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Usability Engineering of Dynamic Biosignal Displays Using Ventilation Data

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Abstract. The aim of this work is to develop and evaluate a multi-stage procedure model for the identification of use problems and optimization of usability using biosignal data. The concept is divided into 5 steps: 1. static analysis of data to identify use problems; 2. conducting interviews within the context of use and requirements analysis to investigate problems in more detail; 3. developing new interface concepts to implement the requirements and a prototype of an interface including dynamic visualization of data; 4. formative evaluation using an unmoderated remote usability test; 5. usability test with realistic scenarios and influencing factors in the simulation room. The concept was evaluated in the ventilation setting as an example. The procedure allowed the identification of use problems in the ventilation of patients as well as the development of suitable concepts and their evaluation to counteract use problems. To relieve users, ongoing analyses of biosignals with respect to the use problem are to be carried out. To overcome technical barriers, further development is needed in this area.

Keywords. Usability Engineering; Medical Device; Data Analysis, Data Visualization; Prototyping

1. Introduction

The usability of medical devices such as vital signs monitors or ventilators is safety and time critical for monitoring and treating patients. Use errors can lead to a hazardous situation and patient harm. The design of user interfaces contributes significantly to the prevention of use errors [1,2]. Use errors in mechanical ventilators are caused by the design of interface elements, the implementation of the task navigation or the representation of medical functions, for example, the naming of ventilation modes [3]. First paragraph.

Mechanical ventilators support patients with insufficient or no self-breathing. Ventilation parameters measured, e.g., respiratory rate, tidal volume, and ventilation pressures depend on the patient's condition and the ventilator settings. The discrete time series values are obtained by sensors at constant time intervals by sampling the

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continuous parameters. They are displayed in real-time to the medical staff as numerical value or as a graph. Alarm messages indicate value deviations outside the set limits.

Dynamic medical data not only matter in patient care. The analysis of dynamic biosignal recordings can provide retrospective insights into the quality of the medical treatment and problems that may have occurred. As part of a root cause analysis [4], conclusions can be drawn about the role of the device and use errors to counteract interface design weaknesses. In the development process, simple concept sketches up to fully developed prototypes are used as a basis for discussion and testing [5]. Realistic displays or simulations with dynamic data are necessary to verify usability in user tests.

In the field of usability engineering, little is known about the retrospective analysis of as well as prototyping using dynamic biosignal data. The aim of this work is to develop and evaluate a multi-stage procedure model using biosignal data to identify use errors and improve usability. Data from the ventilator setting and ventilator interfaces serve as an example for the evaluation of this procedure.

2. Methods

A multi-stage procedure model (Figure 1) was developed in line with the usability engineering process with a specific focus on dynamic biosignal data. It contains the identification of use errors, requirements and the context of use, the development of new interface concepts, prototypes and the performance of usability tests.

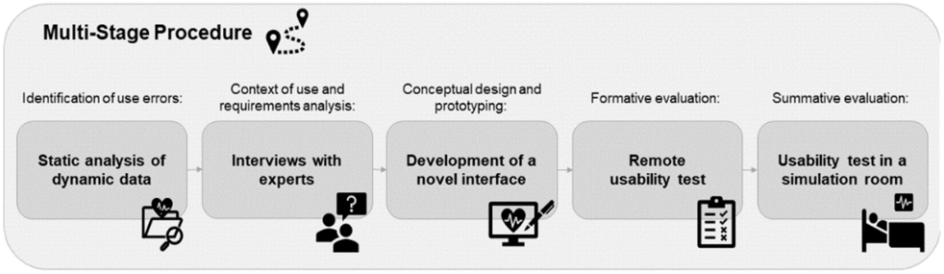

Figure 1. Model of the multi-stage procedure in line with the usability engineering process

2.1. Step 1: Static analysis of dynamic data

A detailed analysis of existing data shall reveal information regarding the quality of the medical treatment and problems that may have occurred. Biosignals available to medical staff during treatment are used only to assess the patient's condition in real-time with limited insight into historical data. A tool that allows a static view of the overall available data, annotation of conspicuous areas, and collaborative work is needed.

2.2. Step 2: Interviews with experts

In the context of the use and requirements analysis, patient-specific issues from step 1 are to be analysed in more detail with suitable methods. We decided on semi-structured interviews with device users to clarify questions regarding the investigated anomalies and medical facts. The interview results will be examined regarding new requirements on the medical device interface counteracting use errors and the context of use.

2.3. Step 3: Development of a novel interface

The requirements from step 2 are the basis for the implementation of new design solution. For the implementation of a realistic prototype of an interface, simulated data from patients are required to ensure interaction between the user and the device.

2.4. Step 4: Remote usability test

Usability evaluations are methods for testing medical devices and identifying problems during use [1, 6]. An unmoderated remote usability test was chosen for a formative evaluation. Due to the Covid-19 pandemic, but also for rapid iterative feedback, moderated or unmoderated remote tests play an increasingly important role [7]. Other formative evaluation methods to identify usability issues could also be suitable.

2.5. Step 5: Usability test in a simulation room

For a comprehensive summative evaluation, the entire socio-technical system in which the interaction with the device takes place must be considered. Influencing factors such as stressors or acoustic noise exposure can promote the occurrence of use errors. Since the application is safety-critical, the usability cannot be evaluated on real patients. In a simulated care situation, the human-machine interaction must be modelled on reality.

3. Results

The development process was evaluated using mechanical ventilation as an example. Requirements were elicited, and concepts were developed and evaluated with a focus on a ventilation problem identified in step 1. In the process, various software artefacts were used or developed. The procedure was carried out by an interdisciplinary team, further medical experts were consulted in the respective steps.

3.1. Step 1: Static analysis of dynamic data

The static visualization was implemented using the open-source software Grafana (https://grafana.com) and a MySQL database on a web server. The Grafana application provides a graphical web interface to configure the data sources and to create a dashboard containing the available data (e.g. insp. / exp. pressure, respiratory rate, inspiratory-to-expiratory ratio, tidal and minute volume, flow (Figure 2), volume). This allowed retrospective analysis, annotation and discussion of abnormalities and pathological processes in the recorded data (anonymized recordings, 2 – 8 hrs each, 50 Hz).

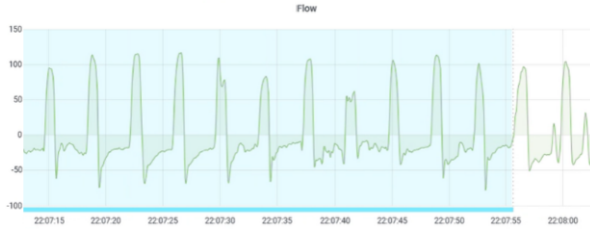

Figure 2. Excerpt of the flow graph of the annotated ventilation data in Grafana

3.2. Step 2: Interviews with experts

The interviews with seven experts (ventilator users with different professional experience, number of participants according to the saturation principle) provided detailed information for one exemplary ventilation problem regarding indicators, e.g., the shape of the curves and their detection during the treatment of patients. In addition to user characteristics, the type of information presented was seen as a factor supporting early detection or overlooking.

3.3. Step 3: Development of a novel interface

First sketches of the graphical concepts were implemented as static mock-ups. For the development of interactive prototypes, no tools were available on the market that allow a quick adaptation of the GUI and the display of dynamic data for the simulation of various scenarios. The GUI of commercially available ventilators are not modifiable from “outside”, so a GUI prototype had to be re-implemented. The patient's breathing mechanics and the ventilator mechanics, including the ventilation tube, were substituted by a bidirectional interface to a real ventilator (data provider), which is connected to a lung simulator [8].

3.4. Step 4: Remote usability test

Twelve Subjects participated and were provided with video recordings of ventilator interfaces with different ventilatory problems to be detected via the online survey tool SoSci Survey (https://www.soscisurvey.de/). The remote test allowed for initial feedback regarding the effectiveness (identification rate of ventilatory problem) and user satisfaction, as well as comments on the adapted interface design compared to the regular interface. As it was an unmoderated procedure, the efficiency could not be measured. [9]

3.5. Step 5: Usability test in a simulation room

The simulation room enables the implementation of a realistic setup including disturbing/ stressful environmental factors for the selected scenarios, e.g. a doctor's visit or the treatment of an acute patient. The evaluation of usability (effectiveness, efficiency, satisfaction and use errors) is performed over the different scenarios, each requiring interaction with different interface elements of the ventilator. A case number of 8-12 subjects allows the qualitative evaluation of a large number of possible findings [6].

4. Discussion and Conclusions

Usability engineering is a core component in the development of software systems and devices [10]. This study provides a procedure for the analysis of existing device data based on a static representation and further investigation of identified problems to improve usability of medical devices. An advantage of analysing dynamic data with static methods is that the health status and the health related progression can be better surveyed. Early pathological processes could be identified in the ventilation data for the detection of which the devices do not offer support so far. Besides the detection of

pathological conditions, it is also possible to identify human-machine interaction errors. Concrete requirements for the enhanced graphical interface could then be identified in a second step. The highlighting of pathological processes in a medical device is intended to support the user but may also contain a new source of use errors. Through the various usability tests, the effect of the newly developed interface could be evaluated with regards to use errors and hazard-related use scenarios. One hurdle is that real data is needed for our approach. In addition, access to users for interviews and participant observations is limited by the lack of time and resources among nurses and physicians.

Particularly in medicine, safe human-machine interaction is a regulatory requirement for patient safety [1, 2, 11]. For translational research and development, innovative usability approaches with biosignals are not publicly available as they are often internal to the company. Ventilators but also ECGs, EEGs or vital sign monitors, all these systems are medical devices that contain dynamic biosignals. The analysis of real ventilation data showed that existing biosignals have the potential to provide insights for research and development. To promote the evaluation of new concepts within realistic scenarios, further development of simple tools and open-source interfaces is required.

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