Development of Medical Device UI-Profiles for Reliable and Safe Human-Machine-Interaction in the Integrated Operating Room of the Future

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ABSTRACT

Nowadays, the number of technical systems in the operating room increases constantly. This ongoing spread of technology has significant impacts on the individual working process steps of the surgical team. Besides improving the therapeutic quality, these changes may also lead to new human-induced risks for patients, therapists and third parties. In particular, within intra-operative activities, which depend on a safe and fast operation, surgeons and nurses rely on sophisticated and efficient solutions in terms of Human-Machine-Interfaces in order to perform their tasks reliably and assuredly. Therefore, proprietary integrated workstations with a central usage cockpit have been provided for the operating theatre in recent years. At the Chair of Medical Engineering, a surgical integrated workstation with open interfaces for the integration of various medical devices from different manufacturers is currently been developed in the context of the BMBF (Federal Ministry of Education and Research) funded project OR.NET. For this purpose a suitable central user interface (e.g. multi-function foot switch, touch screen, diagnostic monitor, etc.) will be implemented, in a way that the functions of the various (networked) devices can be offered to the user by a central user interface. The design of the Human-Machine-Interface therefore depends on the available input and output devices, the interaction elements of the graphical user interface, the available medical technical equipment, as well as the medical intervention and the particular process steps and the environmental conditions within the operating room. In this work, a concept for the development of a Medical Device User Interface Profile (UIP) will be presented, using the characterization of process-dependent medical device functions for the modular design of a central user interface in the integrated operating room of the future. The use of standardized UI Profiles should allow the manufacturers to integrate their medical devices, respectively the provided functions in the OR.NET network, without disclosing the risk analysis and related confidential know-how or proprietary information. The UI Profiles will allow both, an automated optimized selection and composition of various user interfaces, and implicitly an optimal design of a central GUI with respect to the criteria of usability and an integrated human risk analysis in terms of Human-Machine Interaction. Specific operation process steps within a neurosurgical workflow will be the framework for the validation process of the UI Profiles. Till now, the UIP concept has been tested within the integration of an ultrasound dissector and an OR microscope.

Keywords: Human-Machine-Interaction, Human Factors, Risk Analysis, Integrated Operating Room, Dynamic and Open Surgical Network, User Interface Profile

INTRODUCTION

Modern operating rooms are characterized by a high degree of computerization. To facilitate the handling of these systems, integrated operating room systems are developed to optimize the human-machine interaction and enable data exchange. Mostly integrated OR systems are closed and proprietary, so that integration of components from third-party vendors is only possible with great effort (time, cost). To overcome these limitations, cross-vendor standards and concepts for a modular integration of medical devices in the operating room are necessary. Actual standards and concepts do not cope with the requirements for a modular integration. In order to overcome these obstacles a novel integration concept is currently being developed within the OR.NET project (BMBF (Federal Ministry of Education and Research) funded) (Birkle et al, 2012). Currently available standards and concepts cover the requirements for a modular, flexible and plug&play integration very poorly. A management of the entire open system will be realized via central components communicating via standardized interfaces, based on the IEEE 11073 nomenclature. Furthermore, concepts to integrate a process for risk management and certifiability for the integrated operating room and mechanisms to ensure the safety and reliability are actually being developed. Amongst others, a method for human risk analysis is in the focus of the ongoing work within the OR.NET project. This method should allow the manufacturer and the clinic to finally ensure an optimal Human-Machine-Interaction integration in the new open networked OR concept.

STATE OF THE ART

In order to provide an optimal adaption of the existing Human-Machine-Interaction of the OR nowadays into the interaction concept with a new central OR cockpit, including further and different interfaces, the state of the art concerning the characteristics of input and output devices as well as interaction elements for GUI development have been gained. Additionally, the capabilities of the human being, concerning information perception, cognition and motoric movement have been assessed. Furthermore, process-specific factors and environmental factors have been taken into account for the description of a HMI work system in an open networked OR room.

Various input devices for the operating theatre (mouse, touch screen, footswitch, hand switch, etc.) and their characteristics regarding the users' controlling possibilities (finger, hand, foot, speech…) have been analyzed. Additionally the physical characteristics (resolution, sampling rate, delay, accurateness, C/D ratio) and furthermore use space, learnability and dimension as properties for input devices have been analyzed. Concerning basic GUI interaction elements there have been identified the following aspects: entry/edit field, push/command/check/radio/option button, check/list/drop-down list/ drop-down combo box, icon, slider, scale). Interaction elements, e.g. a slider, can also be seen as visualization elements (Hölscher et al, 2008). DIN EN ISO 9241-9 states that relating to displays, interaction elements can influence the information processing/perception (DIN EN ISO 9241-9, 2002).

Visual presentation can be divided into scales (analog, digital, hybrid) and displays (picture, graphic, virtual structure, diagram, alphanumeric sign). According to the fulfillment of the usability criterias (effectiveness, efficiency, learnability and user satisfaction) (DIN EN 62366, 2008) the ergonomic design of visual displays has to be considered. Therefore DIN EN ISO 9241-303 devides into 8 different aspects (DIN EN ISO 9241-303, 2012): perceptional factors (viewing conditions (viewing distance and direction), illuminance, luminance display, visual artifacts (reflection, jitter effects, flickering), readability, readability of information coding (character height/format and bar range) and graphics, fidelity (space resolution, time until image display, color range).

Characteristics of information presentation in DIN EN ISO 9241-12 (DIN EN ISO 9241-12, 2012) provide quantitative data for GUI design: resolution, height, form, color, text/title, contrast, display, position (appropriate (or not), recommended), grouping, affiliation. Acoustic information presentation can be divided into: frequency, loudness, duration, interval duration, sound, repitition, melody, channel number (mono, stereo, surround sound). According to the idea of human engineering, the interface and the environmental factors as well as the work task have to be designed according to the facilities of the human being. Regarding the perceptional process the following factors have to be taken into account: acoustic aspects (loudness, tone, orientation), visual factors (wavelength

(absorption maxima), frequency, accommodation, illumination), haptic limitations (threshold, sensing threshold, bandwidth (skin, finger, muscle, etc.). Regarding the information process of the human being, additionally the cognition process and the motoric process have to be considered. The 3-ladder model of Rasmussen (Rasmussen, 1994), including knowledge-, rule-, and senso-motoric-based behavior is the basis for the adaption of the interface design related to a person's facilitiy. Concerning the integration of process-specific attributes, e.g. environmental factors (loudness, light,temperature, etc.), criticalities, use of input device (directly by operateur or indirectly), extremity occupation, organization, space for input device, distance user to input device or display and many more have to be analysed.

APPROACH

In the framework of the development of a human-risk analysis, a concept for Medical Device User Interface Profiles (UIP) has been conceived, using the characterization of process-dependent medical device functions for the modular design of a central user interface in the integrated operating room of the future. Standardized UI Profiles allow the manufacturers to integrate their medical devices, respectively the provided functions into the OR.NET network. The UI Profiles allow both, an automated optimized selection and composition of various user interfaces, and implicitly an optimal design of a central GUI with respect to the criteria of usability and an integrated human risk analysis. The core of the UI Profile method are the attributes (characteristics of input and output devices as well as GUI interaction elements, human information processing factors, environmental and process factors, task-specific factors) and the dependencies within the attributes, which is described in 4 matrices:

- Generation/selection of interaction element and input device
- Visual presentation of information
- Acoustic information presentation
- Visual grouping

On the basis of these matrices an integrated user interface can be evaluated and later be designed (the exemplary generation of a GUI interaction element is shown in Figure 1). Subsequently, the UI profiles will be defined as additional information in the medical device profile (including identification, type, subtype, functions, manufacturer, etc.) and the UIPs have to be provided by the manufacturer.

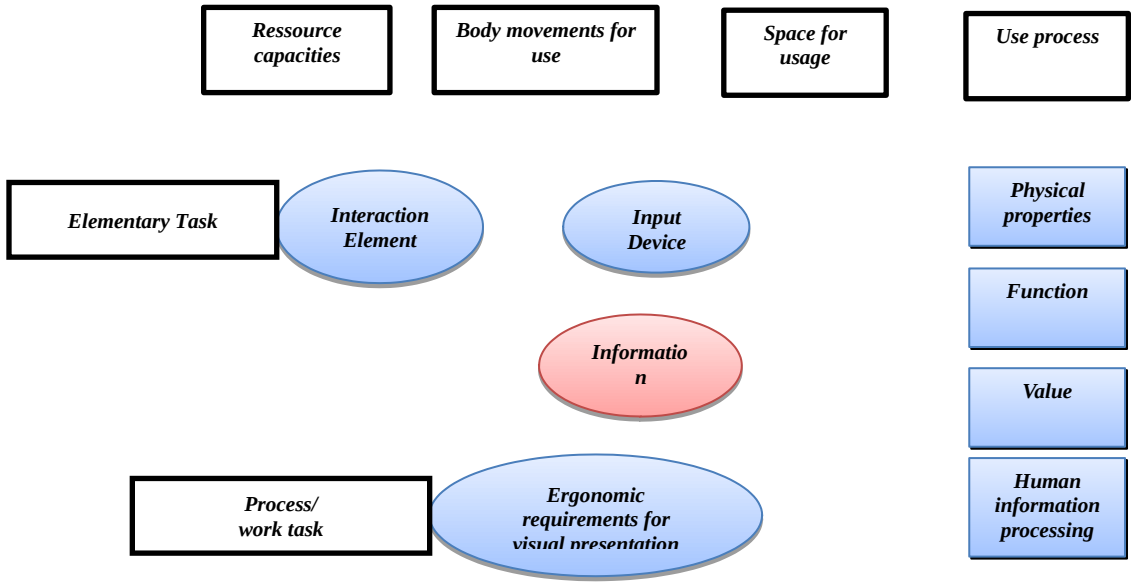

Figure 1: Exemplary generation of a GUI interaction element

https://openaccess.cms-conferences.org/#/publications/book/978-1-4951-2093-0

The elementary task, relating to the use of an input device, is defined as a basic action of the user (DIN EN ISO 9241-400, 2007). Therefore the elementary task can be used as a starting point for the differentiation of the various functionalities of a medical device, which shall be integrated in an open surgical OR network. According to DIN EN ISO 9241-400 standard, user tasks can be described as the combination of different elementary tasks (DIN EN ISO 9241-400, 2007). In DIN EN ISO 9241-420 (DIN EN ISO 9241-420, 2011) seven elementary tasks (quick and accurate pointing, select, pull, follow, drag, alphanumeric input) are described and additionally, a usable (appropriate) input device is assigned to each elementary task in a matrix. Thus, the characteristics of the elementary tasks have a direct influence on the central user interface. Furthermore, discovering and monitoring tasks have to be considered according to DIN EN 894-2 (DIN EN 894-2, 2009) especially regarding to alarm and awareness management in GUI presentation.

Besides the definition of the elementary tasks it is of great importance if the release of a specific function of a medical device requires a confirmation in the dialogue (e.g. increasing the power of a cutting device). Moreover, adequate visual, acoustic or haptic feedback (about status, action and goal) of the users' actions should be taken into account in order to close the information processing loop of a human being according to Rasmussen et al. (Rasmussen, Pejtersen and Goodstein, 1994).

Within the attribute „correlation", the dependency between an elementary task and an input device and/or an visual/acoustic/haptic presentation has been considered. Values (number of digits, point location, numeral system, rate of change, unit, range of values) are always assigned to a specific measure (Schmidtke, 1989)), additionally the controlling dimension (1D-4D) of the input device is itemized (DIN EN ISO 9241-400, 2007). The attribute "physical properties" describes characteristics of input and output devices e.g. resolution, sampling, delay, accuracy, C/D ratio, etc.

The idea of the "Criticality" attribute is that each medical device function/elementary task is linked with a criticality value. Thereby, it is possible to conduct an early risk analysis, which allows to optimize the Human-Machine-Interaction. Actually, different critically levels are being developed, which allow the medical device manufacturers to classify the various functions of their product. The criticality is a unit that expresses which consequences is related to a specific failure/error and is also called "technical" risk. The DIN EN ISO 14971 describes this risk as the "combination of the probability of occurrence of harm and the severity of that harm" (DIN EN ISO 14971, 2013). The rules for the criticality classification have been iteratively developed within the evaluation of the UIP method development. Digest of different levels of criticality (starting with lower criticality):

- Expected operation must be ensured
- Interaction elements should not be presented next to items the same level or higher; for safety-related or urgent tasks, the simultaneous use of audible and visual signals may be preferred
- Grouping with interaction elements with highest criticality must always be presented exclusive; interaction element has only to be activated with foot switch; switches must not be programmable (soft key); functions with high criticality must always be activated

EVALUATION

The evaluation of the concept has been conducted in a workshop with industrial partners using the example of the integration of the device pairing of a surgical microscope and an ultrasonic cutting device. Here, the safety-critical functions, in particular the adjustment of the energy parameters of the US dissector and the release of the US dissector via the OR microscope have been assessed. In a first step, the existing integration has been evaluated regarding usability deficiencies. This usability evaluation has been conducted with the mAIXuse tool, which has been developed at the Chair of Medical Engineering (Janß et al, 2011). mAIXuse provides a formal-analytical methodology and an associated software tool for prospective human risk analysis and model-based usability evaluation. Based on a two-folded approach the interactive use process sequences and their possible influence on the overall process can be identified and the use-related risks can be rated. In the aforementioned (device-pairing)

analysis, problems in the human-machine interaction could be detected and analyzed. Amongst others there have been the following use errors:

- Specific information not available for the doctor (just for unsterile OR personnel)
- Names/titles of the keys on the hand switch are not consistent with the on-screen menu
- Accidental press of the footswitch

Using the UI profiles for the integrated design of the two medical devices (and corresponding functions: parameter adjustment and release), it could be determined that the risks (assessed by mAIXuse) could have been automatically avoided, when using the UI profiles within the integration process. Nevertheless optimization potential of the UI Profiles could have been found, especially when adapting the HMI to existing interfaces like the hand switches of the OR microscope.

DISCUSSION

By now, the approach with the UI profiles shows the potential for a human-induced risk analysis and/or designing an optimized central user interface for the OR of the future. However, there still remain a lot of questions. Actually, the UI profiles are integrated in the device profiles and e.g. the grouping of various functions interactions elements has to be modeled. Besides, more process-specific and environmental factors as well as human cognitive processing factors have to be included in the UI profiles approach. The partition of the integrated graphical user interface as well has to be considered in detail for specific information representation and interaction tasks. Then, the detailed elaboration of the criticality levels still remains and therefore further tests have to be conducted.

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