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UI Profiles: A Key to Mitigating Human-Induced Risks in the Open Integrated Digital OR

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Abstract

Human Risk management poses a challenge for an open integration of medical devices in digital operating rooms according to the ISO IEEE 11073 SDC standard. A User Interface Profile has the potential to improve safety and usability, which defines the HMI characteristics of a medical device in an ensemble, aligning with ISO 14971 and IEC 62366-1 standards. We discuss applications in orthopedics, highlighting UI Profiles' potential to mitigate human-induced and process-related risks.

1 Introduction

In the evolving healthcare landscape, open integration of medical devices benefits the hospital, users, and manufacturers. Manufacturer-independent solutions create greater flexibility, remove the vendor lock, and enable the integration of innovative solutions and reasonably priced devices due to enhanced manufacturer-independent SDC interoperability. Openly integrated OR solutions can reduce the effort regarding administrative overhead and clinical protocols by using dashboards and partly automated documentation. (OR.NET e.V., 2024)

However, adopting these digital plug-and-play solutions presents unique challenges in terms of risk management and usability. Manufacturers and operators are required to meticulously check and secure the mutual influence of different device combinations in advance.

The current work explores integrating machine-readable user interface requirements in these dynamic environments by addressing risk management and usability requirements through recognized standards like ISO 14971 and IEC 62366-1. (DIN EN ISO 14971, 2019; DIN 62366-1, 2021)

2 Risk Management in Open Digital Networks

Risk management in Service-Oriented Device Connectivity (SDC) networks is pivotal for ensuring safety in open networked operating rooms.

The ISO IEEE 11073 SDC standards, a comprehensive system, involve a multitude of entities. These include medical device manufacturers, healthcare delivery organizations, system integrators, IHE (Integrating the Healthcare Enterprise), FDA (Food and Drug Administration), IG-NB (German Notified Bodies Alliance), and the non-profit association OR.NET. Each of these participants has distinct responsibilities, ranging from creating guidelines to implementing SDC communication protocol and enabling modular risk management and usability engineering. (Integrating the Healthcare Enterprise, 2024; Merkel & Schlichting, 2019; IEEE Standards Association, 2023)

For an SDC system to work safely, effectively, and securely, the networked medical devices must provide their functionalities and **requirements for safe use**, ensuring the safety of the entire work system. The complexity increases due to the sensitive nature of the information exchanged, which often includes proprietary, non-public, and internal data.

3 User Interface Profiles

The necessarily provided HMI requirements **regarding safe usage** are not standardized and differ from device to device. User Interface Profiles (UI Profiles) could fill this gap by providing a standardized set of requirements regarding HMI. For each detected HMI-related hazard during the initial risk analysis, a UI Profile specification can be established by addressing its underlying error cause, decreasing the probability of its occurrence, or increasing the probability of its detection. Those could support the risk management and usability engineering process by mitigating risks already at the design phase. The proposed categories in **Figure 1** describe how medical device information should be **displayed** (color, labeling, precision, positioning) and **controlled** (speed, confirmation, error recovery, visual, auditory, or haptic feedback) regarding the defined **use context**. (Yilmaz et al., 2022)

Shared resources in open networked systems, such as displays, tracking cameras, or input devices (foot switches, touch screens, voice or gesture control) need to be available for different medical devices at certain points during surgery. Critical use scenarios in which no appropriate input device is available should be prevented. (DellAnna-Pudlik, 2022)

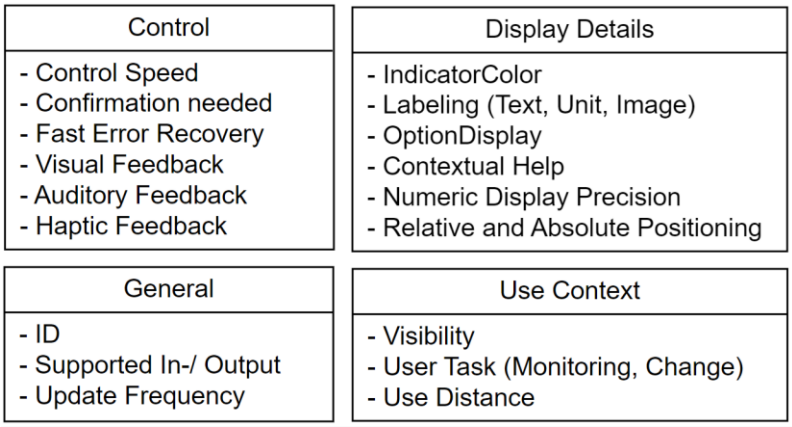

Figure 1: Categories Describing User Interface Requirements

The defined UI descriptors in **Fig. 1** support the designer and the developer during the design and mandatory verification phase as well as the clinical operator during device installation (Yilmaz et al., 2022; IEEE Standards Association, 2023).

4 Exemplary applications

The use of UI Profiles can be beneficial in all areas where data needs to be either displayed or entered. Providing surgeons with suitable, context-sensitive, and process-specific information using appropriate UI controls leads to safer and more useable UI.

Specific UI Profiles can include requirements for real-time data, visualization of alignment angles, and the depth of cut, which is crucial in surgical tasks such as **total knee arthroplasty**, where precision is crucial (Deckey et al., 2021). This could enhance the surgeon's ability to make fast, accurate incisions and alignments, e.g., without looking the data up in sub-menus. Displaying critical parameters in a readable font size at a use-case-specific distance and being grouped with other corresponding parameters could also reduce the cognitive load during medical procedures.

A UI displaying real-time tissue resistance in combination with a previously selected stress threshold can help surgeons avoid excessive force and minimize tissue damage while navigating around critical structures, such as in **spine surgeries**. The UI can provide a comprehensive view of the surgical site, improving spatial awareness and reducing the risk of accidental nerve or spinal cord damage. The UI can also demand to alert the surgeon of potential risks (damaging critical structures), thereby enhancing safety and efficiency.

Robotic surgeries, especially in delicate procedures, demand high precision and control. Surgical robots create the potential for excessive force application during surgery. This can be avoided by using different stress magnitudes and durations for different tissues. (De et al., 2006) Enhanced haptic feedback and visual indications in the UI can improve hand-eye coordination, leading to more precise movements.

5 Discussion

The UI-Profile can be used during the design and verification phase by defining clear acceptance criteria for HMI-related risks. For each detected hazard during the initial risk analysis, a user interface specification is established by addressing its underlying error cause, decreasing the probability of its occurrence, or increasing the probability of its detection. This has the potential to significantly streamline device interoperability by addressing existing issues determined by the IHE, OR.NET, IG-NB, and FDA. (Integrating the Healthcare Enterprise, 2024)

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