Quality management systems - Requirements for regulatory purposes.

[3] Medizinproduktegesetz (MPG) in der Fassung der Bekanntmachung vom 25.11.2003.